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A Moving Target: Genetic Resources and Options for Tracking and Monitoring their International Flows

ABS Series No. 3

Manuel Ruiz Muller and Isabel Lapeña, Editors

IUCN Environmental Policy and Law Paper No. 67/3

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Sociedad Peruana de Derecho Ambiental

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Edited by Manuel Ruiz Muller and Isabel Lapeña

with contributions from:
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Joseph Henry Vogel and Tomme Rosanne Young

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Foreword

It is my pleasure to present this book *A Moving Target: Genetic Resources and Options for Tracking and Monitoring their International Flows*, edited by Manuel Ruiz Muller and Isabel Lapeña, which is published as IUCN Environmental Policy and Law Paper (EPLP) No. 67/3. This book represents an important contribution to the body of ABS literature currently available and is provided at a critical time in the development of ABS as a functional concept and international regime. The IUCN EPLP series dates back to 1972, and has through 35 years maintained a high standard of legal scholarship and quality outputs.

The ABS Series, which includes this book, is the first "sub-series" within the EPLP series, designed in this way to maximize the usefulness and accessibility of these writings to the broad range of participants addressing the ABS challenges at both national and international levels. We believe that this Series offers a substantial contribution that will enable progress on an issue which has, to now, been stymied both by its complexity and by its controversial nature. It is only through the understanding of those complexities that consensus and useful compromise can be attained that will resolve the controversies and enable a functional system for achieving the all-important equity objective of the Convention on Biological Diversity.

Dr. Alejandro Iza
Director
IUCN Environmental Law Centre

September, 2007

Series Editor's Preface

In the course of *The ABS Project*, IUCN's Environmental Law Centre has taken a central position in promoting researched and balanced analysis of critical components of the current discussions of the international regime on access and benefit sharing under the CBD. *The ABS Series* provides the culmination of these efforts, enabling recognized experts to undertake intensive research and present detailed, balanced and reasonable analysis. It operates as a counterpoint to the growing numbers of authors whose work in ABS issues is sometimes more focused on advocacy than research. With this Series, we are trying to take a very different approach and to achieve a very different objective. Simply put, we hope to provide a deeper understanding of the legal, economic, practical and factual issues affecting the debate, and to build our analyses and recommendations on intensive legal research.

In this sense, however, this third book in our Series, *A Moving Target: Genetic Resources and Options for Tracking and Monitoring their International Flows* represents a slightly different approach. Not only are the concepts of "tracking," "tracing," "monitoring," "documenting" and "verifying" various aspects of genetic resource utilization highly controversial as of the time of compiling this book, but they call for the creation of concepts, measurements, oversight systems, and other legal frameworks that are unprecedented (and therefore neither predictable nor evaluable). In compiling this book, editors Manuel Ruiz Muller and Isabel Lapeña have attempted to provide a range of views encompassing many different perspectives, each supported by researched analysis of the relevant facts and law.

In selecting the editors, *The ABS Project* has teamed a recognized international expert (Manuel Ruiz Muller) whose significant body of work over many years has shown a constant desire to help the ABS issue evolve and function, with another excellent lawyer (Isabel Lapeña) whose rigorously developed insights into the issue should be better recognized in the future. Their combined efforts on this book have exceeded the Project's high expectations, resulting in a work that will not only have an impact on the framing of the current negotiations, but will also provide a basis for sound decision-making in implementation of the regime through many coming years. I am very grateful to Dr. Jorge Caillaux and the *Sociedad Peruana de Derecho Ambiental* for enabling them to make this important contribution to international development of this critical issue.

This book and indeed the entire Project owe a great debt to our primary financial supporter, the German Federal Ministry for Economic Cooperation and Development (*Bundesministerium für wirtschaftliche Zusammenarbeit und Entwicklung* or *BMZ*), and especially to Julia Kaiser, Andrea Laux and Frank Schmiedchen – without whom this work could not have been completed. Numerous other partners and collaborators have also made important and sustaining commitments for which we are very grateful.

Finally, I express our gratitude for the support and foresight of Dr. Alejandro Iza and the IUCN Environmental Law Centre. It was through Dr. Iza's efforts that *The ABS Project* became a reality, and his understanding of the difficulties in its implementation as well as his support and the unstinting assistance of the staff of the Environmental Law Centre, including especially Legal Officer Daniel Klein, Project Assistant Ann DeVoy, Senior Information and Documentation Officer Anni Lukács, Documentation Officer Andrea Lesemann and Documentation Assistant Monica Pacheco-Fabig. Collectively, these individuals have been a primary reason that the Project could finish its work and that outputs throughout the term of the project have achieved the level of legal excellence expected of the IUCN Environmental Policy and Law Papers, among which *The ABS Series* has been included.

Tomme Rosanne Young
Series Editor and Project Manager, *The ABS Project*

September, 2007

About the Series

The ABS Series represents a response to two realities: First, the ABS issue is controversial, and technically and legally complex. Because of the constant international concern over controversial policy and political issues, the primary focus of all writing on ABS has been focused on political positions and advocacy, even where the expressed purpose of a particular document is "practical legal advice." Lack of a rigorous body of ABS analysis has been one part of this implementation problem. Many professional inputs are characterized by opinions that are unsupported, or supported only by citations to the opinions of other experts or random references to or excerpts from laws and policy instruments, taken out of context.

To IUCN's Environmental Law Centre, it has become clear that the complexity and the controversiality are linked problems. Solutions to the international ABS controversies are currently stymied by the lack of credible, non-biased technical analysis of the elements and issues of national implementation. Serious in-depth analyses are needed concerning not only the few ABS examples, but also the kinds of legal options that are available and the manner in which they function. Simply put, one cannot build a structure without the right tools – and having the tools is meaningless without knowledge of what they can and cannot do.

The second "reality" faced by this project is the fact that, despite the long-extending international negotiations, genetic resources are being taken, studied, developed and utilized every day. Countries do not have the luxury of waiting for international negotiations to answer their questions, before taking action. It is consequently urgent for all parties (users, source countries, source communities and resource owners, user countries, researchers, middlemen and others) to have some basis for taking these actions. More important, they need to have some certainty that this basis will be robust enough to protect his/its rights, even after international negotiations provide some guidance or assistance to all or part of the ABS issue. Even where national laws and practices exist, they are proving inadequate to this objective, in some measure owing to the lack of technical help, as described above.

Consequently, *The ABS Series* focuses on national implementation and the legal and legislative issues that must be addressed, rather than advocating or addressing a particular side or position in the international negotiations. Through this process, *The ABS Series* seeks to create the best possible basis of researched information on the practical application issue. It is thus not only a tool for national decision-makers but also for implementers. While it is not always possible to be certain that one has been unbiased, we have made an effort, at minimum, to note the existence of other credible positions on the issues discussed, and to give some reasons why these positions were not more fully expounded.

As of this writing, the international process for development of the ABS regime is still ongoing. While not intended to "influence" that process, *The ABS Series* has been designed and written in the hope that a better knowledge of the realities of ABS will enable the negotiators to develop the regime as a functional and effective tool of conservation, equity and international development. As such, we believe that the books in this Series will continue to be primary works of scholarship and professional analysis on which the architects and implementers of the ABS regime will rely long after the negotiations have concluded. In addition, it is hoped that the authors in the Series (or a team of similarly qualified experts) will be engaged to update relevant books from the Series, when the time is right.

Target Audiences: Writing for a broad audience can sometimes be challenging for lawyers. In *The ABS Series,* however, we recognize that our primary audience includes national decision-makers, NGOs and others, as well as lawyers and economists. We have endeavored to present our research in an accessible way, without doing harm to our absolute standard of legal correctness. Although many readers would like a "simplified" pamphlet-style analysis of

the ABS issue, which can answer all of their questions in a few pages, this is not possible – the only simple fact about ABS is that it is not simple. *The ABS Series* provides summaries of the complexities in the issue that legal specialists must grapple with, but at the same time attempts to avoid "legalese" and its companion "econo-ese." In this way, we feel that *The ABS Series* provides both clarity and understandability for the non-lawyer, who may obtain a thorough grounding in the ABS issue through reading these books. For the legal or economics professional, however, these books also provide resources and information that will enable their deeper understanding of ABS issues.

The future: The ABS issue is still evolving. After the commencement of *The ABS Project*, the CBD entered on a groundbreaking process of re-evaluating ABS and attempting to develop the necessary tools, consensus and understanding (e.g., a clearer and more functional "international ABS regime") that will enable progress toward achieving the goals of the CBD. With this decision, *The ABS Project* underwent its first evolution. It had begun as a project aimed at helping national governments to find some positive steps to enable them to try to achieve the fixed language of CBD Article 15. In 2004, it necessarily expanded that focus – embracing the goal of informing all participants and interested persons (at national, regional and international level) regarding the options, instruments, practices and processes that can enable the ABS regime to become a functional mechanism for achievement of the CBD third objective. Only time can decide how far the international negotiations will go toward assisting and supporting ABS implementation. The team of professionals who have worked to provide *The ABS Series* hope that a useful and innovative result is quickly obtained, and that we will all have the opportunity to extend the work of this Series and to guide, analyze and promote the new regime components that will be developed.

List of Abbreviations and Acronyms

ABS	access and benefit sharing
CBD	Convention on Biological Diversity
CESAGen	Centre for Economic and Social Aspects of Genomics
CGIAR	Consultative Group on International Agricultural Research
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
CSOLP	certificate of source, origin or legal provenance
CSR	corporate social responsibility
ESCR	International Network for Economic, Social and Cultural Rights
FAO	Food and Agriculture Organization of the United Nations
GATT	General Agreement on Tariffs and Trade
GMO	genetically modified organism
GR	genetic resource
IDHGD	International Declaration on Human Genetic Data
INBio	National Biodiversity Institute (Costa Rica)
IPR	intellectual property rights
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
MTA	material transfer agreement
MTDS	monitoring, tracking and documentation system
PIC	prior informed consent
PBR	plant breeders' rights
PCT	Patent Cooperation Treaty
PGRFA	plant genetic resources for food and agriculture
TK	traditional knowledge
TEV	total economic value of biodiversity
TMOIFGR	tracking and monitoring the international flow of genetic resources
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Introduction

Manuel Ruiz Muller[1]

Under the Convention on Biological Diversity (CBD), a global international legal regime on access to genetic resources and benefit sharing (ABS) has emerged over the past decade or so. ABS legal instruments of different kinds and features, including international agreements, international guidelines, codes of conduct, regional and national laws and Conference of the Parties Decisions, have been developed.

To be effective and ensure CBD objectives are realized, this ABS regime requires appropriate compliance and enforcement mechanisms. A law or a regime which lacks these will have very limited chances of having practical impact, in the sense that obligations can, given the circumstances, be forced upon those legally bound by them through administrative or judicial actions.

In the context of the CBD and the international regime, these laws and regulations basically lay out the conditions in which genetic resources may be accessed, used and benefits shared. In exercise of their sovereign rights, countries have invested considerable time and effort in designing and developing legal instruments with the goal of ensuring that their economic, social, cultural and political interests in genetic resources are appropriately reflected and safeguarded.

As a key component of the ABS legal regime, as it is currently conceived, contracts (including Material Transfer Agreements – MTAs) have emerged as the preferred legal tool under which a series of rights and obligations are agreed between those providing genetic resources and using them. Whether contracts between the State and an applicant or user of genetic resources (another State, a private or public institution or an individual) and/or between these and a provider of genetic resources (a State, a private or public institution, an *ex-situ* conservation centre, indigenous or local communities or an individual), contracts define issues such as subject matter covered (scope), benefit-sharing obligations, regular reporting requirements, duration of the agreement, liability and infringement measures, choice of jurisdiction, among others.

As useful as contracts are, in the specific context of the international legal regime on ABS, countries (especially countries of origin or those providing genetic resources) are finding it exceedingly difficult to ensure that (a) this international framework assists in safeguarding their interests in genetic resources, especially once these resources cross national borders, (b) obligations in contracts can be fully imposed on the user of genetic resources and contract compliance verified, and (c) closely related to these, practical and cost-effective tracking and monitoring mechanisms allow countries and institutions to remain comfortable in knowing genetic resources are being used as agreed.

Realizing the benefit-sharing objective of the CBD depends considerably on these possibilities. Some progress is being made in this field, particularly with discussions regarding the role and objectives of a certification of origin and legal provenance regime. Increasingly the certificate concept seems to have become a technically viable, albeit still debated option, which is under consideration not only in the CBD forum, but in other international forums such as the World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO). This option would involve creating an agreed "standard certificate" and calling on all to use it as a means to identify geographical origin or source of genetic resources and to ensure valid rights for uses of genetic resources (and possibly of derived products) by those receiving them, as these move along the value-adding chain and research and development processes (including during patent-application processes).

[1] Manuel Ruiz Muller is Director of the Program of International Affairs and Biodiversity of the Peruvian Society for Environmental Law (SPDA), in Lima, Peru.

Countries and institutions, especially research centers, are still concerned that there needs to be a simple way to "see" how genetic resources and derived products are moving and flowing, and verifying whether these movements, uses and applications being given to them, comply with original (or subsequent) conditions imposed in contracts under which they were transferred.

A Moving Target: Genetic Resources and Options for Tracking and Monitoring their International Flows offers a first glimpse at some of the key policy, legal and technical issues surrounding tracking and monitoring of genetic resources, especially as they travel across national borders and among institutions in different countries.

This publication seeks to find answers to two basic questions: 1) is tracking and monitoring of genetic resources possible? and if so, 2) what are some of the main policy, legal, technical and practical challenges associated with tracking and monitoring?

For this purpose, seven experts from around the world have undertaken research on these questions and offer some guidance and recommendations as to how to advance discussions on this issue.

Chapter 1, "Tracking and Monitoring the Flows of Genetic Resources: Why, How and, Is It Worth the Effort?" was prepared by José Carlos Fernández Ugalde, from the National Institute of Ecology in Mexico. This chapter describes some of the key legal, policy, technical and practical issues concerning tracking and monitoring, and offers readers a general approach and possible answers to some of the questions related to these. In particular, this chapter focuses on the concept of "certification of origin and legal provenance," analyzes some of its practical implications and proposes some options as to how to develop a workable certification regime.

Chapter 2, "Transaction Costs of Tracking and Monitoring the Flows of Genetic Resources," was prepared by Derek Eaton and Bert Visser from the Wageningen University and Research Centre. Eaton and Visser focus their analysis on the problem of tracking and monitoring the flows of plant genetic resources for food and agriculture in particular and the complexities of transaction costs surrounding this effort. These authors argue that, at least in the special case of plant genetic resources for food and agriculture, the issue of costs of a tracking and monitoring mechanism and placing these costs on the user of these resources, could have a considerable impact on research, use and overall much needed flows of these resources.

Chapter 3, "Reflecting Financial and Other Incentives of the TMOIFGR: The Biodiversity Cartel", presents an innovative and controversial approach to addressing ABS, proposed by Joseph Vogel, of the University of Puerto Rico. Vogel argues that the bilateral, contractual approach stimulated by the CBD and reflected in the current international regime on ABS is basically flawed and that a new approach, based on economic theory, needs to be considered as a means to support countries' efforts in securing their interests in genetic resources (including in respect to tracking and monitoring). In the context of a biodiversity cartel proposal, Vogel suggests that tracking and monitoring are an element and requirement which will ultimately assist in the development and operations of this cartel.

In Chapter 4, "Challenges Ahead: Legal and Practical Prerequisites for the Development of a Certificate of Source, Origin or Legal Provenance for the CBD," Tomme Young, from the IUCN Environmental Law Centre, presents some policy-, legal- and economics-based alternatives and options to address the issue of tracking and monitoring. Young undertakes a detailed analysis of the viability and practicality of using certificates of origin and legal provenance as a means to support CBD implementation and address benefit-sharing, tracking and monitoring aspects of the CBD.

Finally in Chapter 5, "A Proposal on International Audits to Track and Monitor Flows of Genetic Resources and Verify Compliance with ABS Agreements," Manuel Ruiz Muller and Isabel Lapeña, from the Peruvian Society for Environmental Law, develop a conceptual proposal under which random audits on projects which imply accessing and using genetic resources are agreed internationally (by the

COP of the CBD or the Governing Body of the FAO International Treaty on Plant Genetic Resources for Food and Agriculture). They propose that these audits or valuation exercises could be undertaken by an *ad hoc* group of experts or a specific task force, which could offer policy makers, public officials, ABS focal points, and the public in general, information which is based on tracking and monitoring genetic resources of specific projects. This may assist countries in developing an operational international regime on ABS where compliance and enforcement are the main elements.

Tracking and monitoring the movement and flows of genetic resources around the world has not received much attention over the past few years, in comparison with other ABS-related issues. Only now that it is becoming clear that the international ABS regime needs to address in much more detail, and with much more attention, issues of oversight, compliance and enforcement, have tracking and monitoring appeared on the agenda and caught the attention of experts and policy makers.

This publication and the inputs provided by the different contributors (chapter authors) will hopefully provide fresh, practical and workable ideas that may assist Parties to the CBD (and by extension the ITPGRFA) in their efforts to continue building, strengthening and consolidating the international ABS regime and, ultimately, to comply with CBD principles and the realization of the CBD objectives.

1 Tracking and Monitoring of International Flows of Genetic Resources: Why, How and, Is It Worth the Effort?

José Carlos Fernández Ugalde[1]

Executive summary

Ever since the entry into force of the Convention on Biological Diversity (CBD) there have been considerable efforts to develop specific access to genetic resources and benefit-sharing (ABS) policies at the national and international level; however, the limitations in the existing ABS regime are still apparent. Implementation of the few existing national laws has become an almost insurmountable task (given their very complex nature and features) for many reasons. Countries of origin have not been able to secure their legitimate interests not least because of the role *ex-situ* conservation facilities are playing. Expectations about the role that genetic resources can play in conservation have decreased, particularly due to failures in producing the "billion dollar wonder drug or product" frequently described or expected in the original ABS negotiations and subsequent processes. Therefore the anticipated financial benefits for countries have not materialized.

This chapter argues that one of the important limitations in the current ABS regime is the lack of a monitoring, tracking and documentation system (MTDS) which provides all involved actors in the exchange of genetic resources chain with timely and relevant information regarding flows and uses of these resources. It also proposes that a MTDS could reduce costs of accessing genetic resources; gradually decrease asymmetries of information between users and providers; facilitate the capture of non-monetary benefits; generate a more positive social environment towards bioprospecting; and create incentives for users to comply with ABS legislation.

The key objective of the MTDS would be to ensure a cost-effective tracking and monitoring of genetic resources that would establish a linkage between access and use, particularly outside of the jurisdiction of the country of origin. For this objective to materialize, the MTDS needs to incorporate basic information related to: a certain degree of description of accessed resources; documentation evidencing compliance with national ABS legislation; inclusion of use conditions over genetic resources and general contact details, especially of national ABS competent authorities.

This information could be located and managed as part of a centralized clearing house and the certificate of origin/source/legal provenance may serve as the standardized tool issued by national ABS authorities to support and incorporate this information.

A fresh review of the provisions of the Convention on Biological Diversity (CBD) reveals what is, in essence, the makings of a deal to enhance and redistribute the value of genetic resources. The third objective of the CBD establishes that the benefits arising out of the utilization of genetic resources should be shared fairly and equitably, "including by appropriate access to genetic resources and by appropriate transfer of relevant technologies… and by appropriate funding" (Article 1).[2] In general terms, implementation of its provisions requires specific changes at three distinct stages:

[1] At the time of this writing, José Carlos Fernández Ugalde is an economist, and researcher at the National Institute for Ecology (INE) in Mexico.

[2] In order to articulate this broad objective, the CBD includes a set of specific provisions which include obligations to (a) facilitate access to envi-

- *Provision of genetic resources:* measures to facilitate access;
- *Research and development:* measures to provide and/or facilitate access to technology, to provide for collaborative research and to share the results of research fairly and equitably; and
- *Use of genetic resources:* measures to ensure that benefits are shared fairly and equitably.

Under an ideal regime, the user would find coordinated measures directed at each distinct stage, monitored and enforced by those in the best position to do so from the point of view of efficiency and effectiveness. It would seem obvious that this would require some form of international coordination given the global nature of those industries that utilize genetic resources.

In practice, however, the implementation of these provisions has taken a highly unilateral form: benefits in exchange for access on the basis of prior informed consent and mutually agreed terms on the basis of national access legislation, in other words, a *contractual* approach under the framework of national access legislation. This emerging model consists of two basic types of countries: those that see themselves as providers of genetic resources, which try to implement some form of access regulations; and those that consider they would gain more from the facilitated use, and which do not regulate access for the purposes of CBD and basically encourage their nationals to comply with national access legislation.

More than a decade since the entry into force of the CBD, the failure of the current regime is apparent. Only a limited number of countries have passed access legislation and most of them seem to have difficulties in effectively applying their provisions (Cabrera 2004). The Secretariat of the CBD has records of only 26 national access laws and regulations specifically designed to meet CBD access objectives (Ogolla 2005), and a recent study of access regulations in the Pacific basin has found that only 29 access permits were granted between 1994 and 2004 in the nine countries that had some form of access regulations (Carrizosa *et al.*). The reason this situation has not led to a standstill of biotechnological research, even in those countries, is that users have been able to secure access from *ex-situ* sources and take advantage of the fuzzy line between commercial and scientific use as well as the lack of clear rules on the status of derivatives. In this process, however, they have avoided benefit sharing in many cases.

The expectation of a much greater role of biotechnology in the world economy fueled much of the discussion regarding genetic resources during the early days of the negotiation of the CBD. The CBD recognizes the value of biodiversity as information, the need to enhance this value through facilitated access, and the need to provide a level playing field for all countries in this new technological revolution. Ten years on, however, we face a striking paradox: The value of all global sales for biochemical resources has grown significantly and is currently estimated at almost US$ 500 billion, with more than US$ 50 billion devoted to research and development (R&D) annually.[3] At the same time, the documented benefits being shared in compliance with CBD obligations remains extremely low. Even Costa Rica's INBio has fetched only a few million dollars after about a decade of experience in access contracts[4] (Guevara 2004). This paradox has been fueling part of the international allegations of biopiracy, considering this to be unfair and inequitable.

This paper argues that this situation is not due to lack of interest of Contracting Parties, particularly

ronmentally sound uses (Article 15.2); (b) endeavour to develop and carry out research with the full participation of and, where possible, in countries providing resources (Articles 15.6 and 19.1); (c) take measures to share the results of research and development as well as the benefits from commercial and other utilization (15.7); (d) provide and/or facilitate access for and transfer of technologies (Article 16.1), including measures with the aim that the private sector facilitates access to joint development and transfer of technology (Article 16.4), as well as technologies protected by patents and other intellectual property rights (Article 16.3). Moreover, a greater emphasis is placed on sharing benefits with developing countries (Articles 16.3 and 20.2).

3 Artuso. 2002. This estimate was calculated simply by estimating that for any company, R&D accounts for approximately 10% of gross sales.

4 About US$ 600,000 from 1991–2002 directed to conservation (10% of research budgets) (Guevara 2004). Of course, INBIO is not the only case of benefit-sharing arrangements, although it is probably the longest extant, and the most advanced. The main idea is simply that there is a sharp contrast in orders of magnitude between what is generated in revenue and invested and what is shared in individual contracts.

those that are developing countries, to regulate access, but is the direct result of a limited regulatory model based on access conditions but poor monitoring and enforcement mechanisms at the point where actual benefits occur and should be shared. Countries drafting their access legislation have drafted and passed their regulations in the absence of direct and coordinated support from regulations in countries with users of their genetic resources under their jurisdiction. The perception that as soon as the genetic resources leave the country they "are gone" is often voiced in national discussion on access. There is, therefore, pressure to increase requirements and proofs of compliance with CBD provisions at the point of collection of the materials, increasing transaction costs and discouraging access. The scientific community is often negatively affected, being the first link in the chain.

As a result of this situation, some countries have even started to take stock of their experience and are exploring alternatives to make them more functional, notable examples being the Andean Community and the Philippines. In the case of the latter, it has already passed a reform to make its ABS system less burdensome. Ultimately, however, the degree of flexibility and relaxation of ABS provisions will depend on the effective implementation of supportive measures closer to the point where the actual obligation to share benefits materializes, i.e. during the research and development stages and the point of commercial and other utilization. At the international level, these implementation problems and the need for a more balanced regulatory regime fueled the discussion on the role of user measures during the negotiation of the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of their Utilization and the central drive of the international regime on ABS being negotiated under the CBD.

In order for these complementary measures to be effective, a link between the resource that was accessed and the one being utilized, with some form of monitoring, tracking and documentation system (MTDS) for genetic resources and their utilization must be put in place. This is necessary, of course, if we are to pursue compliance with CBD obligations under the current contractual approach. The CBD has initiated these discussions under the heading of a proposed Certificate of Legal Origin/Source/Provenance. Regardless of the name, the essence of the proposal is the same: to establish some form of documentation requirement that involves proof of legal acquisition of the materials, i.e. acquisition compliant with CBD obligations.

The aim of this paper is to analyze the role of MTDS, the context in which they would be applied and to derive some implications for their design. Section 1 presents the case for MTDS by introducing a number of inefficiencies created by the lack of such systems within the current ABS regime. Section 2 discusses a number of facts in the industry that must be addressed by the MTDS and draws several implications for MTDS design. Section 3 presents a possible set of concrete features for the design of the MTDS. Finally, Section 4 provides a set of recommendations to overcome remaining challenges in establishing the linkage between access and utilization.

1.1 The need for a monitoring, tracking and documentation system (MTDS)

An MTDS, in the context of the current discussion, is simply a system in which users of genetic resources are required to (1) keep minimum documentation on the genetic resources they use, particularly those that are used in connection with the access and benefit-sharing conditions/permits; (2) transfer that information to any third parties that receive materials from them; and (3) provide that information at specific check-points (e.g. intellectual property right applications and product approval processes, etc.). This system requires that there be regulatory agencies responsible for verifying and enforcing documentation requirements. These features, as well as other design considerations, will be described in greater detail in the next sections. In the international negotiations, there has been some argument regarding the nature of the information that needs to be maintained and transferred, namely, source, origin or legal provenance. All of the choices,

however, involve the same basic elements and will suffice for this analysis.

From that basic understanding of what an MTDS implies, it is clear that the current ABS regime lacks such a system. As stated above, some mechanism to monitor, track and document genetic resources and their utilization is needed to enable a more efficient regulatory system to comply with CBD provisions regarding genetic resources. Some of the inefficiencies caused by the lack of MTDS include:

- *Increased costs of access:* Given that there are limited means to ensure compliance at later stages, the only option is to request all guarantees possible at the point of access, which is often translated into elaborate access provisions, at an increased cost.

- *Increased negative effects of information asymmetries and uncertainties:* Demonstrating full compliance with ABS regulations at the point of access requires applicants to establish clear and detailed benefit-sharing provisions, despite the fact that the nature and amount of benefits (if any) are highly uncertain at the outset. It is also a stage at which the provider is less aware of the nature of the possible product.

- *Limited capacity to capture a share of non-monetary benefits beyond what the initial user can offer:* Since the full contract is agreed upon at the outset and the only known or "visible" counterpart is usually the agent seeking access, non-monetary benefits, such as access to technologies and possibilities of collaborative research, are difficult to negotiate beyond the capacities of that initial agent.

- *Increased social resistance to access projects:* The absence of credible means to detect and act upon breach of access conditions leads to greater resistance towards access projects, thereby contributing to biopiracy allegations and the creation of non-legal barriers to access.

- *Increased risk to investors in marketing:* The absence of MTDS limits the capacity of investors to discriminate fair players in the industry and better identify the nature and consequences of their contractual obligations related to access.

- *Supportive legal measures face excessive costs or limited capacity:* It has been argued that a country with users under its jurisdiction seeking to implement measures in support of ABS regulations in provider countries would experience high costs because they would have to undertake research on a case-by-case basis to determine compliance with individual legislation.

- *Reduced incentives to comply with ABS provisions:* Perhaps the most pervasive consequence of the lack of MTDS is the fact that if users see a reduced risk of being challenged in case of violations, they have fewer incentives to comply with countries' of origin or providers' legislation.

In essence, the development of an effective MTDS would contribute to the elimination of these sources of inefficiency in the current regulatory system. It should be noted, however, that on its own, the value of an MTDS is limited. In the absence of a coordinated response, the value of an MTDS would be significantly reduced. There are complementary measures that should be taken in order to take full advantage of the MTDS. Some of the complementary measures include: sanctions for non-compliance with monitoring, tracking and documentation measures as well as ABS provisions, reduced regulatory burden at the point of access, measures to increase awareness of users as well as the public in relation to ABS and the MTDS, and measures to increase the transparency of the transactions.

1.2 Facts and trends in the industry

While an MTDS is desirable, its specific design should take into consideration several characteristics of the economic sectors that access and use genetic resources. The absence of such considerations could result in an MTDS that is either impractical or too costly. This section analyzes a number of facts related to the process of access and use of genetic resources, particularly in the biotechnological sector, and attempts to identify for each of them a number of desirable features that might be included in an MTDS.

It should be noted that many of the features highlighted here correspond to the blue (marine) or white (industrial) biotechnological sectors, while some of the features may be shared equally by the agricultural (green) biotechnology sector. None of these is the primary focus of this paper. Some [many?] of the examples used relate more to the pharmaceutical (red) sector. While it is true that the pharmaceutical model is only one of many in the industry, it is a paradigmatic one, since even relatively distant segments, such as the cosmetic industry, are undergoing changes and gradually becoming more like the former. Some of these changes include regulatory changes, product safety concerns, scientific backing of product claims, demand for "environmentally friendly" and natural products, as well as influence by the animal rights movement (Kumar 2005). Some regulatory initiatives have even considered the creation of "cosmeceuticals" as a new product classification.

1.2.1 Key points – essential inputs and multiplicity of genetic resources

This section will consider two primary facts about R&D. First, research and development of products is a lengthy and risky process, involving both high investment and skilled labor. Second, it is critical to remember that multiple genetic resources are typically involved in a single project. Biotechnological research is, economically speaking "intensive" – that is, it depends on a number of inputs: skilled labor, capital, and genetic resources. All of these inputs need to be adequately compensated in the industry in order to be economically viable in a future CBD compliant world. This would mean a world where source countries all have ABS legislation that is operational and complemented by international measures to ensure that benefits from use are equitably shared. Creative work needs to be rewarded, capital investments need to have an attractive return, and genetic resources need to be recognized so that their providers receive a fair and equitable share of the benefits. A major complication is that, while all of these potential compensations must come from the same revenue pot, there is no simple way of separating the individual contributions of these three distinct inputs. Moreover, a single input will not always ultimately result in a specific profit (although it may be a basis from which informational benefits and other benefits may be derived), in which case all inputs would be without financial compensation. The long periods of time involved in product development also imply that there are financial costs which accumulate over time and, in fact, constitute a significant portion of total costs in the industry.

Implications: Based on the foregoing facts, one can derive the following possible implications for the system that creates and applies the MTDS:

- It should be low cost – that is, its cost should be linked to value in terms of providing, for example, traceability options and returns from the use of genetic resources to the source country while ensuring a level of legal certainty to the user;
- It should promote investment and facilitate research; and
- It should be based on simple rules for deciding on the relative participation of genetic resources, for purposes of allocating a benefit share.

1.2.2 The role of natural products is increasing in complexity, with many genetic resources used in the development of a single product

While one is often drawn to the image of the single researcher working in the jungle and finding the cure for a terrible disease in an extract directly derived from one species, the reality of product discovery is far more complex and the role of a single genetic resource is less clear. A more realistic model would picture the process of searching for useful traits as one involving many genetic resources from many different sources in many institutions interlinked through different types of collaborative agreements. Moreover, once a useful activity is found in a compound, it is possible that the compound would be further refined and improved to enhance its value. In some cases, the compound may be more cost effective if it is extracted from a completely different species that shares the same trait.

Recent analysis of the role of natural products as sources of new drugs (Newman and Cragg 2003) has found that, while natural products still play a major role in drug development, their participation is not necessarily very direct. Natural products provide knowledge or basic genetic/biochemical structure, which is then sometimes turned into a semi-synthetic modification or a full synthesis. The actual participation (direct involvement) of genetic resources/natural products (in this form) in the product or output is harder to characterize, and may be resolved through efforts to clarify the notion of derivatives or the scope of the benefit-sharing obligation. The fact that there appears to be a proportional increase in the share of these products in the marketplace, stresses the importance of addressing this issue in the context of MTDS design.

Therefore, most genetic resources entering a R&D process do not result in "hits" (direct, marketable products). There are multiple processes and exchanges of materials. Information needs to be shared in order to maximize the chances of success.

Implications: For the MTDS, these facts suggest that the system:

- should not require an inspection of genetic resource use at every stage, since in most stages, the information gained would not be valuable and the process would involve high transaction costs. Instead, inspection should only be used to check on progress at critical stages, i.e., at the end of the R&D process and where benefits materialize;

- should facilitate multiple transactions involved in product development; hence, the format of the documentation should be preferably electronic, possibly the exchange of a simple code, which in turn should be linked to a clearing house with complementary information; and

- should utilize a kind of documentation that can be used as a "passport" for further transactions involving both the genetic material and the associated bio-information.

1.2.3 Ever more complex economic and legal interactions between academia and industry

With an increasing role for collaboration and exchange among academia and business, the constellation of contracts and relationships is increasing and becoming more difficult to handle under existing frameworks. As noted by Binns and Driscoll, "at least in the outset of the project, it may be difficult for a party to identify all of its relevant background rights – indeed, many organizations are unaware of all the intellectual properties (IP) – particularly know-how – that they own" (Binns *et al.* 1998). I would argue that this extends to liabilities, i.e. in connection with IP of others that is held (used, not owned) by a party. In this context, developing an effective intellectual rights system to address genetic information and know-how will require institutions to devote more resources to due diligence in biotechnology transactions, analyzing the required patent scope and its validity to ensure freedom from infringement and relevant third party agreements (Gogoris *et al.* 2001). While the proposed MTDS is a new explicit requirement, it represents a lower cost mechanism to inquire about potential liabilities and rights to use specific materials.

Some evidence has been provided to suggest that

there are more alliances, particularly in the area of discovery and leads (Cavalla 2003). According to their data, alliances in the top 20 US biotechnology companies rose from 85 in 1988 to 226 in 1998. Of those, the increase at the discovery and lead phase grew more significantly, namely from 62 to 162 (Cavalla 2003). A recent survey found that the total number of licenses and options executed by US universities had increased by more than 20% (Bouchie 2005).

This fact also indicates that the traditional line dividing the commercial and academic work is becoming increasingly blurred, creating challenges for those seeking to secure exemptions for academic research. To illustrate these trends, a study found that at least 39% of new chemical and biological entities approved by the US Federal Drug Administration originated from outside pharmaceutical companies, with some 24% originating from biotech firms and some 15% from public research. Most of the drugs from public research were licensed to biotechnology companies and pharmaceutical companies (Kneller 2005). In this "relay race" for product discovery and development, without an MTDS that is directly associated with benefit-sharing triggers down the development path, providers will not be able to effectively capture non-monetary benefits effectively from the "first runner." Monetary benefits, e.g. royalties, can be more easily transferred as obligations to other users, while other benefits, such as results from research or access to technologies, are more difficult to secure.

Implications: This development suggests that:

- while adding to the already complex world, MTDS could be designed to provide a platform for a more streamlined management of legal obligations related to genetic materials; and
- (as mentioned), the importance of MTDS as a trigger for benefit sharing at R&D beyond the initial collection should be stressed.

1.2.4 New frontiers of genetic-related exploration

Most exploration of genetic resources has, over the years, focused on plant and animal genetic resources. Recently, and given developing technologies and industrial needs, micro-organisms and genetic resources in extreme environments have become a new source of interest. Scientific and technological developments, however, have created new opportunities, and enabled the exploration of the natural world to extend to areas previously beyond our reach. This is particularly true in the case of microorganisms (Rondon *et al.* 1999). Likewise, recent years have seen an increase in the exploration of the seas as technical barriers which limited past work in this area have been overcome (Colwell 2002). These new frontiers challenge our previous understanding on which we decided which genetic resources were of potential value (and with use are becoming resources with actual value). In addition, this expansion is also taking us into new legal realms, such as bioprospecting in areas beyond national jurisdictions (Lohan *et al.* 2005).

Implications: This development suggests that the MTDS must be able to:

- accommodate new sources and methods as they become available in the future; and
- create an integrated system across a range of sectors, which may well have different obligations.

At a minimum, the various management regimes should coexist without hindering the effectiveness of each other.

1.2.5 *Ex-situ* collections are still valuable and coexist with new collections

Existing biological resources in *ex-situ* collections are still sources of inputs for biotechnological research. Technological advances create opportunities to look at the same materials with new tools and in that sense, constitute materials that are partially "renewed." This means that a significant proportion of materials currently being exchanged have originally been obtained from *ex-situ* collections, both private and public. *Ex-situ* collections are also more valuable to the extent that they are well curated and contain significant information. Accessions of "genetic resources" predating the CBD may release the accessor from ABS obligations; on the other hand, it can also be validly argued that even if materials were obtained prior to

the CBD entering into force, the actual *transfer or utilization* of these materials and genetic resources after the CBD entered into force could be subject to the CBD rules and principles.

Implications: When following the MTDS approach:

- It is important to incorporate *ex-situ* sources into the regime, just as the regime must address any new (geographical or intellectual) frontier by incorporating existing situations.

1.2.6 Increased use of intellectual property to secure market value for inventions

The intellectual property rights (IPR) regime represents an important solution for promoting innovation and attracting investment. In an area very dependent on investments and highly skilled innovators, the biotechnological sector relies on IPRs to secure an option to obtain market exclusivity and capture benefits from marketed products. The number of patents in the field of biotechnology has grown significantly in the past few years and even academic institutions have made increasing use of patents for the protection of potentially valuable inventions. The rapid growth and distinct characteristics of biotechnology have created new technical and ethical challenges to the current intellectual property regime (Welch 2002; Lawson 2004), some of which have to do with the adequate recognition of the genetic resources in the development of new inventions and the distinction between an invention and a discovery.

Implications: Based on this analysis, it appears that the MTDS:

- should be designed to assist in clarifying the role of genetic resources in an IPR application, in particular with regard to the distinction between discoveries and inventions; and

- should utilize IPR systems to the extent practicable, as a valuable stage in the development process and an indicator of commercial "intent"; and as such, consider the IPR application stage to be one of the milestones or stages within the ABS arrangement at which the parties can ensure compliance with mutually agreed terms for benefit sharing.

1.2.7 Various related data management challenges to ensure adequate exchange

The sharp reduction in costs of genetic analysis as well as the sheer volume of data involved has created a need for greater capacity to store and analyze biological data, in the face of concerns that free access to this information will enable the use of genetic resources without benefit sharing. The entire field of bioinformatics is emerging to meet that very need. One particular challenge, however, is data exchange. Data needs to be exchanged for a variety of reasons, from validation of results to expansion of analysis; this, however, becomes more complex in the absence of data standards and exchange protocols. A somewhat related issue, although with a contrasting objective, is the building and management of medical data. The main issue has to do with ensuring the confidentiality of personal data while promoting data exchange among the scientific community. This has led to a range of initiatives aimed at developing data standards (Knoppers *et al.* 2005). These initiatives contribute to reducing the costs of MTDS.

Effective communication among various types of databases is also essential as well as improvements in search techniques. In terms of intellectual property law and practice, none of the existing "traditional knowledge databases" are comprehensive enough to meet the standards by which an applicant can use them in an adequate search for "prior art." If they were to be used in this way, the applicant would have to search a great many databases to get a better response (Simmons 1998; Xu *et al.* 2002).

Just as intellectual property databases could be improved to accommodate MTDS, product approval databases are another area to explore further. For example, in the case of New Biological Entities with marketing approval by the US Food and Drug Administration, it would be difficult to know if it has been in-licensed since information about the patents covering a NBE is not published (Kneller 2005). The tracing of ABS obligations at the product approval level would require that the minimum documentation

of the MTDS be requested and published through public databases or that sufficient information is released to perform that link, e.g. through publishing of patent and licensed data for approved products.

Implications: For the MTDS, this suggests that:

- users are in a better position to decide on the best storage and transmission standards, and the MTDS should be flexible enough to be building upon various data management standards; and
- existing databases could be expanded to become check-points.

1.3 Toward an effective and feasible MTDS

The following discussion provides a summary of the desirable features discussed above as well as some of the benefits of each of them.

Taking into consideration the rationale as well as the desirable features that have been discerned in reviewing the characteristics of the biotechnological sector, it is possible to advance in the delineation of a possible MTDS. This section provides a brief description of an MTDS incorporating the following considerations (Table 1). The intention of this section is to narrow further the set of alternatives available for the MTDS in order for them to be effective, feasible and practical.

Table 1. Desirable features and benefits of an MTDS

Desirable features	Benefits	Challenges
Few relevant check points at end of R&D pipeline.	- Low transaction costs; - Enables facilitated exchange of the genetic resource at intermediate R&D stages; - Serves as trigger for negotiations.	Loss of a degree of control but promotes legal certainty for a source country.
Conveys notion that access conditions, state rights and obligations of users were fulfiled.	Gives some level of certainty to investors.	The MTDS should provide both users and investors with a sufficient and reliable level of certainty.
Rules for assessing relative participation of genetic resources and jurisdictional reach of benefit-sharing obligations.	Provides certainty regarding the limits and problems of practical implementation of benefit-sharing obligations.	It will be necessary to develop an analytical valuation system.

Desirable features	Benefits	Challenges
Electronic codes as primary documentation to be conveyed and linked to clearing house.	- Flexibility to use in various platforms; - Takes advantage of emerging technologies developed by industry; - Can accompany materials as well as data; - Low-cost transmission of users' rights and obligations; - Could serve as platform to manage other third-party agreements.	It may be appropriate to consider the costs of developing, implementing, and updating the system.
Self-declares (through a sworn declaration maybe) the degree of quantitative and qualitative linkage of the technological development to the genetic resource contribution.	Provides a more realistic basis on which to negotiate benefit-sharing arrangements.	
Provision to enable application to new sources.	Creates an integrated system which assists in the management of genetic materials beyond national jurisdictions and *ex-situ* materials.	Would also imply a need to address issues of making the MTDS binding on successors along the value-adding chain and in relation to enforcement of contractual obligations.
Creates exemptions for particular uses that would not fit the contractual model.	Reflects the sharp contrast between the plant breeding model and the model used in this discussion.	- Plant breeding and possibly other sectors may require separate treatment; - There may be difficulties in specifying the differences between types of use, application, research, etc.
Clearing house should include description of materials and, when possible, other relevant information.	- May contribute, as a basis for reviewing "prior art" and describing it in IPR reviews; - Facilitates identification of those with right to file IPR applications.	One problem may arise in the area of non-IPR related uses and potential costs for addressing these situations.

The objective of the MTDS would be to provide a means to monitor and track genetic resources to create a link between access and utilization of genetic resources beyond the jurisdiction of provider countries. As such, the main documentation in the MTDS includes:

a) description of the basic resources, including its geographical origin;

b) evidence of compliance with access and benefit-sharing obligations arising from the CBD and from national legislation;

c) conditions for use, including rights and obligations of users; and

d) contact information of the national authority providing access.

Most of this information would be located in a central clearing house and, as such, the only piece of information to be passed on among users would be the registry number or code associating the material or information being exchanged with the basic documentation outlined above and stored in a public database (clearing house). This code or registry would embody what has been referred to in current negotiations as the "Certificate of Source/Origin/Provenance."

This certificate (or code) would be issued by a designated national authority and according to an internationally agreed standard to avoid duplication of certificates. A single certificate could cover multiple genetic resources, to the extent that they all share the same basic documentation information, particularly with regard to the rights and obligations of users.

The user is then legally forced to maintain the link between the certificate and the material/information by any means necessary, and must convey it to whoever receives the material or the information derived from the genetic resource, as well as pass the obligation to do the same if the materials are passed on (whether by sale, transfer, or indirect methods) to third parties. Just as one would cite an author whose idea we are using in an argument, or acknowledge funding institutions or special collaborations in the resulting work, so the certificate's information identifying and describing genetic resources essential for the development of discoveries or inventions should be disclosed in publications or be incorporated into property rights applications or product approval processes.

Of course, since the total number of species is enormous, not all genetic resources should be recorded – only the essential ones. Criteria should be developed to determine what constitutes an essential contribution. In principle, if the same discovery/invention could have reasonably been developed by substituting specific genetic resources with others previously known, then the contribution of that genetic resource was non-essential. However, again, there are technological challenges and questions as to whether the specific genetic resource was non-essential in a particular case. This is the situation, for example, if the genetic resource is an alternative to the salicylates in aspirin. Does possible use of salicylates in aspirin make the genetic resource non-essential? This criterion implies that some derivatives incorporated in discoveries and inventions would not have to be recorded, because they do not have direct contact with the genetic resource.[5] This criterion, in effect, represents the scope of the benefit-sharing obligation. In order to convey a clearer idea of the degree of contribution of the genetic resource to the overall invention, the disclosure requirement could be complemented with a self-declaration of degree of participation of the genetic resource. A simple but powerful classification system like the one used by Newman and Cragg, consisting of biological and natural products, derivatives from natural products, total synthetics, natural mimics, etc. could form the basis for such categories (Newman *et al.* 2003).

[5] A recent proposal by the European Union (WIPO/GRTKF/IC/8/11) in the context of disclosure requirements in intellectual property rights applications provides for mandatory disclosure of the origin of resources, but only if the inventor had direct contact with the genetic resource, given the rapid growth in bioinformatics and the ability to produce semisynthetic products which still derive value from knowledge gained from genetic resources.

The certificate/code stored would only be requested at specific check-points toward the end of the R&D process, including applications for IPR or product approval. At these stages, the number of genetic resources is not only significantly lower, but their expected value is much higher. Border controls, while in principle appealing as check points, present a number of problems. They are not only difficult to enforce, but they would be involved in significantly low-value transactions, increasing the cost and reducing the effectiveness of the system.

In the case of discoveries/inventions made from *ex-situ* collections or from areas beyond national jurisdictions, specific certificates/codes could be agreed. The rights and obligations arising from such collections would depend on the individual policies as well as international obligations. This, however, would ensure that most biotechnological applications would have a code, minimizing the risk of diluting the obligation by simply saying that the source is unknown.[6] Efforts to identify the relevant certificates and their derived obligations should become part of the due diligence of users of genetic resources.

With regard to the consequences of non-disclosure, there is often some tension in the international debates since, on the one hand, without some penalties for non-disclosure, there is little incentive to comply and on the other, it is often difficult for the enforcement body (or party to the contract) to know that a violation has occurred. Moreover, it has been difficult legally to justify some proposed penalties, such as revocation of patents. A middle-ground solution is to provide for some time to satisfy the requirement, encouraging the companies to research the origin of their materials – through which the system would raise a "red flag" for the corresponding authorities in the source country through the clearing-house mechanism and contemplating the adoption of a sanction for the administrative fault, possibly delaying the permit or patent processing until some explanation is provided. It should be the responsibility of the designated authority to deal with violations of access and benefit-sharing conditions.

For cases where a genetic resource originated in a country that does not have ABS regulations in place, some special codes could be developed by the clearing house and receive a formal acceptance by this country to ensure its legal validity. This could either note that there is no further obligation, or set some minimum benefit-sharing requirements if they were to be agreed upon at the international level. This discussion leaves out the question of equity which could be the subject of another paper.

1.4 Conclusions and final remarks

The preceding sections have attempted to provide both a rationale for an MTDS within the access and benefit-sharing regime being negotiated, as well as some design considerations and possible concrete formulations. Clearly, some challenges remain in the applicability of the MTDS. One of the most critical is to minimize the cost of the overall system or, as noted above, to ensure there is an adequate relation between the system's cost and the value it offers to different countries and actors. The MTDS would add to an industrial sector already burdened with regulations. This, however, does not mean that the ABS obligations should be the first to go.

A second challenge relates to the need to strike a balance between creating and capturing value of genetic resources. While creating value requires exchange, this could be limited if the effort to ensure that those benefits are captured by the provider countries discourages or blocks access. A third challenge is that of articulating the complementary policies and measures needed for the operation of the MTDS and for achieving the ultimate goal, which is the effective implementation of CBD obligations. If user measures are not in place, including credible checkpoints, or access

[6] Both the proposals by the EU and Switzerland (PCT/R/WG/4/13, PCT/R/WG/6/11, WIPO/GRTKF/IC/7/INF/5) call for the disclosure of the origin and source of genetic materials, if known. Furthermore, they propose that there should be no additional obligation on the applicant to carry out research to identify such information. This exclusion significantly diminishes the effectiveness of the disclosure requirement.

conditions are not relaxed, the efficiency gains of the MTDS will be limited.

On the positive side, there seem to be a number of synergies, particularly in the field of data management and searches, where current efforts to resolve the industries' own problems could pave the way for the MTDS. Similarly, the MTDS could be expanded to serve as a platform to reduce the cost of tracking legal obligations related to other agreements, thereby creating a more functional system overall.

Finally, there is one final but most relevant consideration: the MTDS will ultimately assist in supporting the contractual approach on which the current access and benefit-sharing model is based. However, this approach has limitations. Several authors have suggested that a purely contractual approach may be too costly to implement (Janssen 1999; Artuso 2002; Lawson 2004). A recent article by IUCN (Young 2004) suggests that the contractual approach does not have to be the only form of implementation of the obligations under the Convention. However, Young also notes that this approach appears to be dominant in the mindset of negotiators.

But costs are not the only concern. It is true that there will be some form of competition among providers of genetic resources unless they are differentiated in the marketplace (Artuso 2002). This could, in fact, result in lower values for individual contracts. If the contractual approach is not feasible, either because even with the best MTDS design costs are too high, or because contracts are still inefficient, States should be prepared to change the approach altogether to implement the objective of the CBD effectively.

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2 Transaction Costs of Tracking and Monitoring the Flows of Genetic Resources

Derek Eaton and Bert Visser[1]

Executive summary

Over the last few years, attention to the issue of tracking and monitoring the flows of genetic resources has increased. The CBD now recognizes that genetic resources are under the sovereign right of States and, as a result, many countries have embarked on a policy and regulatory process to regulate access to and benefit sharing from these resources. Two new policy scenarios – the CBD and the FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) – have considerable implications regarding transaction costs associated with implementation, enforcement and closely related to these, tracking and monitoring.

In brief, transaction costs are defined as the different costs (monetary and non-monetary) which need to be assumed in the process achieving a certain goal. In the specific context of genetic resources, transaction costs are divided into costs of negotiating access to genetic resources agreements, pre-distribution and post-distribution of materials costs. In the case of the latter, tracking and monitoring are important components of the process of verifying whether or not genetic resources are being utilized in the form which was originally agreed upon. Tracking and monitoring in themselves pose important challenges and imply a series of costs which will have to be borne by the user of genetic resources, the supplier or a potential consumer of a product, given the case.

This chapter focuses on tracking and monitoring of plant genetic resources for food and agriculture (PGRFA) and related transaction costs and their implication, especially in the context of the ITPGRFA. It makes a series of cost calculations and proposes that transaction costs can be measured based on a series of categories: Material Transfer Agreement (MTA) handling; central documentation management; DNA fingerprinting for different samples; database searches in intellectual property offices and, ultimately, legal costs.

The chapter argues that transaction costs of monitoring the overall effectiveness of access and benefit-sharing systems in general are harder to estimate than the actual costs of tracking specific materials. However, monitoring costs in the context of the ITPGRFA are probably modest in comparison to exchange under the CBD. In any case, a tracking and monitoring mechanism should be low cost and almost certainly will have to exclude standard genetic or biochemical analysis of each sample, since the cost of such analysis will most certainly exceed the expected benefit-sharing levels. Only in very specific cases may individual tracking and monitoring be advisable, depending on the nature and potential (or proven) value of a particular resource.

[1] Bert Visser is the director of the Centre for Genetic Resources, The Netherlands (CGN) while Derek Eaton is a researcher at the Agricultural Economic Research Institute (LEI), Wageningen University and Research Centre in The Netherlands. The authors have focused on transaction costs involved in the exchange and use of genetic resources for several years. Practical experience is based on the transaction costs incurred by CGN for collecting germplasm from other countries, notably from Uzbekistan, Kyrgyzstan, Peru and Sierra Leone, and for distributing germplasm in conformity with the ITPGRFA and CBD including an average of 6000 accessions to users in an average of 30 countries per year. The authors also advised FAO on the importance of non-monetary benefit sharing and the ITPGRFA funding strategy (*see* ftp://ftp.fao.org/ag/cgrfa/BSP/bsp30e.pdf and ftp://ftp.fao.org/ag/cgrfa/BSP/bsp31e.pdf).

Evolving property rights regimes over agricultural genetic resources.[2] With the adoption of the Convention on Biological Diversity (CBD), the ownership status of genetic resources has changed. The CBD affirms that such resources come under national sovereignty. In executing their rights, countries have subsequently agreed, under the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), to establish a Multilateral System of Access and Benefit-Sharing (Multilateral System). This Multilateral System constitutes a single regime defining modalities for access and benefit sharing for a substantial sub-set of staple crops and forages. This Multilateral System will be operationalized primarily through the adopted standard Material Transfer Agreement (MTA) regulating and defining terms and conditions for both access and benefit sharing.

Douglas North (North 1990) argues that institutions provide the structure for exchange that determines the cost of transacting as well as the costs of production. In the case of genetic resources, national and international exchange has evolved from one of relatively unencumbered and unregulated transactions, to one in which contractual agreements are negotiated between providers and recipients, either bilaterally or multilaterally as in the case of the ITPGRFA and its standard MTA. The changes in ownership, the increasing role of property rights, and the establishment of new access and benefit-sharing requirements mean that transactions in genetic resources also take on other characteristics. In particular, the cost of reaching and enforcing exchange agreements is affected.

Concept of transaction costs. Changes in the size and nature of the transaction costs associated with exchanging genetic resources are one of the most important aspects of the newly evolving institutional framework that governs the transfer of genetic resources. The attractiveness and feasibility of such arrangements depends as much on the distribution of direct benefits as on efficiency in terms of transaction costs, and their allocation among stakeholders.

In contrast to fees or royalties paid for access to material, in this case, transaction costs are comprised of the costs in the form of both parties use of their own resources (not necessarily financial) in negotiating, concluding and implementing an agreement (contract) concerning the transfer of genetic material from one party to another. Transaction costs are affected by (1) the degree to which investments or resources involved in a transaction can thus not be immediately applied for other purposes (asset specificity), (2) the amount of uncertainty on the conclusion and implementation of the contract, and (3) the frequency with which such transactions take place (Williamson 1987). In the case of the exchange of genetic resources, each of these characteristics increases the total cost of transacting. These rising costs are compounded by the predominance of company secrecy strategies (hidden information) among recipients of genetic material, in particular in the private plant breeding sector, possibly implying greater incentives for opportunistic behavior by recipients, and a consequent need for providers to invest resources in enforcing agreements.

In a previous analysis, we divided the transaction costs associated with the international exchange of PGRFA into three types: negotiation costs, pre-distribution costs and post-distribution costs (Visser *et al.* 2000). Negotiation costs consist of the costs for providers and users of the entire process of arriving at an agreement or contract on (1) the material to be exchanged, (2) the scope of use, (3) any terms for financial compensation, and (4) other rights and obligations. To this could be added the costs for the user of locating the material of interest in the first place.

Pre-distribution and post-distribution costs refer to costs that contribute to implementing and enforcing the agreement. Pre-distribution costs are the costs for the provider of documenting the properties of the genetic material, possibly including the DNA fingerprinting of the material, in order to serve eventually for verification purposes if it were suspected that the terms of the agreement were not being respected.

[2] The terms "genetic resources" and "genetic materials" are used here interchangeably. PGRFA refers to a subset of these materials, also referred to as "plant germplasm."

Post-distribution costs are then the costs of tracking both the use of genetic resources and the registration of plant varieties and of patents covering genes obtained from the provided genetic material. This tracking is undertaken in order to identify possible applications in which parts of the exchanged material may be present and that were not disclosed by the user.

Our earlier analysis focused on the likely scale of these transaction costs under various scenarios in which PGRFA were exchanged under bilateral agreements, as compared to a multilateral system of facilitated exchange. Under simplifying and conservative assumptions, we found then that the costs of post-distribution tracking were the largest component of transactions costs, accounting for roughly one-half to two-thirds of these costs.

What are tracking and monitoring? The Oxford Dictionary describes tracking as following the course or movements of an object or as finding an object after a thorough or difficult search. By the same source, monitoring has been described as "keeping under observation, especially so as to regulate, record, or control." We have used these definitions to distinguish between the following two arrangements regarding the regulated movement of genetic resources.

Tracking systems involve procedures that follow the international movements of genetic resources, from original provision all the way up to inclusion in a commercial product (plant variety) or other inventions, including those applying for patent protection. Thus, tracking systems can also include procedures to review or sample specific identified germplasm (for example in applications for plant variety protection or patents) in order to verify the presence of genetic materials.[3] A tracking system may include provisions that require the tracking of each and every transfer, or it may guarantee that adequate data, sources and mandates are available in case these are needed in those individual cases in which tracking is regarded warranted.

Monitoring systems may function to inform all stakeholders involved about international exchange of germplasm, in particular as it relates to the objectives of international agreements. Monitoring should answer questions on the effectiveness of access and benefit-sharing agreements, and may result in improvements of existing regulations or alternatively in serious changes of such systems to remove the flaws of systems in use. Monitoring might rely on detailed data for each individual transfer of genetic resources or it may analyze in a synthetic approach individual tracking experiences and additional information on other aspects of an access and benefit-sharing system.

In this context, tracking refers therefore to following the flows and use of germplasm. On the other hand, monitoring refers here to a regular assessment of the functioning of the access and benefit-sharing system as a whole.

What follows. The institutional landscape has evolved since our earlier study. The ITPGRFA has been ratified and entered into force, creating various categories of PGRFA in terms of access and benefit-sharing conditions. The most important distinction is between material falling within the Multilateral System of the ITPGRFA, and that which is excluded from the Multilateral System. Exchange of the latter category of germplasm may come under the CBD and its Bonn Guidelines. It is clear that substantial exchange of germplasm will take place both within and outside the Multilateral System. In this paper, we revisit the issue of pre-distribution and post-distribution tracking and monitoring costs, and more specifically the costs of tracking and monitoring the flow and use of genetic resources. More in-depth analysis is relevant given the current discussions surrounding the possible disclosure of origin requirement in patent and plant breeders' rights (PBR) applications, as well as surrounding

[3] "Genetic resources" often refers not only to the germplasm, but also to the indigenous knowledge associated with the use of those genetic resources. Tracking the use of indigenous knowledge will require strategies and methodologies that are different from those for the resources themselves. We will not deal with this issue here any further but this should not be interpreted as indicating that it is any less important.

the possible nature and extent of tracking and/or monitoring in the context of the Multilateral System of the ITPGRFA, and the newly to be developed international regime for access and benefit sharing under the CBD.

The next section briefly considers those elements of the two most relevant international agreements that impact on transaction costs. It then follows with a brief analysis of the impact of current policies on the exchange of PGRFA and on tracking and monitoring. Tracking and monitoring as well as other factors result in transaction costs, but an increase in total transaction costs may have in turn a stimulating effect on the establishment of tracking and monitoring provisions to ensure proper return on investments. Subsequently, the costs and benefits of a number of possible arrangements governing the exchange of PGRFA are analyzed and the options for a low transaction cost international regime are roughly sketched.

2.1 Transaction costs under current international instruments

Transaction costs associated with the exchange of PGRFA are determined jointly by the two international instruments referred to above that provide the framework relevant for these exchanges, and by national legislation and policies which provide for implementation at the national level. Needless to say that other factors (easy availability of desired genetic resources, reliability of the exchange framework, etc.) also influence transaction costs.

The CBD and transaction costs. Transaction costs resulting from the implementation of the CBD include costs encountered when potential providers (sources) and recipients (users) meet to negotiate an exchange of germplasm based on the principles outlined above. Both actors incur costs in the process of arriving at an agreement on a range of aspects to be negotiated such as scope of use of the genetic material, financial and non-monetary compensations, the exchange of information on the use, and other rights and obligations of the parties to the exchange agreement. Further transaction costs are associated with implementing the contractual agreements. These costs include the costs for agreed tracking and monitoring arrangements. Additional costs would be incurred if enforcement actions are undertaken in the case of a suspected failure to abide by the terms of a contract, culminating in private legal action.

The Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits arising out of their Utilization (Bonn Guidelines) are a voluntary instrument containing measures to facilitate access and benefit sharing and serve as inputs for developing and drafting legislative, administrative and policy measures. Suggested measures include among others the designation of a national focal point for access and benefit sharing and the designation of (a) competent national authority(ies). Establishment of such bodies also contributes to transaction costs, although it may lower other transaction costs, e.g., associated with acquiring access to information and with negotiating and decision-making processes.

The ITPGRFA and transaction costs. Under the Multilateral System of the ITPGRFA transaction costs are likely to be more limited but certainly not absent. Where the resource involved is covered by the Multilateral System of Access and Benefit-Sharing, negotiations on individual transactions are not necessary. Documenting each transfer and reporting this to FAO on a regular basis is sufficient. The need for tracking individual samples has been excluded. Access to PGRFA from the Multilateral System is to be compensated with obligatory benefit sharing in the case that a product incorporating PGRFA from the Multilateral System is not available without restriction to others for further research and breeding, or through voluntary (either monetary or non-monetary) benefit sharing if access to such products is not restricted. To organize and oversee such benefit sharing, institutional capacity is needed. Monitoring will result from the need to determine whether obligatory benefit sharing is generally complied with, to which level voluntary benefit sharing is realized, and to what extent voluntary monetary or non-monetary benefit sharing substantially contribute to the objectives of the ITPGR-

FA. Tracking by the provider may be required in those individual cases for which doubts exist on the correct implementation of the obligatory benefit-sharing requirements. Both financial and political motives may lead to the establishment of tracking and monitoring arrangements. In this context, the Governing Body of the ITPGRFA recognized the need for a legal persona representing the Multilateral System as a third party beneficiary regarding the agreed and implemented access and benefit-sharing provisions, and has adopted a Standard MTA that foresees the future creation of such an entity, that may act on behalf of the provider.

The costs of the mechanisms outlined above are not covered by currently available funds. Hence some means must be found to collect these costs from governments, recipients and/or users.

2.2 The impact of transaction costs on current flows of PGRFA

The size of transaction costs can affect the flows of PGRFA through the extent to which potential recipients will seek access to useful resources under the jurisdiction of third parties and to which providers and recipients can efficiently reach an agreement. These two parties do not equally share the costs, and the relative burden borne by each of them needs to be examined, as the resulting balance or lack thereof affects the incentives each faces to conclude a deal.

Our earlier study concentrated on the likely transaction costs of material in the context of bilateral exchange regardless of the extent to which each party would bear such costs. In particular, the transaction costs incurred by recipients might explain recent downward trends in the flow of PGRFA. Recipients of material incur costs in locating the material they wish to access and negotiating an agreement for access to this material. Whereas costs of locating germplasm have not fundamentally changed, in particular the costs for recipients of negotiating an agreement have arguably increased considerably with the CBD, and derive not as much from bargaining over fees and other forms of benefit sharing, as from the uncertainty surrounding current implementation of the international agreements and further developments therein with respect to the terms for benefit sharing. More specifically, the legal framework in which an access agreement operates could further change after its conclusion pending the negotiations in the context of the CBD on an International Regime for Access and Benefit Sharing, possibly imposing additional requirements on recipients or reducing the value of the material to them (e.g., through disclosure).

But most importantly, any international agreement needs implementation at the national and institutional level, in both the source and recipient country and by both the provider and the recipient. Both parties may face uncertainties regarding proper implementation for some time. Under the Multilateral System of the ITPGRFA, after the conclusion of the Standard Material Transfer Agreement, no substantial further negotiating costs will occur, but arrangements on tracking and monitoring will result in costs, and the level of such costs, if translated into higher benefit-sharing requirements, may function as a disincentive for utilization. Vice versa, if benefit-sharing arrangements are perceived by providers as dissatisfactory, it will negatively affect incentives to place germplasm in the Multilateral System. Although the terms and conditions of the Standard Material Transfer Agreement have been concluded, other specific arrangements on benefit sharing under the Multilateral System still have to be established by the Governing Body (e.g., the Funding Strategy, the strategy adopted by the Third Party Beneficiary, identification of beneficiaries) and its effects on both access and types and level of benefit sharing still have to be shown.

The considerable uncertainty that has come to surround the legal environment in which genetic resources transactions take place is probably the most important source of transaction costs at the moment. While international discussions continue on the implementation of both Article 15 of the CBD and the further operationalization of the ITPGRFA, users of genetic resources, particularly plant breeding companies and even farmer communities in developing countries, have been faced with a situation in which

the potential obligations and responsibilities placed on them are largely unknown. These uncertainties relate to potential costs, such as royalty payments or payments to a special fund, but also and probably more importantly to liability. Uncertainty creates higher transaction costs because users are obliged to devote resources to trying to gather more information in order to reduce the uncertainty and to devise strategies for dealing with alternative scenarios. Such alternative scenarios may include the strict avoidance of international exchanges and the tendency to use only collections that can be readily made available, such as a company's own genetic stocks, in-country genebank collections and other collections in the public domain not placed in the Multilateral System. In the case of farmer communities in developing countries it may result in exclusive reliance on locally available varieties.

Uncertainty may well also exist on the side of the provider, who may be uncertain (1) if and whether genetic material may be provided to foreign users under existing national legislation, or – in its absence – existing policies; (2) which benefit sharing should be expected and by whom; and (3) how implementation of the benefit-sharing provisions may be monitored. Serious doubts regarding compensation for access, and the extent, nature and form of benefit sharing may act as a disincentive to handle and process any request for access by foreign parties.

Fowler and Hodgkin (2004) have argued that the types of uncertainty elaborated above have led to a considerable reduction in the numbers of accessions acquired or collected annually by the CGIAR centers over the period 1985–1999. This drying-up of a major germplasm flow also concerns material to be exchanged under the Multilateral System. Most of the uncertainty regarding terms of access and obligations on users under the ITPGRFA has now been resolved with the conclusion of the Standard MTA. Uncertainty at large will remain for material falling under the CBD. It highlights the need to account for transaction costs not only for exchange under the Multilateral System of the PGRFA, but certainly also for the implementation of Article 15 of the CBD, that may be facilitated by the Bonn Guidelines and whatever additional requirements or instruments may be adopted pursuant to the ongoing negotiations of the "international regime for access and benefit sharing."

2.3 The effect of transaction costs on the establishment of tracking and monitoring arrangements

Purposes of tracking and monitoring. The purposes of tracking and monitoring are to verify independently whether conditions for benefit sharing based on the access and benefit-sharing agreement have been met and whether users comply with the agreement, and to monitor whether current access and benefit-sharing agreements are effective, including whether efforts to collect germplasm in the framework of providing access are sustainable and leave no negative effects on the environment, and whether fair and equitable benefit sharing, including on access to indigenous knowledge, is obtained.

Motives for tracking and monitoring. The major motive for devising tracking and monitoring strategies and methodologies on the use of genetic resources, is the expectation of benefit sharing by the providers of germplasm as a result of commercialization. As stated in a previous paper (Visser *et al.* 2000), transaction costs will increase as a result of bilaterally, case-by-case negotiated access to genetic materials. Transaction costs from bilateral arrangements under the CBD would be incurred by both providers and users of germplasm (distinguished as either individual actors or at the national level). Part of the transaction costs under the Multilateral System of the ITPGRFA will be collectively shared. Any financial benefits captured by providers would be essentially a shift from the users' account to that of the providers: any benefit to the provider will form a cost to the user. In addition to such a shift in accordance with the objectives of the CBD and the ITPGRFA, the establishment of new procedures and entities in order to achieve and monitor such a shift will increase the total transaction costs. In other words, whereas on a global level there are no additional benefits, redistribution of the benefits results in increased costs necessary to organize and oversee the redistribution. These total increased costs will form an added motive for tracking and monitoring the use of PGRFA, in particular if such costs will

also substantially bear on the providers or governments representing the providers.

Tracking and monitoring the use of germplasm by recipients, in order to verify compliance with the agreements and ensuring that agreements are not violated, is an essential activity that will have to be undertaken under a bilateral approach according to the CBD, but that may also be undertaken for germplasm use under the ITPGRFA for a minority of cases in which access to breeding products is restricted as a result of intellectual property rights, or in which such rights are suspected to be sought or acquired on the provided germplasm itself. There is little sense in negotiating agreements with benefit-sharing provisions, in order to ensure that providers of PGRFA receive a "greater share" of the benefits, if these providers do not invest resources in ensuring that the recipients respect these agreements. This is particularly the case given the ease with which the lineage of newly registered varieties might be disguised, or not fully admitted. Here, it should again be noted that under the ITPGRFA, the Multilateral System, and not an individual country or institution, should be regarded as the provider, and that comprehensive tracking of individual transactions under the Multilateral System has been excluded.

From a completely different perspective, if tracking and monitoring will show that essentially all use of genetic resources is in line with the provisions of the international agreements, and users undertake necessary efforts to comply with the provisions of the international agreements, this may contribute to building trust between providers and users, and may strengthen a tendency amongst potential providers to provide access and to engage in international exchange of genetic resources. In this optimistic scenario, limited investments in tracking and monitoring may generate considerable returns on investment in the form of improved trust, less uncertainty, increased access, and – as a result – increased benefit sharing. A well-functioning system of access and benefit sharing may in time even lead to reduced expenditures on tracking and monitoring.

Evidently, a default tracking system by which all germplasm movements are actively followed will require substantial investments, whereas occasional tracking for isolated cases may only need limited resources.

2.4 Factors impacting on tracking and monitoring

Sovereignty issues. In the case of the ITPGRFA, countries have exercised their sovereignty by creating and populating the Multilateral System. From a benefit-sharing perspective, the origin of the designated germplasm now in the Multilateral System is no longer relevant. Under the CBD, genetic resource transactions involve a named provider (country, providing institution or community), even where the resources exist in more than one country or community, or occur in more than one *ex-situ* collection. This suggests that tracking the use of genetic resources will be based on the premise of a single source for that particular germplasm under the jurisdiction of a single state. However, it has been widely known and accepted that genetic resources are often not country specific. If the same species, subspecies, or variety is present in two countries, then under the CBD, both countries have the same sovereign rights to those genetic resources occurring in their country, with access and benefit-sharing agreements (which are contract specific) providing the conditions that one of these countries have set. Although it may be argued that genetic differences between individual populations of a specific variety or provenance may still exist, it will be at best very hard and expensive to verify such minor differences. Any access and benefit-sharing agreement under the CBD between two parties may leave out all other parties, and thus, if one country negotiates an access deal to its germplasm, a second country with the same or near-identical germplasm has no way to interfere, no rights to share in possible benefits, or rights to obtain information on such transaction and its implementation. At the same time, it is not bound to the first country's agreement, and may grant its own, separate access to the same resources. A parallel situation exists where material is held in more than one *ex-situ* collection, and where such collections come under the sovereignty of different countries or

international institutions. In this context, not yet taken into account is the expectation that the sovereignty on materials in *ex-situ* collections may be disputed depending on the date of inclusion of that material into the collection (before or after entry into force of the CBD). In other words, tracking the presence of specific resources in a product of genetic resources may remain inconclusive, if it cannot be excluded that such resources have been legally acquired in other countries of origin or from other sources. This fundamental inconsistency in the country of origin concept of the CBD can only be resolved through further elaboration of current access and benefit-sharing concepts.

Possible user exemptions. It has been requested that some exchange and use under the CBD might be exempted from requirements of tracking. A number of institutions (e.g., botanical gardens) have strongly asserted that exceptions should be created under which they can gain access to genetic resources more easily, in particular to allow exchange between botanical gardens. Some have also requested not to be bound by stringent controls on subsequent sharing of the genetic resources and information concerning it. These claims have been based on the public and scientific nature of these institutions – their own research is undertaken to increase knowledge and is thus different from commercial research and development.

Already, botanical gardens have indicated that they do not track lateral transfers of genetic resources to other gardens and collectors and do not intend to do so. A system has been proposed that will seek to ensure that this lack of tracking does not invalidate the access and benefit-sharing system, but it is still not adopted by internationally active associations of botanical gardens, and such a strategy is not likely to solve any problem of further use. It is clear that as soon as botanical gardens are confronted with a request from any third parties, the conditions of the CBD on access and benefit sharing would have to be met. The case described above highlights the fact that no access to genetic resources can exclude future use by third parties, including commercial use leading to benefits that are not automatically and fully shared. A relatively innocuous and simple research exception in an access agreement may thus serve as a major loophole in the international regime.

Problems in tracking and monitoring. The fact that internationally exchanged genetic resources only contribute to a limited extent to the development of final commercialized products makes compliance and monitoring systems regarding the access and benefit-sharing agreements difficult to implement. Product development processes may involve multiple activities that include: a) collecting samples; b) processing and shipping samples to research laboratories in the public or private sector, usually located in foreign countries; c) analyzing samples, including using them in breeding programs; d) transferring samples or half-products between research organizations in the public and private sector; and e) developing and commercializing products. This is an oversimplified description of a complex chain of events where multiple actors interact with the samples and products derived from them. Therefore, final products or processes may not (usually will not) clearly exhibit sufficient genetic or other characteristics to allow one to know unequivocally by simple means which genetic resources contributed to their properties (products) or to their functioning (processes). Furthermore, products may be manufactured (bio)chemically based on the analysis of the molecular structure of genetic resources collected. This includes the construction of genes encoding an identified product from a genetic resource in a new genetic background. The samples may be stored in *ex-situ* conservation centers for years before the appropriate technology is designed to take advantage of them. The world's crop genebanks alone contain over five million such samples. A tourist can take samples back to his or her home country with almost no difficulty and often without any wrong intent. Samples may have crossed borders before the coming into force of the CBD. All these possibilities make controlling or prohibiting illegal access activities very

difficult. In addition, enforcement of national law is very complicated, once the collector has left the area of a country's jurisdiction.

The disclosure of origin requirement. To make the granting and validity of patents or plant breeders' rights on products of the utilization of PGRFA dependent on the meeting of access and benefit-sharing requirements of the CBD or the ITPGRFA, would conflict with the obligations imposed on members of the World Trade Organization by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). In an analysis of options to introduce the concept of disclosure of origin in legislation, Pires de Carvalho (2000) suggests that introduction of such provisions can only be in line with the TRIPS Agreement if this requirement is integrated as a condition of enforcement of the rights rather than as a condition of patentability *per se*. Alternatively, a legal requirement for disclosure of origin including proof of Prior Informed Consent (PIC) might be introduced as a stand-alone obligation required for commercialization, as currently discussed in the European Union (Blakeney 2005). This means that an applicant might obtain a patent, but in the act he is obliged to comply with the disclosure of origin requirement regulated under a separate law. Finally, another option would be to amend patent law to include a requirement on disclosure of origin.

A disclosure of origin requirement, or a certificate of origin requirement in which the disclosure is effected by a document obtained from the provider of the genetic material, appears, thus, possible. Since it will ease the search for prior knowledge, does not involve substantial administration and can be relatively easily verified, such a measure could in principle reduce total transaction costs. Infringers would not be able to get away with illegal practices if a (separate) requirement for disclosure of origin existed, unless they expressly provided an incorrect or invalid disclosure document not recognized as being false. Most importantly, if such a certificate can be created and easily validated, it would facilitate the work of patent officers and those assessing the applications for plant breeders' rights and contribute to lower transaction costs. The sort of care required from applicants of intellectual property rights would be reasonable. They would be required to indicate the origin of the resources that they knew or that they had a reason to know; this is a reasonable care standard. In theory, mere evidence of compliance with the national laws of the countries providing the genetic resources (as far as in existence) would suffice, without imposing on the applicants complicated and costly investigative efforts. These transaction costs would fall on the patent office and/or user. However, from the complex debate towards policy development on disclosure of origin, major uncertainties for users have surfaced, and such uncertainties would contribute to higher transaction costs, if left unresolved.[4]

A requirement for disclosure of origin may have to be implemented at the national level, but should be based on multilateral consensus between governments, since the providing party to a transaction may often be based in another country than the user applying for intellectual property protection of derived products.

The specific situation under the ITPGRFA. Regarding the complexity of tracking and monitoring, the relative advantage (and simultaneously the limitation) of the Multilateral System is clearly its more narrow scope. The ITPGRFA only regards crop germplasm and its Multilateral System a limited number of crops. Having said that, it should first be realized that no other components of biodiversity have traveled the world to the same extent as PGRFA, approximately over the last ten thousand years. Also, in contrast to many non-domesticated species, many crops can be easily exchanged in the form of seeds, rendering physical access both easy and at the same time difficult to control. Given the importance of these species for our global food security and the mutual interdependence of countries with regard to these resources, the Parties to the ITPGRFA agreed on a Multilateral System of Access and Benefit-sharing. Whereas this Multilateral

[4] One such issue concerns the criteria determining whether a patent application must include a disclosure of origin or source.

System offers facilitated access to the crops under the system (35 major food crops and a similar number of forage crops), it requires no standard tracking of the accessed genetic material, although the recently adopted Standard MTA does provide for a dispute settlement procedure. Monitoring and tracking of individual cases is provided for in the ITPGRFA itself (e.g., Articles 19 and 21), and in its Standard MTA (articles 4, 5, 6 and 8). The general need to consider the functionality of the Multilateral System as a whole, and of the implementation of the benefit-sharing agreements of the ITPGRFA in particular, add to transaction costs under the Multilateral System. The following elements in the ITPGRFA may further add to such transaction costs:

- the establishment, and the assessment by the Governing Body, of the coverage of the Multilateral System, in particular the inclusion of collections held by natural or legal persons under the jurisdiction of the Contracting Parties (Articles 11.3 and 11.4);

- the interpretation of the provision that recipients may not claim any intellectual or other property rights that limit access to the provided PGRFA, or their genetic parts and components, in the form received (Article 12.3);

- the interpretation of the provision that access to PGRFA under development is at the discretion of its developer (Article 12.3);

- the provision that access to PGRFA found in *in-situ* conditions will be subject to national legislation (Article 12.3);

- the obligation to provide an opportunity to seek recourse in case of contractual disputes (Article 12.5);

- the agreement by the Contracting Parties to make available information of the PGRFA, to facilitate access to technology and its products and allow for its transfer, and to prioritize capacity building (Article 13.2);

- the agreement to establish a Global Information System on PGRFA (Article 17);

- the agreement to implement a funding strategy for the implementation of the Treaty and its benefit-sharing provisions (Article 18);

- the establishment of the Governing Body (Article 19) and a Secretary (Article 20);

- the establishment of procedures and mechanisms to promote compliance (Article 21); and

- the agreement on a dispute settlement procedure (Article 22).

Whereas the ITPGRFA has managed to trim down the transaction costs by establishing its Multilateral System under which no individual tracking of samples is required, it is obvious that there remain major transaction costs to allow for monitoring of the system and for tracking in individual cases in which doubts over its use have arisen. The decision of the Governing Body to establish an overview of all transactions in the Multilateral System and to document other aspects of the use of materials made available through the System (see Standard MTA, articles 5e), 6.5, 6.7, 6.9, and 6.11), will further add to the transaction costs.

2.5 Concepts and elements of tracking and monitoring

Possible components of tracking. Tracking may be composed of a chain of actions. These actions may concern acts of tracking in a narrow sense, i.e., post-distribution, as well as precautionary action that should enable tracking in a later stage of germplasm use.

At the point of obtaining access, tracking may result in the need for documentation, proving Prior Informed Consent, both from government authorities and from local communities, where appropriate, and specifying the mutually agreed terms on which access and utilization of the genetic resources is to be effected. Genebanks, databases and farmers' registries or, alternatively, specialized central and other databases may serve to document which germplasm and associated indigenous knowledge is in the public domain, and consequently does not qualify for granting intellectual property rights. As a second layer, such databases may also include information on which germplasm and associated knowledge has been made available to which parties, as in the case with the Multilateral System of the ITPGRFA. A third level might include documentation and evidence proving that the use of the resources is in compliance with the terms agreed by the provider. Before or at the point of obtaining access, securing the option for tracking at a later stage might also entail the production of molecular fingerprints. In addition, it will involve Material Transfer Agreements specifying the conditions of the exchange.

In parallel, when the accessed genetic material is used and products incorporating the material are developed, for internal management reasons, users may document which germplasm was received and if and how these genetic resources were used to derive products. In such later stages, users may also fingerprint products to verify the origin of its components and to track the germplasm originally made available for well-defined use.

Whereas the use of documents and the inclusion of exchange data in newly established, or existing but adapted, database systems are likely to become generic, and a necessary prerequisite for the tracking of any exchange, the use of molecular profiles may serve as a back-up option, only to be employed if the available documentation appears unsatisfactory to one of the parties to the contract, or when misuse is seriously suspected or would entail large losses in benefits shared. Across-the-board profiling of germplasm available for international exchange, and of breeding products that may contain DNA of the accessed germplasm, is technically feasible but very expensive and would substantially increase total transaction costs, as will be seen below. Whereas the costs of fingerprinting individual samples will further decrease, the various technologies to use the germplasm will diversify, complicating the tracking to the extent that the advantages of cost reduction of individual fingerprints is lost. Random and modest-intensity sampling of breeding products through the assessment of the presence in the genome of introgressed genetic material is an alternative strategy, complementary to the analysis of products in suspect cases or of high-value products.

Approaches to tracking. Regarding tracking, a series of fundamental choices faces a provider, either a country, an institution, or an international mechanism as the ITPGRFA Multilateral System, including:

- whether tracking is to be introduced and for which purposes;
- whether tracking should rely on written documentation and/or on fingerprinting;
- whether documentation on exchanges should include the first recipient only or the entire user chain;
- which party (the provider or user or both) should maintain the data involved;
- whether pro-active tracking will have to be applied to all germplasm made available or to a random or targeted selection; and
- how the tracking system of choice will be financed.

These choices will determine to a large extent the costs of tracking. A number of the requirements listed above should generally be met by the user, suggesting that the "user country" may need to be involved in their application and enforcement.

Possible components of monitoring. Monitoring may relate to effects of providing access on the conservation of biodiversity, or it may focus on the effects of utilization, in particular the benefits arising out of the use of the genetic resources to which access was granted.[5] In this study, the term monitoring is used only to refer to the utilization of the required genetic resources.

Monitoring may include, amongst others:

- assessing the compliance of providers and potential users with the provisions of legislation regarding access and benefit sharing in negotiating an agreement;
- assessing the scope and volume of agreed or negotiated benefit-sharing arrangements;
- assessing whether benefit-sharing obligations are met by the users; and
- assessing whether the total of agreed access and benefit-sharing arrangements fulfill the objectives and the expectations of legislators and policy makers.

In the case of the ITPGRFA, monitoring is necessary and may include:

- the monitoring of efforts of Contracting Parties to provide benefit sharing in the form of information exchange, technology transfer and capacity building, either directly or through facilitating such contributions by the legal and natural persons under their jurisdiction;
- an assessment of the actual contributions of genetic materials to the Multilateral System by natural and legal persons under the jurisdiction of Contacting Parties;
- an assessment of the interpretation of key articles of the ITPGRFA by users of the genetic material; and
- an assessment of dispute settlements.

2.6 An estimation of transaction costs under different scenarios

Four tracking scenarios. To elaborate on the possible level of transaction costs of tracking and monitoring, we have developed four scenarios varying according to the level of comprehensiveness achieved. We first discuss the scenarios and then categorize the various transaction costs associated with the components of tracking and monitoring. For the principal components that would entail the financial expenses on the part of users, providers or other stakeholders, we then proceed to estimate the costs that would be incurred on an average annual basis. The scenarios are not intended to represent fully coherent and planned options at this point. Such a level of detail and completeness should be the next step in the analysis. Instead, the scenarios should serve to sketch out options along one or more variables, including relatively "extreme" options. Relatively imprecise estimates of the cost implications can then be used to identify options or even specific components for more detailed analysis, if warranted. These scenarios only refer to the exchange of plant genetic resources for purposes of food and agriculture.

[5] In the former case, collecting in the wild might be bound to the requirement of an Environmental Impact Assessment (EIA) that usually investigates the possible effect of the collecting activities on the ecosystems involved. Such collecting might be relevant for transactions under the CBD as well as for transactions of crop wild relatives under the ITPGRFA. The issue of performing an EIA and the associated costs will not be discussed here any further, since there is no direct relation with the costs of tracking and monitoring the utilization of the provided genetic material that form the focus of this study.

Scenario A is the most comprehensive and involves documentation of MTAs, including the data provided to the user regarding the material and any other associated information, both by the provider and by the user(s). Genetic material is followed through the development chain until it reaches the market. Note that the recently concluded Standard MTA for the material distributed from the Multilateral System of Facilitated Access and Benefit-Sharing obliges the recipient or user to notify the FAO when such material is provided to third parties. Scenario A also includes the creation of new centralized regional databases in which all such data are stored. Furthermore, under this scenario *all* distributed material is fingerprinted by the provider and this information is also stored in centralized databases. Finally, this scenario also includes a verification (by patent offices or authorities granting plant breeders' rights) of the information provided in a disclosure of origin or source in the application for IPR protection against the information in the centralized database(s) concerning the germplasm previously accessed by the applicant from providers (or received as a third party from other recipients). Relatedly, under this scenario, upon granting protection, IPR offices will forward basic information concerning the submitted applications.

Scenario B differs from scenario A in that it only requires the documentation of MTAs and associated data as under scenario A, complemented by selective fingerprinting which could be on a random and/or targeted basis. Random fingerprinting may act as a deterrent against misuse, and targeted (post-distribution) fingerprinting might be warranted in those cases where misuse is suspected based on the profile of a commercial product, or where (potential) benefits are extremely large. In order to be feasible it presupposes that the exchanged material will also remain available to the provider in order to allow for DNA sampling at a later stage. Storage of the material by the provider is, however, an increasingly common practice and we therefore do not attempt to estimate increased costs of storage for some providers. Scenario B also includes a system of central databases containing information on the transfer of material as under scenario A.

Scenario C is identical to scenario B except that C relies on decentralized documentation as opposed to centralized documentation, and hence does not involve verification by patent offices of disclosure of origin claims. Decentralized documentation of data on distributed accessions should be available and accessible in the long term and existing databases of many providers might have to be updated. Compared to the first two scenarios, scenario C thus places responsibility for the documentation on the individual providers. The extent to which this includes additional costs depends on the upgrading that some providers will have to undertake, and we do not attempt to estimate these costs below. It does include random or targeted fingerprinting to be executed and documented by providers, as in scenario B. Scenario C will decrease to a large extent the search options for officers examining applications for intellectual property rights, and these search efforts are therefore no longer included in this scenario.

Scenario D only requires any user to provide the MTA at request by the authorities and to document the flow and use of the PGRFA accessed. Systematic fingerprinting is not undertaken at all when material is distributed. In the case of a dispute, or suspected case of misuse, fingerprinting might need to be undertaken at a later point in time. But we do not build this into the scenario explicitly at this point.

In analyzing these four scenarios it should be realized that a substantial number of providers already keep records concerning all material distributed and to which recipients, including also which information was made available, and store as hard copies or in the form of electronic information all contracts covering exchanges. For none of the scenarios do we attempt to make a projection of the possible number of suspected cases of misuse. It is worth noting that these may well vary according to the comprehensiveness of the tracking system. In other words, more comprehensive tracking might have a stronger deterrent effect on misuse.

Table 1: Stakeholders incurring transaction costs under four tracking scenarios

Scenario	A	B	C	D
Cost components (*italics* indicates that these are at least partly estimated in current study)	Comprehensive documentation and comprehensive fingerprinting	Comprehensive documentation and occasional fingerprinting	Decentralized documentation and occasional fingerprinting	Decentralized documentation only
Finding information about available accessions (including characterization information)	Users	Users	Users	Users
MTA *handling*	Providers and users	Providers and users	Providers and users	Providers and users
Documentation (database of exchanges)	Central body	Central body	Providers	Providers
Fingerprinting	Providers	Providers	Providers	
Database searching costs IPR offices (patents, PVP)	IPR Offices	IPR Offices		
Documentation (database) of disclosures in IPRs (patents, PVP) Central	body or separate (inter)national body	Central body or separate (inter)national-body		
Additional costs on collecting data on potential misuse	Providers or central body	Providers or central body	Providers	Providers
Legal costs in case of dispute (arbitration or litigation)	Providers and users	Providers and users	Providers and users	Providers and users

Table 1 summarizes the components of transactions costs (represented by the rows) under the four scenarios for tracking germplasm flows (represented by the columns), and indicates the general groups of stakeholders that would incur these costs. The cost components are organized in order leading from provision of germplasm, to documentation of these flows, to commercialization of a product derived (in part) from the germplasm. Where no stakeholder is specified for a particular cost component, as in the case of fingerprinting under scenario D, this indicates that there is no relevant transaction cost under that scenario. It is important to remember that in most cases, the size of specific cost components in terms of resources, both financial and others, will vary between the scenarios.

We have attempted below to propose some initial estimates in monetary terms for *some* of these transaction costs. These cost components are indicated in Table 1 with italics. For the most part, these are administrative costs, as distinct from other types of transaction costs. In particular, as can be seen in the table, we do not estimate costs for users of acquiring information about which germplasm is available from which providers, or information concerning its characteristics. In economic terms, breeders in both the public and private sectors repeatedly emphasize the importance of these search costs (see, for example, Wright 1997) although they are not expected to vary substantially across scenarios. We also have not estimated how the transaction costs may vary across scenarios according to differences in the uncertainty associated with rights and responsibilities in MTAs and the broader international agreements, or with likely behavior of both providers and users. This is a clear limitation of the analysis. We do expect in general that some such uncertainties would be reduced by more comprehensive scenarios. But incorporating the level of these uncertainties into the empirical analysis would require at the very least, a broad survey of stakeholders, and thus a considerable investment of research resources. Nonetheless, we feel that some insights can be gained by first estimating the transaction costs of a more administrative nature, so that these results may be useful in guiding further investigation of the relationship between differing levels of uncertainty and transaction costs.

Level of transaction costs of tracking under four scenarios. Before embarking on a discussion of the estimates, it should be emphasized that such transaction costs are very hard to estimate, and our figures and calculations could only be based on experience, including personal experience, in germplasm exchange as well as related fields. As such, the calculations should be viewed as informed guesstimates with a very rough level of precision. This should however be sufficient to stimulate discussion and debate on the possible components of a tracking system, and in particular, to identify specific issues for more exhaustive research.[6] In other words, the specific monetary figures produced in this study are not as useful as the discussion on how they were generated and, more importantly, what they imply for a complete comparison of costs and benefits. Note that in all cases, we attempt to be conservative in terms of estimated costs. We also work on the basis of constant annual costs over time and do not make any attempt to examine the likely time path of variables that could lead to annual fluctuations or even long-term trends.

In order to estimate some of the costs involved in a system of tracking of germplasm flows, we rely on a forecast of the annual amount of exchanged material. By this we mean the number of accessions of germplasm that are supplied by genebanks and other providers to those requesting such material who could include both private-sector and public-sector organizations (such as research organizations, or other genebanks) – "users." We are abstaining from fluctuations in this use as these are too difficult to foresee. In an earlier analysis (Visser *et al.* 2000), we estimated the total number of exchanged accessions worldwide at 300,000 accessions or other types of samples on a yearly basis. This included an estimate of 150,000 from the collections of the Future Harvest (CGIAR) Centers held in trust, developed by Fowler *et al.* (2001), as well as an estimate of 150,000 from other publicly-maintained collections.[7] On this basis, we derive our cost estimates using the following calculations, explained according to each cost category.

MTA handling. Costs for processing and storing MTAs apply to all four scenarios. Sending, content

[6] This approach is one typically followed in assessing investment decisions in both the public and private sectors. Initial proposals are first subjected to very crude estimates of costs (and benefits), which then provides an initial basis for decision-making concerning either the overall viability or what further information is required.

[7] Further details concerning this estimate can be found in our earlier paper (Visser *et al.* 2000; in particular, p.9). We emphasize that we consider this estimate to be on the high side, particularly given recent trends which have included a greater reluctance among users to request germplasm due to some of the continuing uncertainty concerning access and benefit-sharing requirements under the CBD and the ITPGRFA. Nonetheless, we think this should be seen as a reasonable estimate of the medium or long-term average number of accessions requested.

checking and storing of a single, previously agreed, hard copy MTA would require, on average, 10 minutes for the provider and 10 minutes for the user.[8] We use an average labor cost (including overhead and benefits) of US$ 50/hour for a technical assistant level in a public agricultural research organization. Such salaries vary of course widely across institutions and countries. Within the Wageningen University and Research Centre, the hourly rate in 2006 was between US$ 100 and US$ 105 (depending on euro/dollar exchange rate fluctuations). We suspect, based on personal experience, that this is close to the maximum on a global scale. Costs in developing countries will be much lower, which is particularly relevant here since a substantial number of accessions are provided for institutions located there. Using a study undertaken in 2001 of salaries for agricultural research personnel in Brazil, we calculate a current (2006) hourly labor cost of US$ 28 on average, varying between US$ 25 and US$ 50.[9] We choose the higher figure (and not even the average) because it corresponds to national level institutions, such as those responsible for national germplasm collections. While the figure will vary among developing countries, Brazil is a useful example. It is more in line with salaries in the Future Harvest Centers of the CGIAR, from which many of the accessions are distributed. Finally, this higher figure does also take into account the large number of accessions distributed from collections in industrialized countries. In summary, without conducting a survey of all such institutions, we feel that this is a reasonable figure to take as an average basis. These assumptions thus imply US$ 17 per distributed accession, or US$ 5.1 million per year.

Central documentation. New centralized databases to document the exchange of germplasm and associated information made available will also add to transaction costs. The active management and maintenance of seven regional databases (representing the seven UN regions often distinguished) has been estimated to cost one person-year for database management at US$ 35,000 per region, and a yearly conservative estimate of the global cost of the necessary data loading from provider sources in the region for each of these databases of US$ 55,000, totaling US$ 630,000 for scenarios A and B. Taking into account the relatively high European salary level, such estimates are partly based on the notion that the three-year 40-country development of the EURISCO[10] database cost approximately US$ 600,000, with maintenance of this database requiring a substantial percentage of the development phase budget. No satisfactory software applications able to handle the processing, storage and retrieval of large datasets resulting from fingerprinting are currently available, but it is assumed that this situation will change within a few years and that the necessary software packages can be obtained from other parties, for example, the Future Harvest research centres of the CGIAR (e.g., GENERATION, the relevant CGIAR Global Challenge Programme).

DNA Fingerprinting. In scenario A, we assume that each accession that is accessed would have to be fingerprinted. This would most likely be undertaken as accessions were requested, possibly resulting in a higher demand based on the increased value of the characterization information. Based on the projection of 300,000 accessions distributed per year, it would be possible to make the cost estimates using some assumptions concerning the likely overlap from year to year in accessions previously requested and thus previously fingerprinted, as well as duplication of distributed accessions held in different collections. Rather than follow that approach, we prefer the simpler assumption that over the medium to long term, all of the unique germplasm accessions will be fingerprinted. Estimates of the number of unique accessions held in collections range between one and two million

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8 This estimate is based on experience acquired at the Centre for Genetic Resources, The Netherlands (CGN) in applying their current documentation practices.

9 These calculations are based on monthly salaries reported for technical assistant category for a wide range of agricultural research institutions in Brazil by Beintema *et al.* (2001; p.74) converted to hourly rates for 2006 assuming 3% annual inflation, an overhead rate of 100%, an average of 104 effective work hours per month.

10 EURISCO forms an on-line accessible database with passport data of over a million publicly available accessions held in European collections. It may act as a prototype for implementation in other regions.

(Global Plan of Action on Genetic Resources for Food and Agriculture) out of the total estimate of 5.5 million accessions (Visser *et al.* 2001; ten Kate and Laird 1999), and we take a median value of 1.5 million. We do not attempt to define a time path for how many accessions will be distributed. Instead, we simply estimate this total cost (as a one-off expenditure) and use the standard financial formula for converting this present value into an annual expenditure into perpetuity using a modest interest rate of 5% (*see*, for example, Sydsaeter *et al.* 1999, p.165).[11]

We furthermore assume that fingerprinting would cost an average of US$ 80 per sample.[12] Thus the total cost (in present value terms as of 2006) of fingerprinting all material is US$ 120 million, implying a perpetual annual cost of US$ 6 million under scenario A. In scenarios B and C, only selective tracking of marketed products would be undertaken. This might be reserved for genetic resources with a high potential value such as those likely to lead to medicinal products or high-value ornamental plants. Assuming the testing of up to five samples further down the product development chain, this might be relevant in 100 distributed accessions (targeted) to 1000 distributed accessions (random) per year. Note that a figure of 1000 accessions per year, comprising both random and targeted, still accounts for only one-third of one percent of all distributed accessions and is itself a conservative figure. While conservative, the extremely limited number of reported cases to date of suspected misappropriation or non-compliance of contractual terms involving the use of agricultural plant germplasm does not warrant a higher estimate. The assumption of 1000 accessions per year results in an estimate of US$ 80,000. These costs are incurred by the provider.

Database searching at IPR Offices. We also estimated costs for IPR authorities to verify information provided concerning the source of genetic material in applications for plant variety protection and patents, using the database developed under the central documentation. For simplicity, it has been assumed that patent applications and applications for plant breeders' rights will include the requirement of disclosure of origin or source, and that in scenarios C and D the authorities granting such intellectual property rights may rely on the information offered and do not need to pursue independent searches for those applications in which it is stated that no germplasm or associated information was accessed, or where the origin has been clearly indicated. Beginning with patents, we assume a modest number of 1000 patent applications per year[13] involving cultivated plants and their wild relatives. To derive an estimate of the additional costs of verifying such applications against a database documenting the potential sources of germplasm, we are required to make some very simplifying assumptions. More specifically, we assume that the verification of such applications will

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[11] The assumption of perpetually recurring expenditure, as opposed to one spread over a finite number of years, coincides with our conservative approach. For example, using the 5% interest rate, changing from a perpetual horizon to a period of 25 years increases the annual costs as calculated here, by 30%. The assumption of 5% is also conservative given historical long-term interest rates and cost of capital. Of course, it would be possible to undertake a more formal sensitivity analysis of the results, but again we stress that we are attempting to be conservative and aim for reasonable lower-bound figures.

[12] At the Centre for Genetic Resources, The Netherlands (CGN), the average cost is approximately US$ 50 per sample (source: internal management documents). Note this is a relatively conservative estimate; CGN staff recently published a study in which a cost-benefit analysis of a rationalization of the genebank's wild potato collection was undertaken (van Treuren *et al.* 2004; *see*, in particular, 2004). That study (undertaken in 2002) involved a cost of at least US$ 130 per accession fingerprinted (calculated using reported costs of personnel and laboratory consumables for DNA extraction and RFLP analysis over a total of 350 accessions characterized). A research organization located in a lower-cost country can generally be expected to undertake the molecular marker analysis for considerably less, given that a major portion of the cost is accounted for by laboratory staff. As is typically done with this current type of study, conservative (low) estimates are used. Personnel communications from staff of some of the Future Harvest Centers of the CGIAR indicate that an average cost is approximately US$ 10 per fingerprinted plant, which has been used in the analysis here. We also assume an average of eight plants sampled per accession to be fingerprinted (*see* Visser *et al.* 2001) to arrive at US$ 80 per accession.

[13] Detailed analysis of trends in biotechnology patents is necessary to make more precise predictions of the number of patents that would have to be analyzed. As noted by Oldham (2004), there are considerable methodological issues to be resolved before precise estimates of indicators in biotechnology patents are available; work in this area is being undertaken by various patent offices with some coordination by the Organisation for Economic Cooperation and Development (*see*, for example, OECD 2002). Oldham also undertook his own analysis (Oldham 2002; pp.23–29) of trends in patent publications in biotechnology over the period 1990–2003 using the EPO's Esp@cenet worldwide database which

involve only an additional 10% of time for examiners to process a patent application in this field.[14] To translate that estimate into additional costs, we note that patent offices in industrialized countries generally run on a cost-recovery basis, meaning that revenue from the various fees for applications, searches, renewals and other services provide the financing for the operations, of which examination of patent applications is the most consuming of resources (Jaffe and Lerner 2004; see for example Annual Reports of the EPO at http://annual-report.european-patent-office.org/facts_figures/). We therefore make the simple assumption that the fee charged for patent examination is a direct reflection of the cost of the search, and take one-tenth of the current search fee, using a rounded-off average between the EPO[15] and the USPTO[16] to arrive at US$ 80 per application as additional costs of database searching.[17] This leads to an estimate of US$ 80,000 per year.[18]

For PVP applications, we follow a similar approach, assuming a total of 2,500 applications per year at an additional cost of only 10% in the average application fee (using an average between the European CPVO and the US PVP Office weighed by the number of applications). This leads to a rounded-off estimate of US$ 100 per application, and a total therefore of US$ 250,000.[19] Adding up the costs for the patent and PVP offices gives a total of US$ 330,000.

Summarizing the differences between the scenarios, note that scenario B is identical to the most comprehensive scenario A, except that standard fingerprinting is replaced by occasional fingerprinting. Scenario C maintains the same occasional fingerprinting but does not include the costs of maintaining the centralized documentation and databases. Scenario C also does not involve the costs of IPR offices searching databases as part of the examination of applications for intellectual property rights. Finally, scenario D does not include any fingerprinting and would only involve documentation by the user in combination with occasional tracking (based on documents only) as in Scenario B. Most users

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covers primarily the USPTO, the EPO and the JPO. His "preliminary" analysis for 2003 indicates 683 patent publications referring to "plant gene" compared to 8343 referring to "gene" in general. Oldham also cites analysis of patent data produced by the OECD in 2003 to which reference here is also made. Using the International Patent Classification System, the OECD found 802 patent publications in 2003 under the classification "plants, processes for modifying genotypes" (A01H1) and 226 under the classification "plant reproduction by tissue culture techniques" (A01H4), totaling thus 1028 publications. These are the two most relevant classifications for patents referring to innovations in which plant germplasm has been used. We also analyzed data retrieved from the Esp@acenet database which indicated, for example, 380 patent publications during the six-month period from March to September falling under the general classification of "flowering plants" (A01H) which includes patents on plants and plant varieties (e.g., as granted in the USA), as well as patents on genetic sequences and their incorporation into cultivated plant species (e.g., as possible in the EC under the Biotechnology Directive 98/44). Thus, on these grounds, we propose that our estimate used here of 1000 applications per year is reasonable and probably conservative (as desired). For at least two reasons, there are likely to be more than 1000 relevant patent applications for which a disclosure of origin would need to be verified. First, these statistics refer to publications whereas the total number of applications to be analyzed includes at least some of those that are rejected. Second, considerable increases in the numbers of these patent applications have been documented for patents published in the class of "plants, processes for modifying genotypes" (though this increase is partially offset by a decrease in the class "plant reproduction by tissue culture techniques"). There are, however, expectations among stakeholders that current use of genetic resources will increase in the future, particularly once the Multilateral System is running.

14 This is based on informal discussions with a European patent attorney experienced in the field of biotechnology as well as with a senior policy specialist in the patent office of an EU member state (who have requested not to be cited) that is relatively active in the processing of applications in the field of agricultural biotechnology compared to other European countries.

15 http://www.european-patent-office.org/epo/fees1.htm

16 http://www.uspto.gov/web/offices/ac/qs/ope/fee2006september15.htm

17 A more systematic assessment would involve further enquiries with patent offices, including access to internal financial records.

18 US$ 80 per application x 1000 patent applications per year = US$ 80,000. Note that this applies to all relevant patent offices as the estimate is based on the Esp@cenet database.

19 Over the past 10 years, the CPVO has received and processed an average of almost 2,000 (1,990) applications per year while the US PVP Office has processed approximately 340 per year over the years 2003 and 2004 (based on figures available on respective websites). Our total estimate of 2,500 per year is somewhat higher then but note that we have not included applications in any other countries. Presumably some efficiencies can be gained through cooperation among PVP offices so that once an application for a new plant variety has been checked in one country, its verification can be recorded in the database, easing the work for other countries. We estimate again only a 10% increase in the costs for the application. The cost for an application at the CPVO is approximately US$ 1115, and the fee in the USA is US$ 432, not including DUS testing, and the average of the two, weighed by relative number of applications processed, is US$ 978.

Table 2: Estimates of selected components of annual tracking costs under four scenarios (figures in million US$; figures rounded to nearest tenth of a million; see text for explanation)

Scenario	A	B	C	D	Stake-holder bearing costs
	Comprehensive documentation and fingerprint-ing	Comprehensive documentation and occasional fingerprinting	Decentralized documentation and occasional fingerprinting	Decentralized documentation only	
MTA handling	5.1	5.1	5.1	5.1	Provider and user
Central documentation	0.6	0.6	0	0	Central body (A, B)
DNA finger-printing	6.0	0.1	0.1	0	Provider
Database search-ing costs IPR offices	0.3	0.3	0	0	IPR authority
Total tracking costs	12.0	6.1	5.2	5.1	
Total tracking costs as percent-age of potential benefit sharing[a]	97%	49%	41%	41%	
Total tracking costs as percent-age of total pri-vate PGRFA investments[b]	24%	12.2%	10.4%	10.2%	
Total monitoring costs	1.2	1.2	1.2	1.2	Parties to the Treaty

[a] Estimated at US$ 12.5 million per year which amounts to 10% of 0.5% of estimated sales in the plant breeding sector of US$ 25 billion (*see* discussion in next section); note here we are not taking into account variations in benefits resulting from differences in the effectiveness of the tracking under the various scenarios.

[b] Estimated at US$ 50 million per year by ASSINSEL (*see* text).

(e.g., plant breeding companies) will already employ some sort of documentation system, thus likely reducing the actual additional costs of this scenario D.

From these very rough and conservative estimations it may be concluded that a major component of the administrative costs of tracking consists of the additional administration of MTA documentation on the part of both users and providers. This cost is estimated at approximately US$ 5 million per year and does not vary from one scenario to another. But comprehensive fingerprinting of all distributed germplasm could more than double that cost. On the basis of the analysis here, it is not possible to say to what extent this fingerprinting will reduce the additional costs required for pursuing suspected cases of non-compliance with MTAs, which should be pursued in further work. Furthermore, other administrative components, such as the costs of centralized databases or their use by IPR authorities, do not appear to be nearly of the same order of magnitude as that of simple document handling, although it would be worthwhile to develop more rigorous estimates to confirm this, including some expert judgment on the added value of such centralized databases.

Transaction costs of monitoring. The transaction costs of monitoring the overall effectiveness of systems of access and benefit sharing are even harder to estimate than tracking costs. The reason for this is that many of the monitoring costs are likely to be hidden costs, made by institutions (government offices, institutional providers and users) that already exist and are required to add the tasks of monitoring to their agenda.

Monitoring costs are most probably more modest in the case of the ITPGRFA than for exchange falling under the CBD. In the case of the former, a single institution, the Governing Body of the ITPGRFA, which is made up of all Contracting Parties of the Agreement, will perform a number of tasks while for transactions falling under the CBD, monitoring may have to be performed by each individual government involved. It is therefore useful to inspect more closely the tasks of the Governing Body and to estimate the investments required to allow the Governing Body to execute those tasks. It should be noted that no formal arrangements have been agreed for monitoring of exchanges under the CBD. However, it can be assumed that the actual need for monitoring will not be different for exchanges under the CBD versus exchanges under the Multilateral System of the ITPGRFA.

First, the ITPGRFA requires that the Governing Body meets at least once every two years. Assuming that such meetings take five working days and that no travel costs will be incurred since the meeting will be held in conjunction with the meeting of the FAO Commission on Genetic Resources for Food and Agriculture, total costs of a meeting can be estimated at least at US$ 200,000, or US$ 100,000 on a yearly basis. Furthermore, under the ITPGRFA a position of Secretary will be created and staffed. Assuming that this will involve a full-time, highly-qualified officer requiring office support, something that cannot be made available from the current staff of the secretariat to the FAO Commission referred to above, this would amount to approximately US$ 250,000. Whereas both the Governing Body and the Secretary will engage in activities exceeding the scope of monitoring, a substantial part of these activities may still be considered as monitoring activities. Subsidiary bodies to the Governing Body and the Secretary may be established, and consultancies commissioned to support the monitoring tasks of these two institutions. The costs of these additional initiatives are taken to equal approximately the costs of hours that the Governing Body and the Secretary will not directly or indirectly devote to monitoring. This leads us to estimate a total sum of US$ 350,000 on a yearly basis to be needed for monitoring of the implementation of the ITPGRFA. Whereas these costs are substantial, they are also close to the minimum that any monitoring mechanism will require.

Transaction costs made by individual Contracting Parties to the ITPGRFA have not yet been taken into account in this estimation. Such costs depend to a large extent on the policy decisions of the Contracting Parties and their internal government structures, and may equal two months per year per delegate per country. At the current membership of over 100 countries and mean salary costs of US$ 50,000 per year, this would result in added annual costs of US$ 800,000. These are costs that are incurred by the governments of the member countries. But again, these estimates are likely to be substantial even at a minimum level (e.g., the salary costs of

those government representatives preparing for and participating in the meetings of the Governing Body).

Transaction costs incurred by countries in developing and implementing legislation. Most likely, the transaction costs incurred from monitoring by individual parties (governments and institutions) to agreements falling under the CBD will further add to the total monitoring costs, but are not further considered here, since the number of transactions under the CBD on a yearly basis is apparently quite small, based on the low number of published reports on individual transactions of PGRFA, and thus the monitoring costs for the implementation of such agreements can be assumed to come under the costs incurred for the monitoring of the ITPGRFA.

Monitoring attempts at the national level have been primarily of a hypothetical nature. The UC-Davis/GRCP study of legislative development trends in the Pacific Rim (Carrizosa *et al.* 2004) shows that most laws and policies regarding access and benefit sharing are comprehensive and, therefore, also costly and difficult to implement. All but one of the countries analyzed in the UC-Davis/GRCP study have proposed measures to ensure that bioprospecting projects comply with access and benefit-sharing regulations. However, none of these monitoring mechanisms are operational yet. Not even the Philippines, which has had legislation in place for many years and has granted access to a small number of bioprospecting projects, has a monitoring system up and running. Likewise, in Costa Rica, the technical monitoring office, charged with monitoring compliance to the access and benefit-sharing agreements, has not been established apparently due to lack of a budget, personnel, constitutional action and political will, and therefore monitoring procedures have not been carried out. Obviously, this is related to the fact that setting up this kind of system is a complex and expensive endeavor. Countries that have had legislation in place since the mid-1990s are still in the process of defining the scope of their access laws, the strategies to protect the knowledge of indigenous peoples, and the conditions to facilitate access to non-commercial bioprospecting activities.

2.7 Costs of tracking and monitoring in relation to expected benefits

Presumably, no Party will want to incur costs, if no benefits are expected or if the expected costs are likely to exceed the expected benefits. This is a basic principle in particular for private industry. But it also holds for the Parties (governments) designing new institutional arrangements governing the international transfer of genetic resources.

What are the benefits of tracking and monitoring the flows of genetic resources? For providers, a system of tracking and monitoring should contribute to the functioning of a transparent system of access and benefit sharing. It will allow the movement and use of genetic resources to be documented and support the case for sharing the benefits derived from their use. With such a system in place, these providers would presumably be willing to engage in exchange agreements, regulated by an MTA. For the users, this willingness on the account of the providers constitutes the benefit that can be ascribed to the tracking and monitoring system. In other words, the users (re-)gain access to the genetic resources shared by the providers.

In this section, we compare the transaction costs in the form of tracking and monitoring with what we think are reasonable estimates for amounts of benefits received and/or shared. We avoid getting into the details of how a mechanism for benefit sharing would function (including its own associated transaction costs). The reasoning here is that transaction costs would, in effect, have to be paid for out of the benefits shared. Or, put another way, the net balance sheet for tracking and monitoring systems involves a comparison of the benefits and the costs. Note though that our approach does not attempt to estimate how much access and exchange of resources would (further) decline if the Multilateral System, including a system of tracking and monitoring, had *not* been implemented. Another issue that we do not address concerns differences in the effectiveness of the various scenarios for tracking and monitoring. We will return to this issue below when we discuss the issue of fraud.

Expected levels of benefit sharing. No figures are available, of course, on total obligatory benefit sharing involved. For the purpose of this analysis here we fol-

low a procedure similar to the analysis in our earlier paper (Visser *et al.* 2000). We begin by noting that revenues from the sale of seed and planting material are estimated worldwide at US$ 25–30 billion (e.g., International Seed Federation website). The Standard MTA of the ITPGRFA specifies two benefit-sharing formulas ranging between 0.5 and 1.1% of sales for material not available for further research and breeding purposes.[20] Given current protection strategies pursued by breeders and the IPR regimes present, most of the material would still be available for further research and breeding and thus not subject to such compulsory benefit sharing. We therefore conjecture that over the next decade genetic materials obtained from the Multilateral System would be present in 10% of newly commercialized products and thus calculate potential benefits as 10% of 0.5% of US$ 25 billion, which amounts to US$ 12.5 million.[21] A second reference point is provided by private sector R&D expenditures in the plant breeding sector which have been estimated at approximately US$ 1 billion per year, and of this, about US$ 50 million (or 5%) is used for maintaining PGRFA collections or an increase in R&D expenditures of about 2.5% and corresponding to an increase of about 50% in costs for the private plant breeding sector in maintaining stocks of germplasm.

A figure of US$ 12.5–25 million for benefit sharing might seem high, particularly to those paying. We emphasize, however, that we are trying to base our rationale on our conjecture regarding what the situation for access and benefit sharing might be in the future after an initial adjustment period (i.e., it would probably only be realistic to move gradually to such an amount for benefit sharing). From another perspective, it is worth highlighting that the costs of implementing the Global Plan of Action on Genetic Resources for Food and Agriculture were estimated at anywhere between US$ 150–450 million.

It appears from Table 2 that a comprehensive system of tracking (scenario A) would not be attractive since almost all (97%) of the potential benefits might be necessary to cover tracking costs. The largest portion of the costs is accounted for by systematic fingerprinting of all material accessed and distributed. When this is done on only a limited basis (scenario B), the costs fall considerably and may be more acceptable, but are still close to 50% of benefits shared, dependent of course on the real costs of handling MTAs. It follows then that other options with decentralized documentation (scenario C) plus possibly dispensing entirely with fingerprinting (scenario D) appear even slightly better, although they are still substantial. Another perspective on these estimates is that any such tracking system (any of the scenarios) might only be economically viable if the benefit sharing can also include contributions from users that are additional to those currently specified in the standard MTA. This would mean either higher percentage formulas, or contributions that might be based also on products derived using material, even when that material does remain available for future breeding and research, or alternatively a substantial level of complementary voluntary contributions. Such a perspective is reinforced by recalling the range of transaction costs in Table 1 that have not been included in the monetary estimates.

Allocating costs of tracking and monitoring. So far the discussion has centered on a comparison of total estimated transaction costs and total estimated benefits. In reality though, the apportioning of both the transaction costs and the generated benefits amongst the various stakeholders is an equally important key factor in establishing whether any system might be acceptable to all parties and effective.

We should revisit the parties involved. Whereas the parties in a Material Transfer Agreement will be the provider and the user of the biological resource,

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20 *See* Annex 3 of the Standard MTA, in particular Article 1, available in the Report of the First Session of the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture, IT/GB-1/06/Report, Madrid, Spain, 12–16 June 2006.

21 A figure of 10% may seem high but could reflect two considerations. First, it is likely that resulting products that generate higher revenues and profits are those for which protection strategies, such as patenting, pursued by the developers might preclude further use of genetic material for further breeding and research. Second, there is an ongoing trend of increased use of patenting of varieties and also of biotechnological inventions incorporated into new varieties.

the provider is not necessarily a government, but may be a natural or legal person under the jurisdiction of that government. Likewise, in many cases the user will not be a government either, but a private company or an independent public sector institution (e.g., a university). In the case of the ITPGRFA, the Multilateral System can be considered a third party beneficiary to the exchange of genetic material, and this third party beneficiary will be connected to the Contracting Parties to the ITPGRFA. Thus, in analyzing the likely or possible apportioning of costs and benefits, next to providers and users, governments should be included in the analysis. A system of tracking and monitoring has to be attractive for each of these three groups in order to be effective.

The capacity and willingness of the user, in particular the private sector that is likely to commercialize products based on the genetic resources obtained under access and benefit-sharing agreements, has been briefly addressed above. The figures above indicate that any system involving elaborate genetic (or biochemical) characterization or complex and costly procedures to obtain written proof of prior informed consent and export permits would add considerably to the total transaction costs. If these were apportioned to the user (for example in charges for fingerprinting "included" in an MTA), then this would be a significant increase in the "costs" already incurred to the private sector in the form of benefit sharing. This may well constitute a further disincentive for such users to even seek access to genetic resources from the providers in the Multilateral System. Consequently, and as a strategic measure, if comprehensive characterization were to be contemplated, it would probably have to be paid for either by the providers themselves, or – in the case of the ITPGRFA – from the Governing Body, presumably out of benefit-sharing funds.

Legislation determining ownership of and access to genetic resources is likely to take into account that the provider may not be a government but an independent entity under the jurisdiction of a government. It may be a local company, or a farmers' community, or university. The capacity of such non-governmental providers, and of governmental providers in developing countries, to track genetic resources and monitor the implementation of the transactions involved will be very limited in many cases, and these providers may have to rely on the government for such endeavors. This also provides a rationale for governments and some central body, perhaps under the auspices of the Governing Body, to organize some aspects of the tracking system and pay the costs.

Thus, governments play a key role in two respects. First, as legislators (collectively), governments may be able to determine to a large extent the level of total transaction costs of tracking and monitoring when deciding to use more complex or simpler tracking and monitoring systems. Second, they can determine to a certain extent how such transaction costs will be apportioned to providers, users and government offices.

In this regard, it is important to evaluate to what extent governments are able and willing to bear part of the transaction costs of tracking and monitoring to facilitate the international exchange of biological resources that may result in benefits, shared between the user and the provider, assuming that they attach importance to promoting domestic socio-economic development. While this question is difficult to answer, it may be too optimistic to expect that governments can afford transaction costs that the user community, including the private sector, is unlikely to find acceptable. In other words, a comprehensive system of tracking and monitoring for which the costs are substantial is not only unattractive for the private sector but also unaffordable for governments.

Current government initiatives in some countries attempt to allocate some of the costs of enforcing access and benefit-sharing agreements to the user in the area of bioprospecting. The Peruvian draft regulation on access to genetic resources would require bioprospectors to pay 15% of the total budget of the bioprospecting project as a bond or guarantee that there will be total compliance with the provisions agreed in the contract (M. Ruiz, pers. comm.). Furthermore, penalties for violations of access agreements would be used to finance facilitating the establishment of access and benefit-sharing agreements as well as the tracking and monitoring involved in such agreements. In Nicaragua, access contracts will have to include obli-

gations for the establishment of an evaluation and monitoring system that will be financed by the access applicant. These examples show that governments will aim to divert transaction costs to users. As a consequence, the acceptance by the users to assume the costs of tracking and monitoring as part of the total costs and benefits is a key factor.

Transaction costs of tracking and monitoring in relation to fraudulent access or use. The costs of a system for tracking and monitoring should ideally also be compared to its benefits in terms of identifying or discouraging fraudulent access to or use of genetic resources. In this context, it is useful to distinguish between two types of fraudulent or illegal activities: cases where access and benefit-sharing agreements are signed but subsequently not adhered to; and cases where resources are utilized illegally, without obtaining any permission at all. The scenarios for tracking and monitoring above are primarily designed to address the first category. Such systems would, in principle, serve to increase adherence to agreements, such as MTAs. We have not, however, made any distinction between the four scenarios in terms of their effectiveness in encouraging such adherence, or in uncovering cases where users violate the provisions contained in the agreements. Indeed, we have not even attempted to estimate a baseline or average result of the various scenarios in this respect.

It is important to emphasize that the tracking and monitoring systems envisaged would have little effect on reducing the cases of illegal access and use. For example, a verification of a disclosure of origin at the point of a patent application requires that the applicant has made such a disclosure. A party seeking to circumvent benefit sharing would probably not include a truthful disclosure of origin, perhaps claiming that the germplasm had been in their own collection for many years predating the ITPGRFA and the CBD. This type of transgression could only be detected with great difficulty, if at all (i.e., with high transaction costs). In this regard, it is worthwhile pointing out that the number of cases in which illegal access and benefit-sharing agreements have been discovered is relatively small, and probably does not exceed thirty cases over the last decade. It is not clear whether this fact reflects the lack of such cases, or the inability of providers to apprehend violators for the various reasons described earlier in this chapter. Such deliberations may form another argument for cautiousness in developing costly tracking and monitoring mechanisms: the added benefits may be more limited than sometimes expected and may be more simply described as only policing the good guys.

In this respect, it should be mentioned that the work of a small number of international NGOs, in particular the ETC Group (formerly RAFI), has been crucial in bringing a few cases to the attention of the public, providers, governments and government institutions involved, and that as a result non-compliance or undesirable misappropriation has been corrected. A small and dedicated task-force might be more effective in detecting illegal access and use than a bureaucratic system that collects information but does not necessarily identify the worst transgressors.

The specific properties of plant genetic resources for food and agriculture (PGRFA). In establishing access and benefit-sharing regimes for PGRFA, such as in the framework of the comprehensive international regime currently discussed within the CBD, and in the form of the voluntary Bonn Guidelines of the CBD as well as the Multilateral System of Access and Benefit Sharing of the ITPGRFA, the specific nature of most PGRFA, as well as their use in breeding and subsequent food production have to be taken into consideration. Even more than for genetic resources in general, the specific nature and use of PGRFA should take into account the balance between costs of tracking and monitoring incurred, and the added benefits obtained as a result of implementation of such tracking and monitoring mechanisms. Some considerations are given below:

- Domesticated species have traveled over the world for a long time, and most countries depend on species that do not originate from that county for most of their food production, making countries mutually interdependent.

- Many farmers and breeders in many countries have added to the genetic properties of the crop varieties that we know today, rendering it difficult to distinguish between these various contributions, and the

extent to which different countries have contributed (what is the country of origin of a 19th century European potato variety?).

- Similarly, in any breeding program, multiple genetic resources will be used to develop new varieties, and it is often difficult if not impossible to attribute specific improvements to an identifiable genetic resource. This is also true for farmers who select plants with new traits from their fields in which they grow several varieties in close proximity.

- These practices also explain why farmers have long relied on a principle of free exchange of the genetic resources they work with.

- The breeders' exemption in plant breeders' rights legislation still recognizes and reflects these major concepts, although the desirable extent of the breeders' exemption has been discussed for many years now.

These statements are true for all PGRFA, whether they are included in the Multilateral System or not. These considerations may show the strong mutual interdependence and speak against the development of systems with high transaction costs that would hamper progress in breeding, whether by professional breeders or by farmers.

2.8 Conclusions

In this contribution we have analyzed the components of possible systems of tracking and monitoring, the flow of genetic resources, and the transaction costs these systems would entail. We have evaluated different scenarios for tracking and monitoring, and although reliable cost estimations are difficult to make and precise data are lacking, we then proceeded to compare the likely costs of these scenarios with the likely benefits generated by access to genetic resources and the proportion that may be shared with the provider based on current or proposed legislation and user behavior. We have also addressed apportioning the costs of any system for tracking and monitoring amongst providers, users and governments. Attention has concentrated on costs for tracking and monitoring that are likely to follow from the implementation of the ITPGRFA and its Multilateral System, as opposed to costs that may follow from the implementation of access and benefit-sharing agreements under the CBD.

Costs to monitor the international exchange systems and/or to track the flow of individual samples may partially be implied in the current international agreements, may be open to conscious manipulation only to a limited extent, and may largely fall on national governments that may seek compensation for such costs from the users.

Comparing incurred costs and likely benefits has led us to the conclusion that any effective system of tracking and monitoring should be low-cost in order to obtain sufficient interest from users and cooperation from governments, assuming that most providers will have to rely on governments for tracking and monitoring. In our opinion, any low-cost tracking and monitoring system will have to exclude a standard genetic or (bio)chemical analysis of the biological resource to be made available, since the costs of such analysis will certainly seriously affect the expected net benefit-sharing levels. Such standard analysis could only be justified by gains in detecting or deterring misuse of resources. While we have not analyzed this aspect in depth, we do not feel that the argument for such gains is very strong.

Low-cost tracking and monitoring systems may involve centralized or decentralized documentation of access and benefit-sharing agreements and of the material and associated information involved in the transfer. Whereas centralized databases would have to be established anew, decentralized documentation in existing database systems may form an alternative if guarantees can be given on the long-term availability and accessibility of the data referred to.

Low-cost systems may also include mechanisms and facilities for occasional tracking of the flow of particular genetic materials, either because they represent

high potential value or because non-compliance is suspected, or as a strategy of random sampling and random assessment of compliance.

Nonetheless, the cost of such low-cost tracking systems concentrating on documentation may still be substantial relative to potential benefit sharing in financial form. Indeed, it would be some time before the benefits specified in the standard MTA would be able to cover these costs. This suggests that financial viability of a tracking and monitoring system urgently deserves attention and further research. Indeed, to the extent that the mere existence of such a system is necessary to build trust among providers, this issue may be of pivotal importance for the success of the Multilateral System.

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3 Reflecting Financial and Other Incentives of the TMOIFGR: The Biodiversity Cartel

Joseph Henry Vogel[1]

Executive summary

Genetic resources are natural information. The physical truth of that statement has tremendous implications when applied to access to genetic resources and the fair and equitable sharing of benefits (ABS). Much of the tortuous evolution of the Convention on Biological Diversity (CBD) owes to suppression of that truth. Established economic theory can elucidate what should now be done to achieve the laudable goals of the CBD. The author of this chapter, Joseph Vogel, is a noted and fiery iconoclast. The strength of his commitment to his research and conclusions, and the unreserved manner in which he expresses that commitment have sometimes distracted his readers from the fact that his work is carefully and intensively researched and his economic analysis is of the highest order. Through his analysis of the transaction costs of ABS, one can evaluate the relative efficiency and equity of an oligopoly over genetic resources and associated knowledge which, in plain English, is a "biodiversity cartel."

This chapter notes a list of caveats that have not been stated to date. First it poses the question: Can economic theory be applied to ABS? Then it suggests that economic theory has been perverted in deceptive metaphors of efficiency. It identifies 16 distortions in ABS, as compared under the Bonn Guidelines and the proposed cartel. Vogel concludes that a cartel approach removes almost all of these distortions.

This chapter suggests a Special Protocol to the Convention on Biological Diversity which is designed to both minimize transaction costs and align incentives. Its transaction costs are compared against those of bilateral bioprospecting under the Bonn Guidelines and the cartel fares very well. This also holds true when one compares tracking and monitoring the international flow of genetic resources under the cartel versus the proposal by the European Union based on the Bonn Guidelines.

This chapter notes that much which is alleged to be biopiracy is actually "gene-dumping." To clarify the situation and its objectives, it proposes to create an arena where the controversy about bioprospecting, intellectual property rights, and the public domain can be aired. Contrary to 1970s wisdom, one must think locally and act globally.

Ronald H. Coase won the 1991 Nobel Memorial Prize in Economics for an idea that he first expressed in 1932 as a 21-year-old college student: transaction costs can explain the nature of the firm and the absence or presence of markets.[2] This simple intuition lends itself well to access to genetic resources and a fair and equitable sharing of benefits (ABS) as mandated under the Convention on Biological Diversity (CBD). Through an analysis of transaction costs, one can explain the nature of the pre-CBD regime over genetic resources as well as the absence of a robust market to emerge in the current regime of national sovereignty. The scope of such analysis is not only explanatory but also prescriptive. By analyzing the transaction costs of the current regime, one can evaluate the relative efficiency and equity of a conceivable alternative. The alternative to be examined here is an oligopoly over genetic resources and associated knowledge which, in plain English, is a "biodiversity cartel."

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[2] *See* the Prize Lecture "The Institutional Structure of Production" by Ronald Coase at http://nobelprize.org/economics/laureates/1991/coase-lecture.html.

In some discussions, one may get the wrong impression that *Tracking and Monitoring the International Flow of Genetic Resources* (TMOIFGR) is an end in and of itself. TMOIFGR is merely a means that will take different configurations given the type of legal regime that governs ABS. The first section of this chapter will revisit the argument that a biodiversity cartel is the most efficient and equitable regime (Vogel 1995, 1997, 2000). In other words, the moving target in the title of the anthology can also refer to one's interpretation of national sovereignty in the context of genetic resources and associated knowledge. The next section will compare the implications of the cartel for TMOIFGR against a proposal that has been advanced by the European Community and its Member States in the World Intellectual Property Organization (WIPO). The final section will go beyond the merits of the cartel and to the uneconomic rhetoric that accompanies popular accounts of ABS. To date, economics-as-rhetoric (McCloskey 1983) has not been deployed very successfully in defining public perceptions about ABS. To illustrate what can be done, I will conclude the chapter by making economic sense of an article from *The New York Times* about bioprospecting.

A caveat is in order. Economists seldom accept facile explanations of success or failure in the allocation of any resource. As this chapter will suggest, the failure of "stakeholders" to achieve significant ABS under the CBD may not be a failure at all; it could actually be the success of those intimately involved in the design of the regime. Undiplomatically, we must question the motivation and legitimacy of the participants in the debate. Those who craft policy are not true stakeholders but agents (i.e., politicians or management) whose incentives will diverge from those of the principals (i.e., citizens or shareholders). Agents should be viewed as neither winners nor losers in ABS; they are merely facilitators or impediments to the most efficient and equitable solution. Their participation began in December 1994 with the first Conference of the Parties to the CBD, held in Nassau, Bahamas. Fast forward to February 2005 and Bangkok, Thailand, and one will hear delegates to the ABS Working Group hinting that a multilateral regime may take 10 *more* years (Grain 2005). Clearly, the agents have become an impediment. To make a facilitator out of an impediment means to align incentives and such alignment lends itself well to economic theory. So, the task at hand is also mundane: in the light of the efficiency and equity of a biodiversity cartel, how will we engage principals to mount pressure on the agents to reform ABS policy?

3.1 Economic logic

3.1.1 The importance of "getting the name of things right"

E.O. Wilson begins a number of his writings with the importance of classification: "The first step to wisdom, as the Chinese say, is getting things by their right names."[3] In the case of ABS, the first step would be getting whatever-it-is-we-wish-to-conserve by its right name. Most people have assumed that that object is "biodiversity" which was defined in the CBD as: "...the variability among living organisms from all sources including, *inter alia*, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems" (Article 2). If strictly applied, such a definition would not be operational as the object of conservation. The inclusion of the variability among living organisms from *all* sources is physically impossible as some biodiversity *within* species is expunged in the simple act of eating (Vogel 1992). To accept the CBD definition of biodiversity and its overarching goal of conservation, one would have to reject the Second Law of Thermodynamics – not a very tenable position.[4]

This criticism of the CBD definition of biodiversity is based on the Second Law which is also known

[3] Wilson 1998, at p. 4.

[4] Sir Arthur Eddington said it best "...[i]f your theory is found to be against the second law of thermodynamics I can give you no hope; there is nothing for it but to collapse in deepest humiliation." The Nature of the Physical World. Macmillan, New York, 1929 at p. 74.

as the Entropy Law. A measurement of entropy exists in the Boltzmann equation which calculates the information of any physical state. From the thermodynamic perspective, it is no metaphor to say that the sequence of purine and pyrimidine bases of DNA is information. From the economic perspective, one would want to conserve information that maximizes net benefits. By so understanding the object of conservation as functions coded in (natural) information, policy-makers could have imported the well-established economics of (artificial) information into the design of the CBD. The reason they did not has much to do with rhetoric. By the mid-1980s, the neologism "biodiversity" had become wildly successful in the mass media; ABS is the lingering victim of that success.

Considering that economists are obsessed with the internal logic of any argument, it is somewhat surprising that economists ever tolerated the word "biodiversity." Rather than returning to square one, i.e., definitions, when square one was still within sight, most simply decided to reclassify biodiversity in terms of economic theory. The classification assigned was "public good" (Randall 1988) which simply means that one's enjoyment of biodiversity does not reduce anyone else's simultaneous enjoyment. Because the value of biodiversity-as-public-good has multiple components (e.g., aesthetic, meteorological, recreational, and bioprospecting), an ambitious challenge suddenly emerged: computing the "Total Economic Value of Biodiversity," (TEV) (Munashinge 1992; Turner *et al.* 1993; Landell Mills[A1] and Porra 2002). Once estimated, a TEV can then be plugged into cost-benefit analysis to determine, say, "the optimal level of tropical forests."[5] Such calculus will give biologists much pause. By the species-area equation of biogeography (MacArthur and Wilson 1967), any optimum that is non-zero deforestation legitimizes extinction. Perceiving this sleight-of-hand, David Ehrenfeld joked that by the time economists have sorted out all the valuation issues, there wouldn't be much biodiversity left (Ehrenfeld 1988). That joke was prescient and one can identify Ehrenfeld's and Randall's chapters in the landmark anthology *Biodiversity* as a bifurcation point in subsequent ABS economic literature. For ease of exposition, I will categorize the two approaches as Track I and Track II.

Whereas Track I accepts TEV and cost-benefit analysis in an "economics of biodiversity" (Perrings 1995), Track II rejects both as an "economics of extinction" (Vogel 1997). Sharing Wilson's sentiment that "[i]n the end, I suspect it will all come down to a decision of ethics,"[6] Track II begins with ethics. Non-negotiable is any further loss of habitat. Rather than calculating an optimum level of conservation (read extinction), Track II asks: What are the most cost-effective modes of achieving conservation? How do we enable society to "live within limits?" (Hardin 1993). Because half of the planet's terrestrial biodiversity resides in tropical forests, "no deforestation" is of utmost priority. Whereas Track II resonates with heterodox economists (Austrian, ecological and institutional) and its allies in civil society, Track I resonates with orthodox economists (neoclassical or mainstream) and its allies in biotechnology.

David Simpson and his colleagues at Resources for the Future wrote the most cited work in the Track I literature on ABS (Simpson *et al.* 1996). They have computed the value of biodiversity for pharmaceutical bioprospecting at precisely US$ 2.29/hectare-year in the hottest biodiverse "hot spot" in the world – the Chocó biome of Ecuador. Like so much of orthodox economics, the calculation depends on a scaffolding of assumptions. A few years later and in the same journal, Gordon Rausser and Arthur Small published a model that, lo and behold, showed that genetic resources have a very high value (Rausser 2000; Small 2000). Well, which is it?

For Track II economists, the answer is beyond our lens of resolution and reflects a poor choice of questions. One should be asking: Does *probable cause* exist to justify public investment in the infrastructure needed to enable a market in genetic resources?

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5 López at p. 3.

6 Wilson 1988 at p. 16.

Anecdotal evidence such as *Thermus aquaticus*, a microorganism that resulted in a billion dollar industry worldwide, suggests that it does (Scott 2004).

Because one can easily establish probable cause, Track II economists would re-allocate intellectual resources away from calculating the value of genetic resources and to the arena of political institutions. How does one make *and* fund laws that would enable a viable market in genetic resources and associated knowledge? One need not reinvent the wheel. Much can be learned from transnational corporations. For example, Edmund Pratt, CEO of Pfizer Corporation, built a system of "nodal governance" in the early 1980s that would eventually end in Trade-Related Aspects of Intellectual Property Rights (TRIPS).[7] Part of the success of the corporate campaign for TRIPS was the simplicity of the message:

1) creating information (R&D) is expensive; while reproducing it (manufacturing) is cheap;

2) without monopoly intellectual property rights (IPRs), everyone waits for someone else to innovate, and then copies the innovation;

3) the market for copies does not generate sufficient revenues for the innovator to recoup the fixed costs of R&D; and

4) few information goods/services are launched; society suffers from technological stagnation.

Track II economists would recommend that conservationists apply the same argument to natural information and appeal to *quid pro quo*:

1) protecting habitats is expensive, while accessing samples (collecting) is relatively cheap;

2) without oligopoly rights, i.e., a cartel, *unenlightened* biotechnology interests will foment a price war and access natural information in a country willing to sell slightly above the cost of collection;

3) the market for samples does not generate sufficient revenues to offset the opportunity costs of conservation; and

4) hence, pressures will mount on wilderness areas whenever opportunity costs are high; society suffers habitat loss and subsequent extinction.

The logic above is straightforward and the argument, symmetrical with IPR. Why has it not prevailed in the 12 years of ABS policy debate? The answer lies in *realpolitik*. Industry has succeeded in privatizing benefits for artificial information through TRIPS and socializing costs of natural information through "The Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising out of their Utilization."[8] To see this, one need only consider the issue of royalties. The Guidelines allow them to be negotiated on a case-by-case basis and are silent about whether the rate negotiated should be disclosed to the public. From the viewpoint of industry, such silence is very welcome. Novartis, for example, offered Brazil a rate which is insignificantly different from zero: 0.5% (Pena-Neira *et al.* 2002). Tellingly, the category "royalty" in the Guidelines [letter (d) of Category 1 of Appendix II] gets no more play than "Access fees/fee per sample collected" [letter (a)] and the list of monetary benefits [letters (a)-(j)] is followed by a much longer list of non-monetary benefits: capacity-building, technology transfer, and the like [letters (a) through (q) of Category 2]. The impression is unmistakable: little money will change hands in ABS, and be happy with those non-monetary benefits! However, *disinterested* economists on either Track I or II will be uneasy. By virtue of the benefits of Category 2 being non-monetary, measurement of their value is all but impossible [e.g. (n): "Institutional and professional relationships..."] and the possibilities for fraud seem infinite. Even if one were to very generously assume good faith on the part of all parties, such non-monetary benefits would be a form of earmarking and earmarking is anathema in the economics of public

[7] Drahos at p. 260-261.

[8] *See* Decision VI/24 of COPVI at www.biodivi.org/decisions

finance. Earmarking precludes the allocation of the budget to those activities with the highest social return (Southgate 1997).

3.1.2 An analogous argument for associated knowledge

The economic justification for a biodiversity cartel over genetic resources can be extended to the knowledge associated with those resources. To appreciate the logic, one should distinguish between "random" and "ethno-" bioprospecting. The former refers to a search for commercially useful natural information that is unbiased by the artificial information residing in traditional communities. The latter biases the search. The literature on random- and ethno-bioprospecting does not use the nomenclature "natural" and "artificial information" even though such terminology would be readily understood by the scientific community. Instead, experts speak of "traditional knowledge" and "genetic resources." When referring to the bioprospecting literature, I will use the established terminology and only revert to the terms of artificial and natural information when making the economic argument.

The literature in ethnobioprospecting emphasizes that traditional peoples have accumulated much useful knowledge about the genetic resources in their environments. That knowledge can now augment the probability of a "hit" in modern screens for bioactivity. Although the CBD contemplates benefit sharing when such hits occur, the CBD is not clear regarding the rights of communities regarding the benefits. Unlike its provisions for ABS, the CBD's language is weak and hortatory in all mentions of community rights, starting with the Preamble,

> *The Contracting Parties, Recognizing the close and traditional dependence of many indigenous and local communities embodying traditional lifestyles on biological resources, and the desirability of sharing equitably benefits arising from the use of traditional knowledge, innovations and practices relevant to the conservation of biological diversity and the sustainable use of its components* [italics mine] (Para. 12).

Doubts about benefit sharing in the CBD were voiced immediately from experts in diverse disciplines. Darell Posey, an anthropologist, wrote: "[t]he word 'desirability,' in itself, is hardly strong enough to bind the State to legal implementation, besides which, no criteria for or mechanisms to implement this concept are provided in the CBD or elsewhere."[9] Dinah Shelton, a legal scholar, was similarly circumspect: "...the state's obligations are limited to 'encouraging' the equitable sharing of benefits. No right to compensation is explicitly recognised."[10] Despite non-committal wording like "desirability" and "encouraging," the CBD does provide sufficiently strong wording to empower communities to negotiate. The word "approval" in Article 8(j) would enable "holders of such knowledge" to withhold knowledge if they do not expect "equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices." Such withholding can become the leverage needed to create a market in traditional knowledge.

Although a market in traditional knowledge could be created, the economist would still be a wet blanket for any hope of fair and equitable benefit sharing. He or she would duly point out that the mere ability to sell does not mean that any one will buy. Demand may not intersect with supply. In the case of traditional knowledge, three basic problems undermine the demand. *The first is that of the public domain.* Much traditional knowledge is already in the public domain and lies beyond legal claim. It is not only archived in libraries but can also be found in on-line databases. Why pay for new information if you can get the old for free? Recognizing this problem, many conservationists believe the solution is a *sui generis* legislation

[9] Posey at p. 7.

[10] Shelton at p. 25.

that covers knowledge already in the public domain. Such opinions were often expressed in WIPO's fact-finding missions on intellectual property and traditional knowledge conducted in 1998-99 (WIPO 2001). In the vanguard of such reforms is Peru which became the first country to institutionalize *sui generis* protection for knowledge published in the last twenty years (Venero 2003). Despite the high hopes for the Peruvian legislation, the economist would still press: Why pay for leads from the last twenty years, if you can get the older information for free? As troubling as such loopholes are for *sui generis* legislation, more troubling is its apparent retroactivity. The rhetorical implications are disastrous for the material welfare of Third World countries. One need only imagine Bayer A.G. arguing for compensation on its expired 19th century patent over aspirin.

Without retroactivity, *sui generis* protection would be limited only to that knowledge not yet in the public domain. In other words, the first problem could be eliminated for traditional knowledge not yet published. Nevertheless, the economist would still not be hopeful even for that subset of traditional knowledge. *The second problem is that of competition.* Much of the unpublished traditional knowledge is diffused among communities and ethnic groups. For example, many ethnic groups in Peru (speakers of Quichua/Quechua) are also found in neighbouring Chile, Bolivia, Brazil, Ecuador, and Colombia. Competition for PIC will drive the benefit for access down to the marginal cost of being interviewed - a few hours of work and that at the minimum wage. The rents needed to motivate the conservation of unpublished traditional knowledge will have been eliminated.

As if the economics of Track II were not dismal enough, *a third problem exists - the fact that identical genetic and/or knowledge resources exist in several countries or communities.* Under the CBD, the State is sovereign over the genetic resources while the communities can only withhold approval from accessing knowledge associated with those genetic resources. This means that the State can collect randomly without the consent or participation of the communities. One need not be a Philadelphia lawyer to appreciate this loophole: the State can circumvent "approval" of the communities by simply collecting "randomly" in the general proximity of a settlement.

The solution to problems one and two is the transformation of traditional knowledge into trade secrets and their subsequent cartelization. Claimants would be identified by filtering databases managed by traditional communities and benefits would be distributed to communities that share the same trade secret (Vogel 2000). Unlike the first two problems, the third problem has no technical solution - just political ones. In the political arena, NGOs must raise the transaction costs of *faux* random bioprospecting. Success is obtained whenever the State perceives that it is more revenue-enhancing to share its royalties with traditional communities than to defraud them.

Success would bring new questions in its train: How much should the State (or more accurately, the Cartel of States) receive for being sovereign over the genetic resource? And how much should communities (or more accurately, the Cartel of Communities) share for their associated knowledge? Microeconomic analysis can shed much light on what are the limits of efficient sharing. Through some reasonable assumptions about the production function of ethnobioprospecting, one can show that a 50-50 split of royalties is the maximum that the State will be willing to pay communities for their traditional knowledge (for a mathematical proof, see Box 1).

Box 1. The behavioural economics of efficient sharing

In the language of mathematics, the problem for the State is to maximize its share of bioprospecting profits, π, which equals gross revenues (the royalty rate, p, it receives on sales, Q) less costs (the share of royalties, c, it pays to the Communities). However, Q is also a function of c. In other words, higher royalties paid to the Communities will induce more inputs of secret traditional knowledge and more hits. Q will rise with c but not indefinitely as diminishing returns set into c. A simple function that expresses this relationship is the square root. Suppose that the relationship between the reward to the communities and the final product can be characterized by $Q(c) = a\sqrt{c}$. The State wishes to

$$\text{MAX } \pi = p\, a\sqrt{c} - c\, a\sqrt{c}$$

Solving for the first order conditions, yields

$$c = 1/3\ p$$

The proof that 1/3 the royalties collected by the State should go to the Communities hinges upon the assumption that $Q(c) = p\, a\sqrt{c}$. Suppose that the relationship is linear, $Q(c) = ac$, then the first order condition yields $c = 1/2p$ which means one half the royalty collected by the State should go to the Communities. However, linearity violates the assumption of diminishing returns. Hence, a State that shares 50% of its royalties with the Communities has approached the upper limit it can justify under the reasonable assumptions of profit maximization and diminishing returns.

The question of sharing is not finalized with a 50-50 split between the State and the communities. An embedded question is how one shares the benefits *within* the community. The easiest solution would probably be a disbursement of money among all families of the community. Microeconomic theory implies that money is always at least as good, and almost always better, than in-kind transfers. However, the easiest solution may not be the most effective in encouraging participation. Traditional knowledge is seldom evenly distributed within a community; usually it is concentrated in the shaman. Although a *pro rata* division of money would not contradict the CBD, such disbursements would not leave the shaman with very much incentive to participate in ethnobioprospecting; he or she may even become resentful that others within the community are benefiting equally despite the unequal burden of stewardship. Without the cooperation of the shaman, little traditional knowledge will be deposited in the regional databases that is not already freely accessible in the published ethnobotanical literature; one returns full circle to *the first problem*. How can the shaman be induced to participate without a disproportionate compensation? Here behavioral economics has much to offer. In the synthetic literature of economics and psychology, it is well known that status is a strong motivating force (Alhadeff 1982; Frank 1985). *In order to align incentives in ethnobioprospecting, the shaman should select the public goods which will be funded from the benefits for access.*

3.1.3 "Tilted playing fields" and the theory of second best: The counterintuitive argument

The previous discussion may not be the right rhetoric to convince politicians. It is too economic. Politicians prefer the language of sports and will even assume that metaphors from cricket, football, or rugby can capture the nature of an economic problem as well its solution. An opportunity to persuade politicians arises in their own rhetoric of "tilted playing fields." Applied to ABS, the metaphor suggests that we level the playing field and design a legal system which entails fewer distortions.

What are the distortions of the Bonn Guidelines? How do they compare with those of the Biodiversity Cartel? Table 1 makes such a comparison and the Cartel fares very well. However, advocates who think in terms of economics should temper their enthusiasm and recall some basic theory. In a seminal paper entitled "The Theory of Second Best," the mathematical economists Richard Lipsey and Kelvin Lancaster showed "it is *not* necessarily true that a situation in which more, but not all, of the optimum conditions are fulfilled is necessarily, or is even likely to be, superior to a situation in which fewer are fulfilled."[11] In less technical language, second best means that one cannot claim that a legal system that removes a distortion or even a series of distortions will actually improve efficiency as long as another distortion still stands. The sports metaphor fails because playing fields in cricket, etc., occur in three-dimensional space whereas institutional distortions lie in an abstract hyperspace of multiple dimensions.

One can illustrate the theory of second best in the justification for monopoly IPRs. A competitive market in information will never fulfill the optimum conditions from microeconomic theory, viz.

Price = marginal cost = average cost.

Instead,

average costs >> marginal costs = price,

and innovators will go broke. The granting of a monopoly IPR allows the possibility that the price equals or exceeds the average cost. As analyzed in the previous section, natural information does not share any right, under the Bonn Guidelines, analogous to the monopolies of artificial information under TRIPS. Therein lies a tilted playing field. Consumers of R&D in synthetic/combinatorial chemistry are paying a "monopoly rent" for complex information, while those of natural product chemistry pay none. Rent in economics has a distinct meaning that is somewhat abstract. It is the payment in excess of the cost of the factor. For patented products that arise from synthetic/combinatorial chemistry, consumers pay a full monopoly rent for such R&D. For patented products that arise from natural product chemistry, consumers pay only a monopoly rent on the *value added* to the genetic resources. So, the tacit subsidy or tilt is *pro* bioprospecting and *contra* synthetic/combinatorial chemistry. To level the playing field, one would have to charge an oligopoly rent for natural information. However, in light of the theory of second best, advocates of a biodiversity cartel should not seize on this justification unless all the other optimum conditions are also satisfied. What are they?

The question requires reflection. Not only is it difficult to identify all the tilts in institutional hyperspace, it is also easy to misidentify them. For example, bioprospecting in plants appears to be favored over animals. Toxins have evolved much more often in plants than they have in animals, and many can be manipulated into medicines. However, the asymmetry between plants and animals does not qualify as a distortion. It arises from the evolution of defensive strategies and not from human institutions. One can illustrate this point by a counterexample: a misguided tax on the bioprospecting of plants would not level the playing field; it would further distort it.

Sixteen tilts can be identified in the playing field of the Bonn Guidelines. Again, in light of second best, one cannot say that the Cartel is optimal simply because 12 of the 16 tilts would be eliminated and

[11] Lipsey and Lancaster at p. 11.

three diminished. As explained in the table, still present would be the tilt favoring the bioprospecting of the human genome. Nevertheless, that tilt may be offset by another in the opposite direction. One recalls that The Human Genome Diversity Project of the early 1990s was dismantled due to human rights violations; its reincarnation in the new millennium under the Genographic Project may suffer a similar fate.[12] If the additional transaction costs in accessing the human genome offset the differentially favorable ABS rules of the International Declaration on Human Genetic Data 2003 (IDHGD), then the Biodiversity Cartel is approaching the rare case of a "first best" solution.

Table 1. Tilted playing fields in the hyperspace of ABS

Ceteris paribus, where the Bonn Guidelines tilt	How they tilt	Explanation of presence/absence in a biodiversity cartel
1. Users will prefer to work with non-ratified countries rather than ratified countries.	No clear obligation to share anything when resources accessed in non-ratified countries.	Absent. Royalty rate invariant regardless of source; collected as a duty on imports from non-ratified countries.
2. In marine zones, users will prefer to gather resources from waters beyond the Exclusive Economic Zone (EEZ), rather than those within 200 nautical miles (nm) of a country.	The International Seabed Authority (ISA) of the United Nations Convention on the Law of the Sea (UNCLOS) enjoys monopoly power over the seabed. Even though still not functional, its role focuses on minerals and any authority over "living resources" is disputed. In contrast, countries can compete for low-royalty bilateral bioprospecting within their EEZ.	Absent. Royalty rate invariant regardless of source; for waters beyond 200 nm, royalties remit to the ISA.
3. Users will prefer to go to countries which are not members of the Group of Like-Minded Megadiverse Countries, which is committed to "harmonizing" benefit sharing.	Greater negotiating power to extract low royalties from non-members.	Absent. Royalty rate invariant regardless of source.
4. Users will prefer to go to weak governments and those that have not adopted any law, policy or process for dealing with its sovereign rights over genetic resources, rather than to strong governments.	Greater negotiating power to extract low royalty from weak governments.	Absent. Royalty rate invariant regardless of source.
5. Where traditional knowledge is involved, users will prefer to deal with countries w/few patent attorneys, and little patent-related experience over countries w/many patent attorneys.	Greater negotiating power to extract low royalty from countries w/few patent attorneys.	Absent. Royalty rate invariant regardless of source.

[12] *See* https://www5.nationalgeographic.com/genographic/

Ceteris paribus, where the Bonn Guidelines tilt	How they tilt	Explanation of presence/absence in a biodiversity cartel
6. Users will prefer to get samples from *ex-situ* collections (and persons who have previously collected samples and moved them across national boundaries) rather than to engage in direct *in-situ* collecting in the source country.	Some users still believe that the genetic resources of biological samples held in pre-CBD *ex-situ* collections are "in the public domain" and, therefore, may be used without compliance with ABS. Try competing with someone giving away a substitute for free!	Absent. Royalty rate invariant regardless of source.
7. Users will prefer to find and use traditional knowledge which they can argue is in the "public domain" instead of traditional knowledge that is or may be proprietary knowledge of the country or community.	Published traditional knowledge pre-CBD is public domain. Again, try competing with someone giving away a substitute!	Absent. Royalty rate invariant whether public or secret traditional knowledge, distribution is distinct when secret (split between Cartel of associated knowledge and that of genetic resources).
8. Users will prefer to utilize microorganisms rather than multi-cell organisms.	Elevated transaction costs in policing microorganisms as easier to camouflage country of origin as a non-ratified CBD country.	Absent. Royalties remitted to general fund of Cartel to defray fixed costs when claimants cannot be identified.
9. Users will prefer to use plant extracts or other commodities, rather than genetic resources obtained through ABS.	Whitewashing: easy to export plant extracts as commodity to a non-ratified CBD country and avoid ABS altogether.	Absent. Royalties charged on species independent of how accessed.
10. Users will prefer random bioprospecting when possible, rather than ethnobioprospecting.	Fewer transaction costs in negotiating access; possibility to whitewash secret traditional knowledge as if randomly accessed.	Absent. Same royalty rate whether random or ethnobio-prospected, simply distributed differently. Incentives to white-wash eliminated.
11. Users will prefer widely dispersed rather than endemic genetic resources.	Through competition, lower royalty rate can be negotiated on widely dispersed resources with multiple "countries of origin."	Absent. Same royalty rate whether widely or narrowly dispersed.

Ceteris paribus, where the Bonn Guidelines tilt	How they tilt	Explanation of presence/absence in a biodiversity cartel
12. Users will prefer to use human rather than non-human genetic resources.	ABS is stronger than similar provisions under IDHGD.	Present but offset. Elevated transaction costs on human genome bioprospecting seem to be a countervailing distortion.
13. Users will prefer symbolic phenotypic expressions rather than genetic resources.	With digital photography, truly impossible to police images that arrive instantaneously into a non-ratified country.	Diminished. For patents on designs inspired from nature, transaction costs are surmountable; for copyrights on images that include nature, transaction costs appear insurmountable.
14. Users will prefer simple over complex molecules.	It is easier to recognize a natural source when the genetic or biochemical characteristics of its components are complex. Similarly, transaction costs of determining provenance of simple molecules are markedly higher than complex molecules. Possibilities arise for whitewashing as if simple molecules were the product of synthetic/combinatorial chemistry.	Greatly diminished. Due to the number of potential claimants in the Cartel, greater scrutiny of patent applications.
15. The system will favor natural product chemistry rather than synthetic/combinatorial chemistry.	Through the price war induced by Material Transfer Agreements (MTAs), no rent is paid for complex information that, had it been created artificially through synthetic/combinatorial chemistry, would have enjoyed a monopoly rent.	Absent. The costs of accessing natural information from the wild will approximate more closely the costs of creating artificial information in the laboratory.
16. Paradoxically, users will often prefer non-viable relic populations over species whose habitat is sufficiently protected to assure sustainability.	Biogeographic islands provide access over the time-horizon of industry even though the population of the species bioprospected lies below critical dispensation for survival.	Greatly diminished but not eliminated. Royalty share is calculated on percentage of habitat in countries of origin. The tilt persists in the Cartel for endangered endemic species whenever politicians are not positively reinforced from the royalties on endemics.

Point 6 in Table 1 deserves explanation. When genetic resources are recognized as information, the issue of when the medium of that information, viz., the specimen, left or entered a country is irrelevant. The countries of origin still have a claim, much as an author still holds copyright no matter in which library the author's book happens to be shelved. Thanks to the path-breaking work of the ESCR Centre for Economic and Social Aspects of Genomics (CESAGen), we now know that hundreds of thousands of patents have been granted and millions more are pending on products and processes involving natural components since the CBD was ratified in 1993 (Oldham 2003). The implications for ABS are staggering. Biopiracy is happening on a vast and almost unimaginable scale.

3.2 Institutionalizing a new regime

3.2.1 Special Protocol to the CBD

The legal vehicle for a biodiversity cartel is a Special Protocol to the CBD. At a minimum, the Protocol would incorporate the following features:

1. The amendment of national laws on applications for intellectual property rights to require a specific and confirmable disclosure of the species of origin for the biochemical developed into a biotechnology.

2. Scientific analysis to determine the taxon in which the biochemical is found and the geographic range of organisms belonging to that taxon. Using Geographic Information Systems technology, a mechanism (possibly the Clearing House Mechanism of the CBD) would identify the countries that would be collective claimants for each biotechnology.

3. The establishment of a fund to receive an oligopoly rent of 13% on net sales of biotechnologies that use the biochemical and their distribution to cartel members according to the representation of habitats in the taxon in which the biochemical is found. The country that provides the physical samples negotiates an appropriate payment (whatever the market will bear) for the right to enter and collect the natural information bioprospected (usually ranging from 0.5-2%), above and beyond the rent.

4. The establishment of databases of traditional knowledge at the community level to determine what has already fallen into the public domain and what can still be transformed into a trade secret.

5. The filtration of any patented biotechnology from random bioprospecting against the traditional knowledge databases to determine whether there is a coincidental match. If so, then the 13% rent will be divided between the Cartel of States and Cartel of Communities that hold the secret traditional knowledge. In the case of direct ethnobioprospecting, 6.5% of net sales accrue to the Cartel over genetic resources and 8.5% to the Cartel over associated knowledge.

6. A tracking of holders of intellectual property to uncover any uses of a biochemical to determine whether the rent has been paid to the fund.

7. Whenever the rent has not been paid, a trebling of the royalty on prior sales of the biotechnology export and its deposit into the fund; whenever a biotechnology has not disclosed its use of a genetic resource, the trebled levy will remain in effect for the duration of the patent.

The Special Protocol will drastically reduce the transaction costs of ABS in the long run. Nevertheless, significant transaction costs are involved in institutionalizing the cartel in the short run. Table 2 compares the costs under the two regimes.

Table 2. The transaction costs of ABS

Under the Bonn Guidelines	Under the Cartel	Are the transaction costs of the Cartel (much greater than) / (greater than) / (the same as) / (less than) / (much less than) those of Bonn?
1. Establishment of a Competent Authority to handle the flow of petitions for access.	Once a ratified member to the Special Protocol, there is no additional government approval for access as long as other legal requirements are met [e.g., phytosanitary norms, obligations under Convention on the International Trade in Endangered Species of Flora and Fauna (CITES), etc].	(Much less than) No special bureau is needed to evaluate, grant, and monitor access under the Cartel.
2. PIC on a case-by-case basis for random bioprospecting to determine mutually agreed terms within each country. Opportunities arise for rent-seeking behavior.	Flat royalty is the mutually agreed term. Filtration against Traditional Knowledge (TK) requires a network of databases managed at the community level.	(In the short run, much greater than). Cartel requires databases on TK, herbaria, and training at community level to prevent random bioprospecting from coinciding with TK. (In the long run, much less than). Once databases on TK, etc. are established, titles can be clouded whenever access to secret TK has been illicit. (In the long run, much less than) The Cartel is a standardized mechanism for benefit-sharing; Bonn is case-by-case. (In both the short and long run, much less than). The Cartel obviates rent-seeking behavior in PIC; Bonn requires much oversight to prevent it.
3. PIC on a case-by-case for ethnobioprospecting within each contracting community.	Identification of public good projects to which funds will be used; standardized PIC across communities.	(In the short run, less than). Easier for shaman to identify public good project than achieve community consensus.(In the long run, much less than). Due to legal challenges of "fair and equitable" by communities left out of any bilateral agreement under the Bonn Guidelines.

Under the Bonn Guidelines	Under the Cartel	Are the transaction costs of the Cartel (much greater than) / (greater than) / (the same as) / (less than) / (much less than) those of Bonn?
4. Amendment of the Patent Cooperation Treaty (PCT) to require disclosure of species.	Amendment of the PCT to require disclosure of species.	(The same).
5. Disclosure requirement triggered by intent of R&D.	Disclosure only at the moment of patent or other IPR protection.	(Much less than). Unlike Bonn, one would not have to disclose the source before even beginning R&D. Instead, one simply reports the species in the patent application.
6. Sanctions still undefined for failure to disclose or disclosing falsely.	Temporary trebling of base royalty rate to 39% when failure to pay but no failure to disclose. Permanent trebling of base royalty rate with discovery of failure to disclose.	(Much less than). A simple penalty that is consistent with GATT fine structures.
7. Political hurdles to transform the voluntary Bonn Guidelines into a binding instrument.	Agreement of 66% of the Parties for the Protocol to enter into international law	(Much greater than). One has to convince principals in the industrialized countries that it is also in their interests to pressure their agents to adopt a Special Protocol.

3.2.2 A cascade of means and ends

From an analytical perspective, a Special Protocol is one of the means to the end of institutionalizing a biodiversity cartel. But the cartel is not the ultimate end; it is one of the means to the end of fair and equitable benefit sharing. Similarly, fair and equitable benefit sharing is one of the means to the ultimate end of conservation. Where does the Tracking and Monitoring the International Flow of Genetic Resources (TMOIFGR) fit into this cascade of means and ends?

TMOIFGR is a second-tier means to the end of a biodiversity cartel and is explicit in point 6 of the proposed Special Protocol. Table 3 allows comparison of TMOIFGR under the two systems: on the left-hand side is a summary of the highlights from a proposal based on the Bonn Guidelines; on the right-hand side, the implications of a Cartel.

Table 3. Tracking and monitoring of international flows of genetic resources

According to the Proposal by the European Community and based on the Bonn Guidelines*	According to the implications of a cartel legalized through a Special Protocol to the CBD
a) a mandatory requirement should be introduced to disclose the country of origin or source of genetic resources in patent applications	a) a mandatory requirement should be introduced to disclose the species of origin in patent applications
b) the requirement should apply to all international, regional and national patent applications at the earliest stage possible	b) the requirement should apply to all international, regional and national patent applications
c) the applicant should declare the country of origin or, if unknown, the source of the specific genetic resource to which the inventor has had physical access and which is still known to him	c) [NOTHING REQUIRED]
d) the invention must be *directly* based on the specific genetic resources [italics added for emphasis]	d) the invention must be based on genetic resources and/or traditional knowledge not in the public domain
e) there could also be a requirement on the applicant to declare the specific source of traditional knowledge associated with genetic resources, *if he is aware that the invention is directly based on such traditional knowledge*; in this context, a further in-depth discussion of the concept of 'traditional knowledge' is necessary.	e) the requirement that species be filtered against the indigenous databases to determine whether there are any "hits." In the affirmative case, the royalties will be shared according to the terms established in point 5 of the Special Protocol
f) if the patent applicant fails or refuses to declare the required information, and despite being given the opportunity to remedy that omission continues to do so, then the application should not be further processed	f) if the patent applicant fails or refuses to declare the required information, and despite being given the opportunity to remedy that omission continues to do so, then the application should be processed but the royalty rate trebles from 13% to 39% for the life of the IPR protection

According to the Proposal by the European Community and based on the Bonn Guidelines*	According to the implications of a cartel legalized through a Special Protocol to the CBD
g) if the information provided is incorrect or incomplete, effective, proportionate and dissuasive sanctions should be envisaged outside the field of patent law	g) if the information provided is incorrect or incomplete, effective, proportionate and dissuasive sanction is specified, e.g., trebling of the royalty rate for the life of the IPR protection
h) a simple notification procedure should be introduced to be followed by the patent offices every time they receive a declaration; it would be adequate to identify in particular the Clearing House Mechanism of the CBD as the central body to which the patent offices should send the available information.	h) Some mechanism [possibly the Clearing House Mechanism (CHM)] will maintain royalties in escrow until sufficient funds accumulate to cover the transaction costs involved in their disbursement. Should that threshold never be met over the patent life of the biotechnology, the mechanism will appropriate the royalty stream to defray the incremental fixed costs of managing the fund. It will also retain royalties for genetic resources which are endemic in any non-ratified CBD country until that country ratifies the Protocol.

*Directly quoted from Proposal by the European Community and its Member States for Disclosure of Origin or Source of Genetic Resources and Associated Traditional Knowledge in Patent Applications (16.12.2004).[13]

3.2.3 Principal-agent problems

One should expect resistance to the institutionalization of a biodiversity cartel. This expectation is based on a synthesis of transaction costs analysis and the theory of groups in formal economics (Olson 1965). It can be summarized in three steps:

1. agents inflict expenses on principals who are diffused,

2. the transaction costs of protest for any one principal is greater than his or her personal loss even though aggregate losses among principals exceed aggregate benefits to agents,

3. acting selfishly, principals hope that other principals, i.e., co-victims, pursue action against agents; inasmuch as redress will be a public in nature, the silent principals will be able to free-ride.

The principal could be a citizen or a shareholder and the agent, a manager or a politician. Applied to ABS, the principals in biotechnology ventures are the shareholders and the agents, the management. Despite the textbook wisdom "to diversify" one's financial portfolio, many shareholders invest disproportionately in biotechnologies because they understand that industry and are "in for the long-haul." Their exposure is not irrational given the principal-agent problems systemic to brokerage houses. The shareholders would rather risk a downturn in the sector they know than be defrauded by the advice given by a Merrill Lynch or Morgan Stanley for sectors they do not know. However, the concentration is only *inter*-industry; *intra*-industry, these same shareholders diversify according to the financial performance of each biotech firm. Unlike the shareholder, managers in biotech are in for the short-haul and are rewarded according to the expected profits of the firm. Because access to genetic resources consummated for a royalty of 1/2 of 1 percent is more profitable than a royalty of 15%, managers foment a price war among supplier countries. What is good for the management of one firm is disastrous for the industry when practiced by the management of all

[13] *See* http://www.wipo.int/tk/en/genetic/proposals/european_community.pdf#search='Disclosure%20of%20Origin%20or%20Source%20of%20Genetic%20Resources%20and%20Associated%20Traditional%20Knowledge%20in%20Patent%20Applications'

firms.[14] The resulting downward spiral in price erodes the long-term sustainability of genetic resources and associated traditional knowledge which, in turn, shrink the future possibilities of biotechnology and the expected value of the portfolio.

The unfolding story of Vioxx, a block-buster drug produced by Merck, Inc., is the most recent illustration of how agents (management) act against principals (shareholders) in the biotechnology sector. The story bodes ill for the Bonn Guidelines and I shall re-tell it through the lens of the principal-agent problem.

The marketing division of Merck recruits prestigious academic physicians to engage in medical education of any new product (Prakash 2005). Obviously, the agent is the academic physician, but who exactly is the principal? The principal is not Merck even though Merck foots the bill of the agent. The principal is the patient. The academic physician has simply been persuaded by the evidence of the efficacy and safety of the new drug and is engaged in medical education. What happens when the agent is no longer convinced of the efficacy/safety? Prof. Gurkirpal Singh of Stanford University found out. Exercising the Hippocratic Oath, he asked in a public forum "how many heart attacks, how many strokes, how many deaths were occurring in each one of the groups, and what were the actual number of patients at risk, and how many ended up having an event?"[15] The darling of Merck was quickly converted to its enemy. Dr Louis Sherwood, Medical Director at Merck, placed calls to Stanford accusing Singh of having made "wild and irresponsible public statements about the cardiovascular side effects of Vioxx."[16]

This statement was made on October 28, 2000 and the leverage applied was the US$29 million that Stanford receives as an annual research budget from Merck. Vioxx remained on the market until the fall of 2004; during that time, an expert at the FDA estimates that 38,000 people died because of the side effects.[17] Through the lens of the principal-agent problem, one would hypothesize that agents at Merck attempted to corrupt another agent and leave the principals, i.e., the shareholders, holding the bag of liabilities. Evidence that would not refute the hypothesis comes from both shareholder value and the personal decisions of the CEO. From a high of $91 in January 2000, Merck stock plummeted as low as $25 in the wake of the news; in advance of the nosedive, the CEO cashed out his stocks.

The lesson from Merck is simple. One cannot create any system that relies on trust. Yet trust is exactly what the Bonn Guidelines require. As long as companies can invoke the confidentiality of contracts, Material Transfer Agreements (MTAs) can be consummated with royalties that are fractions of one percent. Evidence of such tricks is common in Big Pharma. For example, to secure tax relief from the "American Jobs Creation Act" in October 2004, Big Pharma now attributes its profits to international sales – a most curious claim given that prices are substantially higher in the U.S. than overseas and more than 60% of sales are national (Berenson 2005). Unlike the Bonn Guidelines, a biodiversity cartel assumes no trust. Assiduous auditing of the royalties is the *sine qua non* of points 3 and 5 of the Special Protocol. One need only recall that Genentech, once a paragon of biotech entrepreneurship, was fined US$ 300 million for having failed to pay royalty payments to the City of Hope Medical Center (Pollack 2002).

It would be naïve to assume that the governments of the South have been the hapless victims of ruthless biotech management from the North. They have often engaged in aggressive rent-seeking behavior. The "timing of benefits" in the Bonn Guidelines encourages more of the same. It allows governments

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[14] Economists will recognize this as the fallacy of composition: what is true of a part is not necessarily true of the whole. Ecologists will recognize it as one of the many manifestations of the "tragedy of the commons," so vividly elaborated by Hardin (1968).

[15] Listen at http://www.npr.org/templates/story/story.php?storyId=4696609

[16] *Ibid.*

[17] *Ibid.*

to collect benefits now under the rubric of "up-front payments." Again, one sees the unctuous nature of Track I economics. Such payments are rationalized by Track I economists as the simple consequence of discounting future benefits! In contrast, economists using Track II logic will invoke *realpolitik*. The up-front payments are the inverse of a phenomenon well documented by political scientists: NIMTO (not in my term of office) - decisions made now that generate costs later. Because ABS implies benefits over time, not costs, NIMTO has morphed into SIMTO: solely in my term of office - the benefits from access now, the costs of conservation later. An extreme example of SIMTO behavior comes from Ecuador, which routinely appears in the top ten slots for most corrupt country by Transparency International. Gustavo Noboa, interim president (2000-2003) and currently a fugitive in the Dominican Republic, wanted to sell hundreds of millions of dollars in future contracts on oil exploration during the last weeks of his administration. The money now, the oil production later. Fortunately, the Ecuadorian Constitution foresees such chicanery and the judicial branch prevented it. Like those constitutional protections in Ecuador, the Biodiversity Cartel would prevent SIMTO and a related problem to which I have already alluded. In deference to the analytical power of political science, I shall call it FIMBY: first in my back yard.

FIMBY occurs whenever a country beats its neighbor in the race to the bottom of ABS. Just as SIMTO is the flip side of NIMTO; FIMBY is the flipside of NIMBY: not in my back yard. If agents in the competent authority can muster a PIC before counterparts do so in a neighboring country, then one of those multiple non-monetary benefits will come their way. It will take the form of a pet project administered by an NGO in which the agents have a conflict of interest. Most frustrating of all is the fact that many such projects are irrelevant for conservation. In order to save biodiversity, there is usually no need to do something. There is a desperate need for governments to do nothing. I refer specifically to road building. The opening of highways in the Amazon has been and continues to be the leading agent of deforestation (Wunder 2000; Laurence 2005). Few of these roads are privately funded and even when privately funded, they still need government authorization. Item 3 of the Special Protocol would discourage authorization for such road–building-cum-habitat-fragmentation. Royalty shares are calculated as a percentage of extant habitat and are paid over time; less habitat, lower future royalties over time.

3.3. The role of rhetoric in ABS policy making

3.3.1 The Group of Like-Minded Megadiverse Countries

Nothing in the previous sections involves novel economic logic. The fact that such logic was not reflected in the design of Article 15, augurs poorly for the institutionalization of a Special Protocol. The challenge for conservationists is to use rhetoric in a fashion that coincides with economic thinking. Particularly persuasive are tight analogies and an appeal for *quid pro quo* or universality. As already argued, the justification for an oligopoly over natural information and associated artificial information is the same justification that the biotech sector has used successfully for monopolies over artificial information. Unfortunately, stated as such will convince no-one! Few people outside the economic profession can define the word "oligopoly" and many will confuse it with "oligarchy." Likewise, "natural information" appears only in journals of molecular biology. In contrast, every one knows the meaning of a "cartel" and "biodiversity" also enjoys much currency in popular speech. Even for policy makers who pay lip service to economic theory, a "biodiversity cartel" is easier to communicate to law makers and their constituents than is an "oligopoly of natural information."

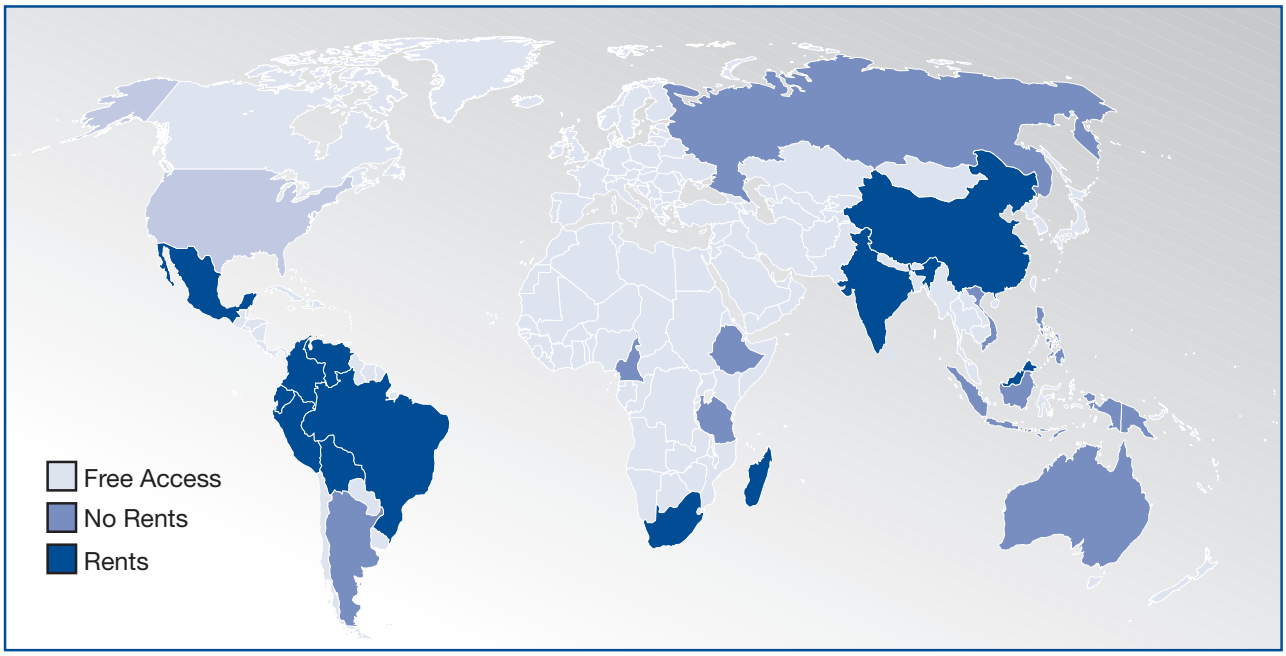
Despite the rhetorical advantages of a "biodiversity cartel," advocates must also recognize its disadvantages and confront them headlong. Biotech management will exploit the pejorative connotations of the "c" word, viz, gambling, drug trafficking, and prostitution. Perhaps in anticipation of such tactics, the biodiverse-rich countries opted for a synonym. China, Brazil, India and nine other nations met in Cancún, Mexico in February 2002 to form an alliance which would later be called the "Group of Like-Minded

Megadiverse Countries" (Stevenson 2002). Their numbers have expanded to 17 and the Group now constitutes a majority of the 25 most biodiverse countries (see Figure 1). Through the lens of economic theory, what the founding members of the Group launched was not an alliance but a cartel, as evidenced by the pursuit of rents tacit in the member's objectives:

> *(d) To explore jointly ways to interchange information and harmonize our respective national laws for the protection of biological diversity, including associated knowledge, as well as for access to genetic resources and the distribution of benefits derived from its use...*

> *(h) To drive the development of an international regime that promotes and effectively safeguards the just and equitable distribution of benefits from the use of biological diversity and its components. This regime should consider, inter alia, the following elements: the certification of the legal provenance of biological material, prior informed consent and mutually agreed terms for the transfer of genetic material as prerequisites for the application and issuance of patents, in strict adherence to the conditions of access granted by the countries of origin of this material.*[18]

Figure 1.



Note: The Group of Like-Minded Megadiverse Countries affords the possibility to capture rents (dark-shaded). The biodiverse countries which ratified the CBD but are not members of the Group (medium-shaded) can expect an elimination of rents through competitive bidding for common genetic resources. The biodiverse country that has not ratified the CBD has no expectation of rents and considers genetic resources "open access" (identification of biodiverse countries based on *World Atlas of Biodiversity*, UNEP/WCMC, 2002).

[18] Cancún Declaration, February 2002, http://www.unido.org/file-storage/download/?file_id=11803)

Inasmuch as a biodiversity cartel is grounded in the same economic theory that justifies monopoly IPRs, the Group of Like-Minded Megadiverse Countries erred greatly in choosing a name. Whereas "cartel" is provocative and means business, the word "group" is pusillanimous and suggests accommodation. Moreover, the word "cartel" invites frank talk. As Paul Krugman, a distinguished Professor of Economics at Princeton University and weekly columnist of The New York Times, points out "good economics is also good politics."[19] Just as Northern industry has persuaded governments through economic logic to respect monopoly IPRs despite the odious connotations of monopolies, those same governments should also be able to accept a biodiversity cartel as an analogous means for the efficient and equitable allocation of natural information. In September of 2002, the president of Venezuela, Hugo Chávez, became the first world leader to speak openly in favour of a "biodiversity cartel" (Doyle 2002). The venue was well chosen: The Earth Summit, Rio+10 in Johannesburg, South Africa. Since Rio+10, Mr Chávez has emerged as an international persona and Venezuela could assume a role in ABS reminiscent to its heady days in the 1960s when it launched OPEC.

3.3.2 ABS as a subterfuge for a campaign against the IPR system

The biodiversity cartel recognizes the desirability of intellectual property rights as a mechanism for efficient resource allocation. Many participants in the ABS debate do not. Logically consistent, these critics must also be critics of the biodiversity cartel and they indeed are. In a farcical ceremony at COPVII held in Malaysia, the NGO Erosion, Technology, and Concentration [(ETC) (formerly Rural Advancement Foundation Institute (RAFI)] derided the Group of Like-Minded Megadiverse Countries as a "biodiversity cartel" and named it "runner-up" for the 2004 Captain Cook Award.[20] Such protests against the IPR system are not just good theatre; reasons exist to oppose monopoly IPRs that are also grounded in good economics. A serious challenge begins with estimates of the "deadweight welfare loss" of any IPR monopoly. In the case of pharmaceuticals, one would also call into question the rationale for granting the monopoly, citing that annual budgets on marketing surpass those on R&D. An examination of that R&D also reveals product differentiation in "me-too" drugs (Angell 2004). To top off the economic case against pharmaceutical IPRs, competitive alternatives exist: governments could buy patents in open bidding and then throw them into the public domain for generic production (Kremer 1998). As worthy as is this debate, it is nevertheless a separate kettle of fish; indeed, a red herring for ABS. The CBD explicitly accepts the legitimacy of IPRs in Article 16(5). Critics of IPRs loudly denounce acts of biopiracy and have scored some notable successes (e.g., the cancellation of the Maya-ICBG project in 2001). To avoid being "RAFI'd,"[21] bioprospectors now dance, linguistically speaking: what they do is no longer "bioprospecting", but "biodiscovery" or even "biotrade."

The advocates of a Special Protocol would do well to concentrate on how language is framing the unfolding debate about ABS. Should the term "biopiracy" be associated with the cartel, then the advocates must insist that the critics be explicit regarding the implications of biopiracy. As emphasized, most definitions include a flat rejection of the monopoly IPR system. That rejection has several logical implications. First and foremost would be the free nature of the value-added. If one gives away the value added to a genetic resource, should one also have to compensate the country of origin for that resource? If no, then there still would exist a claim of biopiracy – taking from the poor to give to the rich. If yes, then how would one sustain compensation? The only answer is *bigger* government. However, both free access and *bigger* government go against the spirit and letter of the CBD. Framers of the Convention set out to

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19 Available online at http://query.nytimes.com/gst/abstract.html?res=F70611F6355C0C708DDDAF0894DD404482; http://www.truthout.org/docs_2005/printer_061305H.shtml

20 *See* http://www.captainhookawards.org/

21 McManis pointed this out at p. 460.

overturn the doctrine of "Common Heritage of Mankind" and garner private funds for conservation through sustainable use. So, an enigma emerges. Why is the public so receptive to claims of "biopiracy"? A plausible explanation is the fallacy of equivocation (McManis 2004). The public confuses "biopiracy" with what can more accurately be labeled "biofraud" and a host of other neologisms (see Box 2).

Box 2. Not quite synonymous: A BioLexicon of ABS

The northern dialect

- Biodiscovery: "the commercialization of native biological material or a product of biodiscovery research."[22]
- Bioprospecting: "The developing field wherein biologists, chemists, and other researchers are compiling a database of the commercial potential of many species."[23]
- BioTrade Initiative: "Its mission is to stimulate trade and investment in biological resources to further sustainable development in line with the three objectives of the Convention on Biological Diversity...conservation of biological diversity; sustainable use of the components; and fair and equitable sharing of the benefits arising from the utilization of genetic resources."[24]

The southern dialect

- Biofraud: "The contracting of biodiversity and/or traditional knowledge without having paid an agreed economic rent to all who could have supplied the same input."[25]
- Biopiracy: "The appropriation of the knowledge and genetic resources of farming and indigenous communities by individuals or institutions seeking exclusive monopoly control (usually patents or plant breeders' rights) over these resources and knowledge."[26]

Neologisms in the light of economics

- Biobetrayal: Northern conservationist NGOs promoting Material Transfer Agreements (MTAs); Southern competent national authorities signing off on those MTAs.
- Biograb: Identification of a vulnerable country or a community, which will grant prior informed consent to access its genetic resources or traditional knowledge.
- Biolooting: Unlimited access to the genetic resources of a country or the traditional knowledge of a community through a comprehensive MTA.
- Bioridiculous: The typical royalty of 0.5% (one half of one percent) on net revenue.
- Biospeak: Calling genetic information, access; calling the price of that information, benefits; and calling the sale "access and benefit sharing."

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22 *See* www.aar.com.au; http://www.legislation.qld.gov.au/LEGISLTN/CURRENT/B/BiodiscovA04.pdf#search='Definition%20of%20Biodiscovery' at p. 70.

23 *See* www.environment.jbpub.com or http://en.wikipedia.org/wiki/Bioprospecting

24 *See* http://www.biotrade.org/QuickPlace/biotrade/Main.nsf/h_B4BD9585D70EA32CC1256C0000352A94/8CE3DC12F9D60922C1256C0000352C55/?OpenDocument

25 Vogel, J. (ed.) 2000, at p. 125 in Spanish text; English version online at www.thebiodiversitycartel.com

26 RAFI (Rural Advancement Foundation International). 1995. Conserving Indigenous Knowledge: Integrating Two Systems of Innovation. Independent study to the United Nations Development Programme. Ottawa: RAFI.

3.3.3 Choosing the right metaphor: Is the U.S. a haven for biopirates? or is it gene-dumping?

As we have seen from the application of economic theory, the non-ratification of the CBD by the U.S. poses a monumental threat to benefit sharing for the countries that have ratified the CBD. Further aggravating that threat is the biogeography of the U.S. The habitat of many species in the U.S. extends outside U.S. jurisdiction: Hawaii, Guam, and Samoa (ecosystems similar to those found in the jurisdictions of South Pacific Island nations), Alaska (Canada and Russia), Puerto Rico (Latin American nations), *ex-situ* genebanks, botanical and zoological gardens, and possibly even U.S. embassy grounds. A comparative advantage has emerged for the U.S. in bioprospecting simply for not having ratified the CBD. This became apparent shortly after the CBD entered into force in December of 1993. The chairman of Bayer AG expressed diplomatically the rationale for the relocations of laboratories: "North America [U.S.] has not replaced Germany as a location for business, but there are certain innovative activities which are best performed in the U.S."[27] While foreign firms were coming to America to test their genetically modified organisms (GMOs), American firms, using the same logic, were staying home to bioprospect.[28] One could say that the US had become a haven for biopirates.

The metaphor "haven for biopirates" is provocative and provocation is a good thing for public debate. Unfortunately, the metaphor extends the contradictions inherent to the word "biopiracy" and contradiction is a bad thing for public policy. What is an alternative metaphor that better captures the implications of the U.S. not having ratified the CBD? An economist might suggest "gene-dumping" and point out that the free access to the genetic resources of the U.S. is in the context of significant opportunity costs for habitat protection. For example, under the 1968 Endangered Species Act, the red-cockaded woodpecker (Picoides borealis) has frustrated much development in piney woods of the southeastern U.S.; the happy re-discovery of the ivory-billed woodpecker (Campephitus principalis) in 2005 will constrain it even more.[29] To the extent other countries do not afford similar protection to endangered species, the U.S. can be said to be dumping its genetic resources on world biotechnology markets and frustrating ABS as a source of economic rents for conservation overseas.

What can be done? The metaphor we choose will bias the recommendations we advocate. When one chooses "gene-dumping," a policy implication emerges straight out of GATT: "...the imposition of a duty. The countervailing duty is essentially a tariff designed to 'counter' the effects of the foreign export subsidy."[30] The GATT definition of "export subsidy" applies whenever the patented biotechnologies are sold more cheaply overseas than in the U.S., thereby complementing and strengthening the rationale for item number 7 in the proposed Special Protocol.

3.3.4 A case study: Reporting ABS sans economic theory

The Bonn Guidelines are *prima facie* evidence that economists do not have the ear of policy-makers. Advocates of a cartel should not despair. Instead, they should take their message to the public. The best venue is the mass media of high status. But even there, one cannot escape the problem of transaction costs; applying economic theory is work and journalists may fear that the very language of economics will turn off editors and readers alike. Fortunately, as we have seen, the economics needed to make sense of ABS is not *that* difficult and corresponds to what is covered in an introductory college course. Given the fact that tens of millions of people around the world have formally studied economics, and a good number are concerned with conservation, the potential readership is huge and potentially influential. One could even say that

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27 *See* Nash at D5.

28 *See* RAFI at 5.

29 *See* Fitzpatrick J, M. Lammertink, M. Luneau, Jr., T. Gallagher, B. Harrison, G. Sparling, K. Rosenberg, R. Rohrbaugh, E. Swarthout, P. Wrege, S. Barker Swarthout, M. Dantzker, R. Charif, T. Barksdale, J. Remsen, Jr., S. Simon and D. Zollner, 2005. "Ivory-billed Woodpecker (Campephilus principalis) Persists in Continental North America". Science 308(5727). 3 June 2005. 1460-1462.

30 Available at http://www.sidsnet.org/francais/latestarc/trade-newswire/frm00316.html

the serious journalist has little choice but to report ABS in the light of economics. Once the logic of a biodiversity cartel becomes apparent in the mass media, agents will begin to feel pressure to act in the interests of the principals.

Nothing persuades like a well-chosen example. So, I have combed through the news media to find an article that epitomizes both the problem of reporting bioprospecting *sans* economics as well as the opportunity of making whole the sundry facts presented. I have found a fairly comprehensive story (2090 words) which appeared on the front page of the Science Times Section of the May 7, 2002 edition of *The New York Times* (NYT), approximately one month after the sixth Conference of the Parties to the Convention on Biological Diversity (COPVI). The author is Andrew Revkin who has won accolades in journalism for going the extra mile to get the story right – quite literally in the case of *The Burning Season* (Revkin 1990). Despite Revkin's scientific background and journalistic skill, there is no economic reasoning in "Biologists Sought a Treaty; Now They Fault It." This should not surprise us. The sheer volume of Revkin's productivity (some 829 bylines in the NYT since 1996) may preclude the downtime necessary for making economic sense of bioprospecting. Moreover, the work in organizing the story in the light of economics is intrinsically different than that of tracking down facts and tying them up into crisp prose. An economic interpretation requires that the journalist tease out causes and effects and then display the chutzpah to voice unwelcome implications. The result will be a story that will not sit well with many of the sources of the sundry facts. Inasmuch as Revkin has not done this, an opportunity arises to unify and connect the hitherto unrelated facts.

Because many newspaper readers never get beyond the title of an article, analysis should begin there. Irony carries a certain *cachet* and Revkin sets the tone with "Biologists Sought a Treaty; Now They Fault It." Pity that that title misrepresents the sequence of events that culminated in the CBD. The text of the CBD was the product of arduous negotiations that took place in the late 1980s and early 90s under the auspices of UNEP in Nairobi, Kenya. The representatives from the North and South were so divided that they never settled their differences; instead they immortalized them in a wishy-washy language that was faxed out of Africa just hours before the inauguration of The Earth Summit in Rio de Janeiro, in June 1992. Revkin's article could have just as ironically, and much more accurately, been entitled "Critics of the Convention on Biological Diversity Foresaw Failure from the Outset."

Even when readers are drawn by the title, most will probably not get beyond the first 100 words. This is unfortunate as the misconstrued irony in "Biologists Sought a Treaty; Now They Fault It" is quickly compounded: "...biologists say, in many tropical regions it is easier to cut a forest than to study it."[31] That salvo is immediately supported by a quote from Dr Douglas C. Daly, curator at the New York Botanical Gardens: "Something that was well intentioned and needed has been taken to an illogical extreme." Revkin then builds the story to elucidate Daly's thesis, showing how nationalist groups have become so obsessed with biopiracy that they are running scientists not only out of countries but out of their own fields of study. "Christiane Ehringhaus, a German botatist pursuing a doctorate at Yale, was teaching Brazilian students and studying plants in the state of Acre in the Brazilian Amazon when newspapers implied that she was collecting seeds and insights from indigenous people in pursuit of drugs... the resulting difficulties had prompted her to abandon botany altogether..."[32]

With a modicum of economic theory and the chutzpah to expose the vested interests in bioprospecting, Revkin could have integrated the sundry facts into a more comprehensible whole. Let's return to that opening statement about the relative ease of cutting the trees versus the difficulty in studying them and then move on to Christiane Ehringhaus. The essential fact needed to resolve the paradox is the non-

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[31] Revkin 2002 at p. 2.

[32] *Ibid.*

ratification of the CBD by the U.S. Revkin missed the significance of that fact: genetic resources that wind up in the U.S., by hook or by crook, are the property of no one and, hence, fair game for R&D. Any biologist who comes to study the environment may inadvertently or advertently facilitate "biopiracy." Regarding the disheartened Christiane, Revkin quotes her as saying: "First...they drove me completely away from medicinal plants and now from plants, period." Had Revkin thought like an economist, Christiane's comment would have raised a red flag. Any botanist researching medicinal plants is there to throw such knowledge into the public domain through publication, thereby disenfranchising both the country of origin and the traditional peoples. Should the published traditional knowledge provide a lead for R&D, then the resultant biotechnology will enjoy a monopoly patent both in the U.S. and, under TRIPS, the country of origin. What Revkin portrays as irrational xenophobia – the exclusion of foreigners from collecting medicinal plants in Brazil – is economically quite sensible. Inasmuch as there has also been gene-culture co-evolution between ancestral peoples and their environment, the exclusion of all plants makes similar economic sense.

Nowhere in the article does Revkin broach the topic of royalties. The omission constitutes a conspicuous absence of economic thinking. Had he cast the story in the light of economics, the magnitude of royalties would have taken central stage. From there, follow-up stories could have emerged regarding the rationale of a biodiversity cartel and its role in the overarching goal of conservation.

3.4 Conclusion: On being (not just thinking) outside the box

Selim Louafi and Brendin Tobin recommend that "[t]he development and implementation of an efficient system of ABS governance requires one to look beyond the law.., in the direction of the network of actors and institutions on which implementation will depend."[33] In a similar vein, Tomme Young has implored policy makers to "think outside the box"[34] with respect to ABS. This chapter suggests that the box which confines our thought is national sovereignty over genetic resources. Thinking in that box has led to flawed solutions like the Bonn Guidelines and, not surprisingly, to calls to think outside the box. Outside that box is the biodiversity cartel which sounds radical but is really a rather conservative proposal, grounded in the same economic theory that justifies monopoly intellectual property rights.

Louafi and Tobin are correct: a network of actors and institutions does exist. However, they are wrong to assume that the network is acting in good faith in the design of ABS. That network will exclude anyone who thinks outside the box. The Vioxx story is a grim reminder of what will happen to any agent who bucks the corporate system of subservience to more powerful agents. Unfortunately, Merck is not a "bad apple" nor is the medical faculty at Stanford the only victim of the principal-agent problem. Across the San Francisco Bay, Prof. Ignacio Chapela was denied tenure because he had the audacity to publish in Nature his findings of transgenic pollution, thereby risking corporate grants at UC-Berkeley (Quist 2001; Chapela 2001). Can any non-tenured professor analyze the MTAs so coveted by industry? Complementary to an intimidated faculty is a cowed news media. Can any journalist make sense of the sordid facts of bioprospecting if his newspaper draws income from the source of those facts?

To think outside the box, we must live outside the box. Fortunately, academic freedom and a free press have not yet become the transaction costs of a biodiversity cartel. Nevertheless, both could use a bit of help (Cary 1999). It is not enough that the facts, opinions, and analysis of ABS float in cyberspace or appear in printed anthologies like this one. They also need a physical space where people can discover how ABS integrates with the international IPR system and how that system is impacting their material welfare.

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[33] Louafi and Tobin at p. 2.

[34] Young at p. 289.

Because the issues involved can raise passions, apathy is not the problem. Ignorance is. To understand more easily how economic theory applies to ABS and IPRs, the public should be given a range of stimuli. For example, many citizens would be intrigued by the hallucinogenic properties of *Banisteriopsis caapi* and its role in indigenous cultures in the Amazon. They should able to touch specimens of the thick and twisted vine and, through video clips, see how shamans administer *B. caapi* in diverse religious ceremonies that induce altered states of consciousness. Integrated into such a display could be a chronology about how the plant patent was discovered only years after it was filed. The ensuing international uproar translated into a legal challenge which was also a flamboyant affair. The trajectory of *B. caapi* affords many counterintuitive lessons about the IPR system (McManis 2004); primary among them is that the CBD rewards prior acts of biopiracy (Alarcon and Morales 2000). B. caapi is not an anecdote. No less dramatic an example is the endangered poison dart frog *Epipedobates tricolor.* Thumbnail-size specimens were spirited out of Ecuador in the 1970s and, according to rumors, in a U.S. diplomatic pouch to avoid CITES. A toxin in the skin of *E. tricolor* was isolated and used in the R&D of an analgesic (ABT-594) that is orders of magnitude stronger than the morphine family *but* non-addictive. In homage to the frog, the patent-holder, Abbott Laboratories, named the principal agent "epibatidine." Under the Bonn Guidelines, no country of origin stands to gain anything for *B. caapi* or *E. tricolor*; however, under a Special Protocol, a 15% royalty could still be negotiated and divided among countries of origin according to their respective share of the habitat. The storyline behind *B. caapi* and *E. tricolor* is not unique (Delgado 2002) and every region in the world probably has a similar experience. Because the biodiversity cartel is unabashedly a top-down approach, citizens must "think locally and act globally." What is needed most is *engagement*.

I close with this suggestion: advocates of "fair and equitable benefit sharing" should schmooze a philanthropist or a government to build a museum dedicated to the controversy of bioprospecting, intellectual property rights, and the public domain – no strings attached – and let the exhibits travel.

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4 Challenges Ahead: Legal and Practical Prerequisites for the Development of a Certificate of Source, Origin or Legal Provenance for the CBD

Tomme Rosanne Young[1]

Executive summary

Discussions regarding the role, nature and features of a certificate of source, origin or legal provenance (CSOLP), in the context of the Convention on Biological Diversity (CBD) and other international forums (including the World Intellectual Property Organization and the World Trade Organization) have intensified over the last few years.

A degree of consensus exists in relation to the fact that one of the areas (if not the most important area) where less progress has been made is in compliance, enforcement and oversight as part of the overall access to genetic resources and benefit-sharing regime (ABS). This has been linked to a traditional distinction made between users and providers of genetic resources and their different responsibilities with regard to ensuring benefits derived from the use of genetic resources are equitably shared.

And although some research has been undertaken and recommendations have been made as to how to make best use of the CSOLP (proof of compliance with ABS legislation; tracking of resources; verifying uses under national jurisdiction), these have not always been based on well founded data and analysis, and so there are still fundamental questions to address especially with regard to the specific purpose and objective a CSOLP would have and its overall implications.

This chapter offers a detailed analysis of the rationale and justification behind a CSOLP regime and addresses fundamental questions regarding its objectives, advantages and disadvantages and practicalities it will have to consider in order to become operational. It also analyzes the situation of similar certificate-based regimes (property, car licenses, etc.) in order to understand why these are functional and serve a purpose. Based on this, it is argued that to date, most CSOLP proposals seem to rely on a certification of authenticity or product certification scheme which may not be the ideal approach in the context of international genetic resources exchange. The chapter also argues that to create an appropriate incentive for a user of the CSOLP, the challenge lies in tying the CSOLP to clear commercial benefits. The incentives to use a CSOLP should be of such nature, that the CSOLP becomes an unavoidable option for users. To date in any case, given the existing problems of identifying and proving cases of misappropriation of genetic resources or non-compliance with ABS legislation, proponents of the CSOLP seem to be focusing on achieving more ideal objectives (or objectives which are mostly based on anecdotal evidence) rather than linking it to disincentives generated by the deterrent effect caused by (non-existent) ABS-derived sanction regimes (at the national or international levels).

[1] At the time of writing this chapter: the author is the Senior Legal Officer of IUCN and the Series Editor for the ABS Series, in which this book is included. Prior to her current position, she worked in over 35 countries as a legislative draftsman addressing environmental and conservation laws, and the legal means for ensuring their effective implementation. She came to that work from an earlier life in the private practice of commercial law, corporate finance, and industrial law, and believes that the intersection of environmental and commercial specializations is essential to the achievement of conservation objectives. This essay represents some of the results of several months of the author's focused legal and factual research into ABS implementation, supported by more than ten years of in-depth research into the policy, legal and practical implementation of ABS and the obstacles that have interfered with its effectiveness. It does not necessarily represent the views or positions of IUCN or any of the sponsoring organizations that have contributed funding to this series.

At base, all legal, regulatory, and market systems operate through a combination of four factors - objectives, rules, compliance mechanisms, and enforcement/oversight. In developing an international system of ABS, each of these factors presents a matrix of legal and practical challenges. The last element (enforcement/oversight), however, is currently viewed as both the most difficult and the most important. Until a set of strong and durable incentives can be created (to encourage users to seek ABS agreements and to value their reputation for compliance with them), the most important issues to address will be those relating to finding and addressing instances in which genetic resources are used without permission.

Up to now, although several mechanisms have been sketched out as possible means for compelling ABS compliance,[2] all of them depend on the ability to know when genetic resources have been accessed and used, and whether benefits have arisen. As noted below, however, this determination is very difficult to make, both practically and legally. As a practical matter, however, there are significant difficulties in identifying uses of genetic resources, and even in knowing when such resources have been accessed. From a legal perspective, it is very difficult to find an "objective standard" that can be used to clarify the difference between a legal collection of biological specimens, and the unauthorized access to the specimen's genetic resources.

For the present, it is essential to develop some kind of mechanism to enable this kind of oversight. This objective has evolved into the quest to develop a certificate of source, origin or legal provenance (CSOLP). The exact nature of this tool, however, has still not been agreed as yet, nor have detailed practical proposals regarding the contents and mechanisms of the CSOLP been outlined. This chapter examines the challenges of the CSOLP in the ABS regime, considering its role in ABS processes, as well as some specific questions of contents, harmonization, and enforcement/implementation. While it raises problems and concerns, this chapter's intent is to promote the development of the tool, and to maximize its "value added" in the international ABS regime.

4.1 The challenges posed by a CSOLP

For purposes of this chapter, there are two kinds of challenge to be described – the first are the design challenges (the expected role and purpose of the CSOLP), and the second are the practical challenges (on-the-ground issues of how a CSOLP will function effectively).

4.1.1 The "design" challenge: Expectations relating to the CSOLP

There are several primary theoretical questions that must be answered at the outset, before any serious effort can be made to design a CSOLP and formally introduce it into ABS markets and practices. In essence, it is critical to determine first, what role the CSOLP will play in the implementation of ABS, and second, how this specific object can be supported by a certification/registration (CSOLP) mechanism.

Before beginning this inquiry, it is important to raise an even more basic question - the purpose and scope of ABS itself.[3] One of the most difficult problems underlying efforts to create and implement ABS is the lack of motivation for the primary actors. Of all the specific groups directly involved in ABS:

- provider countries and communities;

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2 Discussed in UNEP/CBD/ABS/3/7.

3 As of this writing, the scope of the international ABS regime appears to be entirely open for negotiation (*see* Report of the Ad Hoc Open-Ended Working Group on Access and Benefit Sharing on the Work of its Fourth Meeting, UNEP/CBD/COP/8/6, 15 February 2006; and CBD COP Decision VIII-4 (Kuala Lumpur). While it is hoped that some direction for the negotiations will be forthcoming soon, this chapter is written with the intent that its contents will be useful in designing the CSOLP for international purposes, and in adapting it for use in each country as they adopt legislation under the new regime as eventually developed.

- user countries (countries with jurisdiction over entities using genetic resources); and

- the users themselves (collectors of genetic resources for scientific purposes, researchers, and developers of products utilizing these resources);

only one group (provider countries) is strongly motivated in favor of the development of a functional ABS regime.[4] For both user countries and users, compliance with ABS requirements can be costly and difficult, even when those requirements are legally unambiguous and operationally feasible. For many users, in fact, compliance can actually increase the possibility that they will be the target of negative publicity, lawsuits and other claims of "biopiracy."[5] Thus some users feel that the current ABS systems actually punish companies that comply. At the same time, non-compliant companies may be untouched, owing to the technical inability of provider countries and NGOs to detect use of GR, and their legal inability to know what is happening in private laboratories and factories, especially when those facilities operate in another country – beyond the jurisdiction of the source country.

Hence, while a voluntary CSOLP may be made possible by providing incentives for ABS-compliant companies to obtain certificates, the larger question is "what motivates companies to comply with ABS in the first place?" It is appropriate throughout this chapter and this book to keep this question in mind, and to consider how a CSOLP can be part of a larger commercial incentive for ABS itself – an incentive that is sufficiently strong that it can outweigh both the costs and publicity risks of ABS compliance.

4.1.1.1 Role of CSOLP in the ABS regime – needs to be addressed

The single most important question about the CSOLP is one that has not been comprehensively examined, including the primary question: *What heretofore unaddressed systemic purpose will be served by the certificate?* Generally, the certificate is spoken of as a tool to provide documentation of ABS compliance and/or a listing of persons who have "accessed" certain genetic resources. Before considering the practical challenge (how this system can work), it is important to ask why such documentation is needed. In answer to this, three justifications are usually given for the CSOLP:

- to provide the user with simple and positive proof that he has met the ABS requirements of the source country, which he can show when questioned about compliance;

- to provide the source country with a way to track the movement and use of genetic resources; and

- to provide a basis for informing the user country regarding genetic resource uses that are ongoing under its jurisdiction.[6]

In addressing these, there are two factors to consider – how a certificate system can accomplish these objectives, and what benefit will be obtained when they are fulfilled.

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[4] Although not further discussed in this essay, this fact suggests that the basic premise of this essay – the need for incentives and motivations for user compliance with ABS regimes – is also applicable at the "meta" level, where there is a need to integrate incentives and motivations into the international regime that will encourage and induce user countries to comply with their obligations to adopt measures with the aim of sharing the benefits from the utilization of genetic resources, as called for in Article 15.7 of the CBD. This issue is further examined in another book in this Series, Tvedt, M.W. and T. Young, *Beyond Access: Exploring Implementation of the Fair and Equitable Sharing Commitment in the CBD* (IUCN, ABS Series.)

[5] *See* IUCN Canada, "Analysis of Claims of 'Unauthorised Access and Misappropriation of Genetic Resources and Associated Traditional Knowledge'", (Information Paper in the 4th Meeting of the Ad-hoc Working Group on ABS, UNEP/CBD/WG-ABS/4/INF/6; a later version of which will be reprinted in Book 5 of this Series.)

[6] A great many objectives have been cited for the CSOLP, including (i) to promote the ABS objectives of the CBD; (ii) to secure recognition of sovereign rights over genetic resources; (iii) to empower indigenous and local communities; (iv) to facilitate continuing open flow of resources; (v) to reduce the need for strict ABS laws; and (vi) to reduce pressure for development of a sui generis regime for TK. (Reports and Presentations, especially presentation of B. Tobin and I. Calle, "Taller Sobre Certificados de Origen y CITES" (IUCN, INRENA, INE, SPDA – Lima, Nov. 2003) to be posted at www.iucn.org/themes/law/abs01 (site under reconstruction at time of writing)). Of these, only the three mentioned in the text appear to be directly affected/affectable through the use and recognition of a CSOLP.

[a.] Simplification of documentation for the user

The simplification of documentation can be very important, where clear uses of that documentation exist. As everyone knows who has ever applied for social security benefits, the collection of relevant documentation in forms that are officially recognized by a government agency can be extremely difficult. In order for standard certificates and registries to be useful, their processes must be rigorously overseen so that information collected is *exactly* comparable across all forms.

It can be even more difficult to obtain documentation of compliance with a permit once it is obtained. In most cases, unless the law clearly authorizes the government to confirm compliance, it is almost impossible to get such official confirmation. Consider for example, the environmental licensing of industrial facilities. A facility must usually get a permit to discharge "process water" into a river, or even onto land (where it will seep into groundwater). That permit will contain certain conditions regarding the treatment of water before discharge. Thereafter, the holder of a permit may wish to sell the facility, and may seek a statement from government that his facility is in compliance with the conditions of his water discharge permit. Such a statement may be almost impossible to obtain, since government officials fear that such a statement could prevent them from demanding compliance if a problem is later discovered. Even when the facility meets all relevant standards, it is difficult (and sometimes impossible) to obtain documentation, signed by an appropriate official, proving this fact.[7]

Where documentation requirements exist, they may vary greatly, even within the same country. If two different agencies (or two different units within a single agency) both require documentation of an event, it is possible that each will focus on a different aspect of that event, each requiring a different kind of documentation. For this reason, most standard documentation systems are developed after the laws requiring documentation are already in place – to ease the burden of both applicant and agency, by ensuring that the standard document is appropriate for all relevant uses.

The current CSOLP proposals are innovative in their attempt to develop the documentation before the reporting requirement is developed, and even before the system in which it will be used is outlined. The assumption is that a CSOLP will be created by international negotiation, in a way that will satisfy all relevant needs that may arise in the future, including those that are included in the results of the international negotiations, those that are developed or applied at regional or national levels, those that are required by "biodiversity cartels,"[8] and those required under national legislation of the user and provider countries.

Assuming that they are able to devise a certificate to fulfill all of these needs, the first objective (simplification of the ABS project for the user) will be accomplished only where the CSOLP

- is official;[9]
- is issued based on clear legal authority of the issuing agency;[10] and

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7 In some countries, buyers and sellers are now called upon to consider actions and conditions that may have happened in the past. For example, in the U.S., the owner of property that has been contaminated by unpermitted discharges of hazardous waste must pay the price of cleaning up that waste, even if he did not place it there, and did not know about it when he purchased the property. UNITED STATES Comprehensive Response Compensation and Liability Act, 42 United States Code 9501 *et seq.* A consequence of this liability is that buyers seek assurance that the property has operated in compliance with its environmental permits – a statement that virtually no government official would be willing to make, because it exceeds his authority and might make him or the agency liable, if contamination is later found on site.

8 Discussed in Chapter 3 of this book.

9 The need to have evidence of official decision-making is the most critical evidentiary requirement in most permit systems. In a recent innovation, the Cartagena Protocol on Biosafety proposes the use of the web-based Biosafety Clearing-house (BCH) as a method for satisfying this need. Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Nairobi, 2000), Article 20 and elsewhere.

10 Unfortunately, even where general authority is specified in statutes, the issuance of permits to use national or sovereign resources is often challenged under claims that the issuing agency's authority did not extend to the matters covered by the permit. (These matters are discussed in two forthcoming INF documents (one to be submitted at AHWG-ABS 4, and the other at CBD COP-8) setting forth the results of detailed research into the issue of "unauthorised use of genetic resources" in the CBD system. Both are being written by the author of this essay and will be submitted by IUCN Canada and the CBD Secretariat. Examples and statistics supporting this statement will be provided therein.)

- releases the user from liability, so long as the certificate was valid (non-counterfeit) and provided by the statutorily authorized agency.

The first two factors can be found where the issuer country's legislation provides a clear objective standard guiding the issuing agency regarding the conditions that must exist in order to issue a certificate. Each country must specify a "checklist" of the objective factors that must be met by an applicant, to qualify for a certificate. The checklist regularizes the process and, to some extent, protects the government official who issues the certificate.[11] Of course, the standard also ensures that certificates are only issued when the necessary conditions have all been met. As long as such legislation is complete, and in place, the issuer can give an official certificate, for whatever purposes are described in the law. It will be important, however, to specify those purposes, to avoid the abuse of ABS certificates.

The third factor is both the most important and the most difficult. Users frequently complain that due to the uncertainties of national ABS negotiation and permit systems, they do not have a commercially acceptable level of certainty about their rights, even after the ABS arrangement has been signed. The primary source of this lack of "user certainty" is the fact that formally signed ABS arrangements can later be challenged, under a variety of theories, such as insufficient PIC and MAT compliance, as well as equity and traditional knowledge.[12] While the goal of promoting user certainty must be reviewed in context, the fact remains that users are frequently dissuaded from attempting to obtain ABS permission by the fear that such permission will later be challenged or rescinded. Such challenges may be against either the user directly or the national agency. Depending on its specified scope and purposes, a CSOLP may partially insulate the user against such claims.

[b.] Tracking the movement and use of genetic resources

Concerning the second reason cited for creating a CSOLP system (facilitating tracking by source countries), it is less clear how the CSOLP can achieve this. The practical concerns about tracking are dealt with in Part 4.1.2 of this chapter. From a design standpoint, however, the critical question is whether and how a certificate will add value to the ABS system. Existing ABS arrangements typically include provisions calling on the user to notify the provider country in the event of a transfer of the genetic resources/rights to any other person or individual.[13] As presently envisioned, the CSOLP will be part of the ABS negotiation requirements (i.e. the CSOLP is not a tool for locating users who are not voluntarily participating in ABS negotiations). In essence, this provision will be a second requirement imposed on those who voluntarily comply with source country ABS legislation. There is no indication of any element of this provision that would force or encourage persons who are not complying with the general ABS provisions to obtain a certificate. Arguably, then, the certificate will obtain data which the source country would already know.

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[11] A recent study notes that the majority of claims against users of genetic resources or traditional knowledge have been brought by NGOs, indigenous groups and other non-governmental groups. IUCN Canada, cited in footnote 5. If the certificate or other government approval insulates the user from such claims, there remains a possibility that the claimants will turn their wrath against the official or agency granting the certificate.

[12] One of the most common explanations for the failure of ABS comes from the industrial and research communities, which have strongly stated that the primary impediment to ABS function is the complexity of national regulation, which increases the transaction costs and engenders a lack of legal certainty for users regarding the value of the ABS arrangements, once granted. Recognized by many experts, and adopted into key provisions of the Bonn Guidelines, these claims do not always stand up to scrutiny. *See*, Cabrera, J., *A Comparative Analysis on the Legislation and Practices on Access to Genetic Resources and Benefit Sharing (ABS): Critical Aspects for Implementation and Interpretation (IUCN/BMZ, 2004); and Young, T., Summary Analysis: Legal Certainty for Users of Genetic Resources under Existing Access and Benefit-sharing (ABS) Legislation and Policy,* published as UNEP/CBD/ABS/3/INF/10 (3rd Ad-hoc Working Group on ABS, Bangkok, 2005). As a practical matter, national ABS measures cannot give absolute or near-absolute certainty to users because governments have sovereign and fiduciary obligations to protect their rights and interests and those of their citizens.

[13] As discussed in Book 5 of this Series, a database of contracts for genetic resource use, or other sophisticated use or patenting of biological and agricultural resources and products, is being developed through the World Intellectual Property Organization. When available, it will enable comparisons among a variety of different existing contracts and approaches. In draft form, it and some instruments contributed to it, form the basis of this statement.

This third objective (increasing user countries' knowledge about the use of their genetic resources) suggests a particular challenge for the CSOLP – to link the certificate requirement to some kind of incentive that will encourage all users of genetic resources (even those who do not know about, or do not bother with, the more general ABS requirements of the user country) to obtain certificates. As discussed below, through such an incentive, the CSOLP could become a major force in the implementation of the international ABS regime.

[c.] Informing the source country regarding ongoing GR uses

The single most significant obstacle to the goal of a functional ABS regime has been the fact that user countries (the only legal entities capable of regulating users after the genetic resources leave the source country) have not generally adopted any of the measures required under Article 15 (and elsewhere in the convention) relating to regulation of users. ABS obligations have been largely ignored by "user countries," which have mostly not attempted to:

> *take legislative, administrative or policy measures ... with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources*[14]

and

> *take legislative, administrative or policy measures ... with the aim that ... developing countries, which provide genetic resources, are provided access to and transfer of technology which makes use of those resources ... including technology protected by patents and other intellectual property rights.*[15]

Currently, the positions of many developed countries[16] continue to be based on the presumption that because the ABS system focuses on contractual documents, there is no need for legislative measures at all to meet the first requirement quoted above, and that the second above-quoted requirement is subsumed by the first. Consequently, as further discussed in the second book in this series, countries with "users of genetic resources of other countries" under their jurisdiction have generally not adopted legislation to require or encourage such users to comply with benefit-sharing obligations, nor legislation enabling or facilitating oversight by or on behalf of providers. While a few have proposed "voluntary disclosure of source/origin" of genetic resources in patent applications, those proposals (and other discussion of "mandatory disclosure of source/origin") do not include any ability to use the disclosure as a basis of an action to compel the companies to share benefits, nor do they provide the necessary legal basis that would enable the country's courts to develop a consistent body of decisions regarding the meaning and interpretation of basic concepts in ABS contracts – concepts which do not exist in any country's national law or case law.[17]

The few countries that have stepped up to consider and develop actual "user measures" (aimed at enabling/promoting benefit sharing), have focused on the concept of patent law, and the possibility of including a "voluntary disclosure of origin" within the national and international regime governing recognition of intellectual property rights. The "user measures" required in the CBD, however, are based on objectives that extend well beyond disclosure-of-origin in patent applications (the primary user measure taken and proposed by user countries to date).[18] While some of

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14 CBD, Article 15.7.

15 CBD, Article 16.3.

16 Although not all developed countries have provided publicly accessible statements reflecting their position, a few have. *See*, e.g., Oxley, A. and B. Bowen, undated (pamphlet circulated at CBD COP-8, 2006), "Developing an Effective International Regime for Access and Benefit Sharing for Genetic Resources Using Market-based Instruments." Australian APEC Study Centre, Monash University.

17 The 4th book in this Series: Shakeel Bhatti, *et al., Contracting for ABS: The Legal and Scientific Implications of Bioprospecting Contracts* is generally focused on this point.

18 For a particularly well-focused examination of these issues, *see* Tvedt, M.W. *Intellectual Property Right Law in the Context of Bioprospecting and Genetic Resources.* Proceedings from the Norway-United Nations Conference on Technology Transfer and Capacity Building, Trondheim, FNI 2003.

the needs relate to direct legislative requirements, as mentioned above, others could be aimed at enabling developing countries to take action in legal systems that are expensive and technically inaccessible from their perspectives. For example, in order to meet the spirit of Article 15.7, user country legislation may need to consider practical concerns that prevent developing countries from seeking access to their courts (whether through legislation or by creating special administrative systems).

Regarding notice to user countries about known users and uses under their jurisdiction, it is true that a CSOLP, as a formal and official document (see above), might be relatively easy to use in this way. This role, however, may conflict with the expressed objective of promoting the certificate through voluntary mechanisms and incentives, given that most private organizations and persons might be uncomfortable at the thought that a foreign government was sending communications about them to their own government. The potential for the user government to use this information in other official ways (under tax and customs law, for example) might constitute further disincentives for companies contemplating ABS compliance.[19]

4.1.1.2 Motivations for CSOLP compliance

From a theoretical or design perspective, the most important question is how the CSOLP will be implemented and/or enforced. Genetic information can be distilled and studied from virtually any specimen of any life form on the planet. At a minimum, this means that it is impossible to control the use of genetic resources by placing firm controls on sources of physical material, because it will be impossible to oversee all such sources. It is also not possible to identify or restrict all movements of biological material, or to maintain awareness of the location of all such physical resources (on the chance that their genetic resources might be utilized). Most important, the majority of the activities relevant to ABS occur in private areas (laboratories, testing facilities, multiplication facilities, factories, etc.) – areas which are usually outside of the source country. Even the user country government will often need a specific legal justification (and formal documents) in order to enter and search such facilities.

[a.] The need for legal mandates

It is important to consider the former paragraph from the perspective of the development of a "legal regime" – that is a formal replicable system for implementation of the benefit-sharing requirement. To some, the legal focus on the prospect of physical controls and enforcement actions may sound cynical, implying that all users are unprincipled. In fact, however, it is just the opposite. The creation of a legally clear and mandatory system protects the law-abiding users, more than any other single group.

Consider this – already, the conscientious user of genetic resources incurs not only the costs of gaining permission for that use, but also the future obligation to share some portion of the financial or commercially valuable proceeds of his work. By contrast, a non-principled user will have neither expense. In light of current technological limitations, if he exercises a relatively low level of care to prevent others from knowing the source of his material,[20] he can avoid any serious possibility that his utilization of a particular species or variety (or the source/origin of that species) will be discovered. By avoiding the ABS negotiation process he can ensure that his name is not known on the country's list of "bioprospectors" and further lessen the chances that any agency, NGO, indigenous

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[19] It is notable that the opposite objective (providing notice to the named source country that a user has listed it on a patent application) is sometimes given for the patent disclosure proposals.

[20] Nearly all existing claims of misappropriation of genetic resources (i.e., cases that involved an actual utilization of genetic material, as opposed to attempts to patent existing varieties) arose because the user made public statements regarding the source of genetic material used in the product. Thus, for example, the Kenya Thermophiles claim arose because a multinational company mentioned that one of its products was based on microorganisms from the Soda Lakes in Kenya, and the Tricolor Frog claim arose because the inventors of a new drug named it "epibatidine" after the Tricolor Frog (*Epibatides tricolor*), because an article describing the frog's unique poisons gave the developers an idea about how to create a pharmaceutical. *See*, Mgbeoji, I., 2006, *Analysis of Four Claims of "Unauthorised Access and Misappropriation of Genetic Resources and Associated Traditional Knowledge."* IUCN-Environmental Law Programme, The ABS Project, Bonn Germany, which will be reprinted in Book 5 of this Series.

or other group will target him as a potential misappropriater.[21]

As a result, the less-principled user will have at least three substantial advantages over the conscientious user. First, his efforts will not be delayed by the sometimes lengthy processes of negotiating an ABS agreement. Second, he will not incur the costs and additional delays involved in full compliance with the country's "access" laws – because his collecting activities, if not labeled "collection of genetic resources" will probably be entirely legal. Finally, of course, he will not have the additional costs of benefit sharing to restrict or affect his determination of whether the new product will be profitable on the market. If the CSOLP is required, it is relatively certain that the unprincipled user will not obtain that either, thereby saving any additional costs and time involved in obtaining the certificate, and the possible additional delays that the patent agency or other user-country agency may incur in acting on applications that are known to involve genetic resources from a source country. Even if ABS compliance is fully and formally mandatory, and clear penalties are stated, an unprincipled user may simply include the possible penalties in his financial planning as a "cost of doing business."[22]

This situation becomes problematic for the principled user because he is in business. Commercial enterprises operate on the basis of a key financial "truth" – that companies that do not operate profitably will fail, and that companies whose products and activities are significantly more expensive than the similar activities of their competitors cannot in the long run operate profitably.[23] Where the unprincipled user does not feel compelled to comply, the inevitable consequence is that conscientious users will have to make a choice between two options – (1) fall behind their unprincipled competitors until they either go out of business or are forced to cease any work involving genetic resource utilization, or (2) succumb to business forces, and begin to engage in conduct similar to less-principled users. (As a result, some (perhaps many) conscientious users engage in a third, interim option – since they have doubts about the legal issues and applicability of ABS, they assume that they have a "legitimate legal basis for non-compliance" in each particular case, accepting the risk of penalty if it is later found to be wrong.[24])

For these reasons, the call for clear legislation does not indicate a belief that there are no principled companies, but only a concern that these companies will be seriously jeopardized if their compliance with ABS principles operates as an anti-competitive force.

[b.] Voluntary provisions (incentive-based compliance)

The business need for enforcing or overseeing compliance with ABS, however, must be viewed in conjunction

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21 Research indicates that the companies which are known to be involved in ABS negotiations at the national level are among the most likely to be the targets of claims of "biopiracy" and misappropriation. *See* IUCN Canada, "Analysis of Claims of 'Unauthorised Access and Misappropriation of Genetic Resources and Associated Traditional Knowledge'" (Information Paper in the 4th Meeting of the Ad-hoc Working Group on ABS, UNEP/CBD/WG-ABS/4/INF/6; a later version of which will be reprinted in Book 5 of this Series.)

22 *See*, generally, Anton, M. *et al.*, "Proceedings of the International Expert Workshop on the Enforcement of Wildlife Trade Controls in the EU, 5-6 November 2001, Frankfurt, Germany," (IUCN, TRAFFIC). In practice, such companies make compliance decisions based on a balancing test, comparing the costs of compliance against a combination of the likelihood of being caught and the financial and other consequences that would then arise.

23 For this reason, it is often stated as axiomatic that no commercial entity will undertake any activity that costs money (or time) unless there is a financially reasonable objective to be served. This is not saying that commercial entities wantonly break the law, but only that they cannot stay in business if they expend money and time in a way that makes their products more expensive than their competition, or makes their production systems lose money.

24 This approach is the basis for the entire branch of tax law in developed countries. It is against the law and potentially criminal to "evade" taxes (that is, to fail to pay a tax that is known to apply). One who does this may end in jail or at least have to pay very large "criminal fines," and be held to other strict penalty provisions. By contrast, however, it is generally known that each taxpayer's tax situation is unique, and it is sometimes difficult to be absolutely certain how the tax law will apply to your own situation. Hence, a taxpayer who takes a "reasonable position" but is later found to be in error, must pay only the normal penalty assessed to those who miscalculate their tax liability. *See*, e.g., AUSTRALIA: AAT Case 9768, 29 ATR 1040, 94 ATC 461 (Administrative Appeals Tribunal of Australia, 1994); UNITED STATES: West Custom Digest 220K5263.15 ("Attempts to Defeat Tax; Evasion"); 90, Am. Law Rev. 1280 ("Wilfulness or intent as an element of offenses denounced by Federal Income Tax Law"); 85 Am.Law Rev. 880 ("... prosecution for attempted evasion of taxes"); US Tax Code (26 U.S. Code) § 6531.

with the significant (perhaps insurmountable) lack of technical solutions that will determine compliance and identify instances of non-compliance. Typically, countries can address non-compliance trends of this type by taking one or more of the following actions:

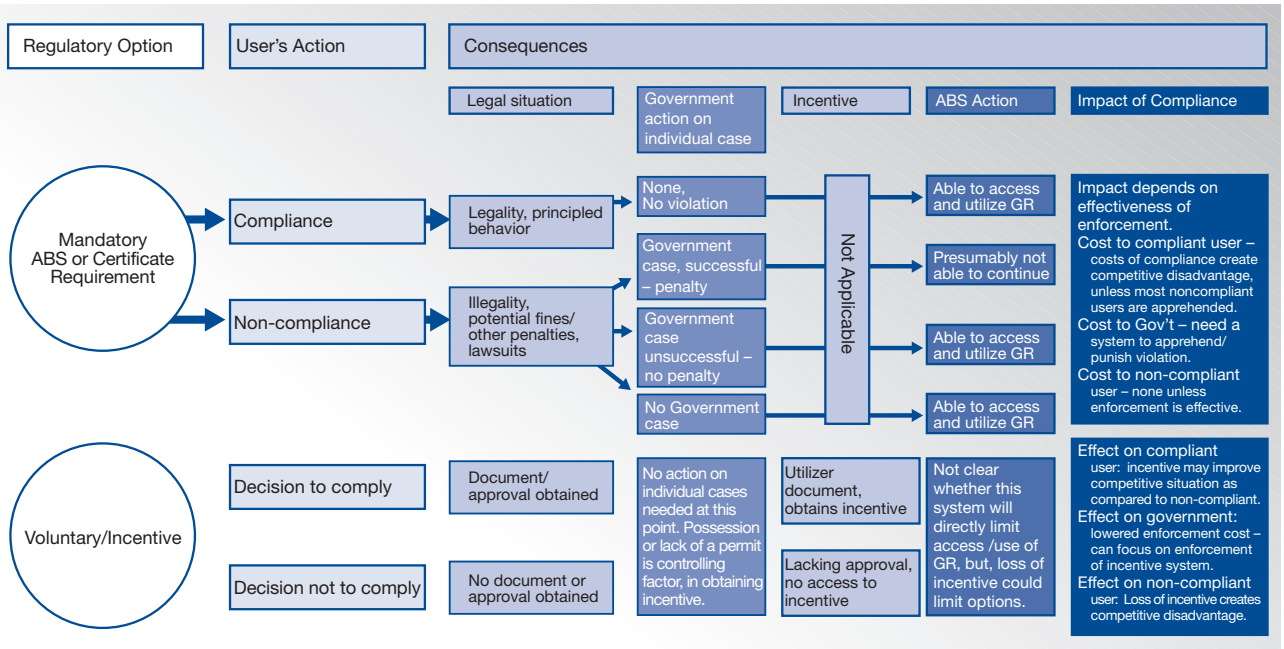
- decreasing the amounts charged to compliant users (including "transaction costs");
- increasing the level of enforcement (so that the chance of being caught increases); and/or
- increasing the penalties for violation.

These solutions do not appear to be options when applied to ABS, however, because on one hand, the possibility of apprehending a violator of ABS requirements is extremely low; and on the other, the payment of fees and benefits to the source country is the primary reason for the existence of the ABS system (so that lowering these amounts seems an inappropriate solution). Hence, unless the penalty for violation is extremely high, the basic mathematics will not provide an incentive for compliance. This suggests that there is little difference between mandatory and voluntary legislation in the ABS context.

This does not spell the imminent end for ABS, however, only for a shift in emphasis.[25] Legislatively, it is almost certainly preferable to create a voluntary system that works utilizing other forces, than to create a mandatory system that cannot be effectively enforced. At the same time, however, this statement requires some explanation. The term "voluntary" does not imply that the user can choose not to take the "voluntary" action and still receive the same benefits as one who does. Nor is it synonymous with "charitable." Rather, "voluntary" refers to a chain of events. One who voluntarily chooses to take the "voluntary action" commences a chain of events that leads to a certain result. One who does not take the voluntary action, cannot achieve that result.

Paradoxically, the primary difference between voluntary and mandatory are that voluntary systems, if well designed, may be better mechanisms for enforcing ABS. This is shown in Figure 1:

Figure 1:



[25] *See* Tobin, B. 1995. "Putting the commercial cart before the cultural horse: a study of the International Cooperative Biodiversity Group (ICBG) Program in Peru." In: Zerner, C. (ed.), *People, Plants and Justice*, Colombia University Press. 2000.

If the CSOLP system (and/or ABS itself) are to add something to the ABS framework, they must find a way to provide a recognized benefit, or avoid an otherwise unavoidable cost or other disadvantage. Given the evidentiary problems facing ABS enforcement, it is probably not enough to say that complying users will avoid violating the law. Although this may be sufficient for the most principled users, those users are already in the fold.

Rather, the objective of creating an additional process requirement (which will add to the costs of both users and governments) will be to bring other users into compliance. This means that the benefit provided through CSOLP compliance must be recognized by companies and entities who do not currently see a reason to comply with ABS requirements, including:

- unprincipled users;
- users who do not already know about their ABS responsibilities; and
- users who believe that they have a legitimate basis for taking the position that ABS does not apply to them, pending direct decision on this point by national courts or other authorities.

Incentives for CSOLP compliance must be sufficiently valuable that (at minimum) they outweigh the cost of obtaining a CSOLP. The nature of the benefit may differ depending on whether the user is already compliant with ABS or not.

Thus, for companies already planning to obtain an ABS arrangement, one incentive might be "streamlining," if the CSOLP process operates as a way of shortening and simplifying ABS compliance while still appropriately protecting the provider. However, such an incentive might not encourage a non-compliant user to obtain a CSOLP, since streamlining can probably not make the process take less time than it takes to ignore the process entirely.

It is important to note that there are two ways to approach the incentive issue. One is to consider the incentives to participate in the ABS system, and the other is to separately consider the incentives that can be linked to the CSOLP itself. As a concrete, objectively verifiable item, the CSOLP may be easily linked to governmental benefits beyond the ABS structure itself, including those managed by completely different governmental sectors, including, for example, providing evidence for a tax deduction, providing a streamlined process for other permits (such as permission to introduce GMOs into a country) or providing evidence for other requirements (such as serving as an indicator of "corporate social responsibility" in countries that impose CSR requirements on foreign companies seeking to permission to operate within their jurisdiction).

4.1.2 The practical challenges: How a CSOLP will function effectively

The design analysis clearly indicates that simple command and control ("comply with ABS or you will be penalized") approaches may not be effective. Instead, development of a CSOLP must begin with determinations about how the certificate process can add enough value to the ABS process to be worth the cost of design and implementation of the system.

This determination must be based on the ability of the CSOLP to increase certainty and compliance, and/or to enable enforcement and oversight, not only with regard to compliant users, but also with regard to those who are currently non-compliant. This ability must be based on solid operational matters, rather than questions of good faith or public relations. The parties will have to consider not only the objectives they wish the CSOLP to achieve, but also come to some decision about whether and how it can do so.[26]

[26] In this connection, the difference between the objectives stated by the Parties in the ABS regime negotiations, and the objectives addressed by tracking and tracing proposals are sometimes very different. Although the Parties' objective is to find a way of overseeing transactions and ensuring/enforcing ABS requirements on users after they have obtained samples, most proposals give as much or more weight to the objective of

These questions (whether and how the system can achieve its objectives) call upon the Parties to take two initial actions regarding the CSOLP:

1. find a *legal mechanism* – a functional/governmental/contractual process that integrates the CSOLP into commercial operations; and

2. create an *unavoidable linkage* between that mechanism and particular benefits (i.e. to ensure that *all* those who comply with the CSOLP receive the benefit, and that *only* those who comply with the CSOLP receive the benefit).

Once the *legal mechanism and unavoidable linkage* have been agreed, then, as noted in other chapters of this book, the technical questions of what the certificate should certify and how (practically and scientifically) it can be validated and tracked, can be formally considered.

Many assumptions have been made about the impact of creating a CSOLP. These assumptions are based on the expectation that once a CSOLP has been created, users will comply with it. Up to this writing, there has been little or no analysis of whether such assumptions are valid,[27] or what factors will increase the likelihood that the CSOLP will be effective once it is in place. Since the CSOLP proposals are all theoretical, there is no direct experience with them to provide some indications of the practical issues affecting their validity and functionality.

However, sources of guidance and experience do exist in other sectors, where an astounding variety of important governmental objectives are successfully imposed on both principled and unprincipled individuals and other entities without primary reliance on direct oversight by governmental prosecutors. These provisions rely on other reasons (incentives) which encourage, sometimes virtually mandate, compliance. To address practical challenges of the CSOLP, it is essential to begin with an examination of these laws, to determine how existing certificate-based systems and registries operate as controls on commercial activity.

This section seeks to provide a clearer understanding of the underlying reasons why certificate systems can function effectively in some contexts and not in others. That knowledge may enable the Parties to make a workable decision about how a CSOLP system can be used. These examples demonstrate that the key to success is not in the design of the certificate (a relatively simple question), but in the more complex issue – design of the system so that the permit requirement is integrally linked to a desirable commercial or individual result (or to the avoidance of an undesirable result).

The following discussion considers several kinds of governmentally established uses of certificate systems and registries, including so-called "voluntary certification systems." It considers a number of different types of systems, looking for each at its objective, its specific mechanism, and the incentives and benefits that motivate users to comply.

4.1.2.1 Certifying ownership of intangible and other property

One of the earliest certificate/registry systems was created to prevent commercial abuses and unfair practices in commercial and investment transactions. The desired objective in setting up these registries was to curb abuses that often occurred where the property being sold was either intangible or immovable. Lacking any official protection for buyers, unprincipled "sellers" might easily convince an unsophisticated person to buy an interest in a company, a piece of

evaluating the process – that is, determining whether the ABS system is functioning efficiently. Although the true efficiency of the process can only be determined by knowing whether in fact it is leading to compliance, most process evaluation proposals focus instead on the time and cost to the user in seeking a certificate, and do not consider questions such as the user's compliance or the possibility that some users are ignoring the entire ABS issue with impunity.

[27] This gap is particularly notable, when considered next to the assumptions made about ABS at the time the Convention was adopted. It was expected, for example, to provide an incentive and funding for conservation of biodiversity and to be implemented through a mix of user-country and provider-country measures. Its unexplained elements were expected to be resolved through the application of national property and contract law. *See* Glowka, L., F. Burhenne and R.H. Synge, *A Guide to the Convention on Biological Diversity,* IUCN Environmental Policy and Law Paper No. 30 (IUCN, 1994) at 5. None of these expectations has proven to be correct.

land, or some other commodity, that the purported seller did not own. All one had to do was print a few official-looking documents.

Several kinds of registry and regulatory systems were created to address this kind of concern. For example, most countries have created official land registries to prevent this kind of abuse in the real property industry. These registries include all owners of any interest in property including easements, mortgages, and in some cases tenancies. Many countries have similar registries for cars and types of other large moveable property. IPR laws address a different side of this issue, focusing on protecting the owner of intangible property (protectable ideas) from those who would effectively take a part of his interest without his consent. A related concept, stock exchanges, and other registries of stocks, bonds and investment certificates were formed to give the purchaser an official resource which can confirm that the "stock certificates" or other documents evidencing ownership of intangible property are genuine.

All of these (and many other) systems provide two kinds of protections. First, they allow the purchaser to confirm, before closing the deal, that the seller has a valid interest in the property being sold. So long as he has taken this step, the buyer is both practically and legally protected against claims that the purchase was fraudulent, and the property not owned by him or her. After the purchase, of course, the buyer promptly registers his ownership in the same system. This protects both seller and buyer. The buyer then knows that no other person can sell or place encumbrances on the property without his consent.[28] For the seller, there are very different, but equally compelling benefits. For example, if the transaction is not recorded, the seller will be liable for all property tax, even though he no longer actually owns the property. Usually this factor alone would be sufficient to prioritize the official recording of any property transfer. The seller also knows that he will not be liable for actions taken or damage caused by the property, once it has formally left his ownership.

In financial terms, the registry's method of distributing costs of oversight and management is different from that of a standard command and control regime. After the initial costs of equipping and setting up the system (including database system development and entry of pre-existing records), the cost analysis of such a registry focuses on the cost of the clerical and administrative staff. The basic governmental costs of enforcement of the registry system are relatively small, because the benefits to the parties make it self-enforcing. On the strength of these incentives, the government has no need or interest in enforcing the registry as a requirement. In the interests of promoting and protecting the national commercial system, however, the government has a compelling duty to ensure that the registry is complete, accurate, up-to-date, accessible and tamper-proof. Hence, it is not enough to simply open an office and input the parties' records into the electronic or paper filing system. Each record must be checked for accuracy (so that it is comparable to all other records); the officials must confirm that it contains all appropriate seals and stamps (to verify that the documents are not fraudulent) and continuing efforts will be necessary to ensure that the registry is safe from outside manipulation.

In addition to accurately entering this material into the property database, they must provide or enable the provision of an access system by which property owners, prospective purchasers and lenders, and others may obtain complete and verified records from the system. The access system is not inexpensive, but it is possible for it to be provided by private companies, which provide not only a clear and accurate report of all existing documents and conditions affecting the title to the property, but also insure the accuracy of this "title search."[29] The fees paid by such

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[28] There are exceptions to this, particularly with regard to government tax liens and encumbrances placed by a court, based on the owner's failure to meet his financial obligations.

[29] In North America and Europe, a specialized industry has developed which utilizes these public records to provide insurance to buyers, sellers, lenders and others regarding the exact status of title to property. *See*, e.g., Machlin, J. and T. Young, 1988 (updated annually) *Managing Environmental Risk* (Thompson-West, Eagan, MN) at §§ 11.19 *et seq.*

title-search companies for access to public records can provide a large share of the total governmental cost of maintaining the registry. These costs, plus the costs and profits of the title-search company, are in turn paid by the buyers, sellers and lenders who need dependable, insured title information.

This is an important aspect of the title registry system – the ultimate (quite large) cost of using the system is borne by the person who needs system information. In the case of the ABS system as currently perceived, such searches will most frequently be sought by providers, to verify compliance. Hence, the costs of the system will fall squarely on countries, communities, and individuals – primarily from developing countries.[30]

4.1.2.2 Protection from market abuses

In some conventional markets, a single entity or a small group of entities may constitute all of the primary buyers (or the primary sources) of a commodity. If the entire group joins forces, it may be possible for them to control the price for the commodity through concerted action. In addition to being anticompetitive, this can result in serious oppression of those on the other side of the transactions.

Examples of this situation include the market in precious gems. At the time of extraction, there is a relatively small group of buyers, who purchase (to cut and/or resell) all such gems. If they worked in collaboration (and outside of public scrutiny) these companies could artificially set the price for their commodity. With no other option, sellers would be forced to accept lower prices and inappropriate limitations of their rights, in order to sell their production. Another example is the relatively small group of countries which have crude oil resources to sell on world markets. They, too, have the ability to control availability of this resource, and thus cause worldwide price increase or decrease. In many countries, however, these same concerns have led to the regulation of most kinds of larger commercial entities, as a means of protecting their shareholders who (without such protection) may be similarly at the mercy of decisions by major shareholders and directors.

National and international registries and certification, coupled with market transparency regulations, help assure that these markets are transparent, and that market manipulations are subject to government or international scrutiny. Thus, for example, gem-class cut diamonds may be traded only in one of the 24 "diamond bourses" in the world through which the trade in these stones is tightly controlled, but subject to strict commercial standards.[31]

As trade in other products has become increasingly specialized by commodity, commodity exchanges have formed, to provide the same level of transparency and market control, protecting suppliers, traders and ultimately consumers.[32] Currently, a great many entrepreneurs and governments are attempting to develop similar institutions to regulate the use of the "carbon trading" mechanisms created under the Kyoto Protocol.[33] In some cases, members of the limited group of purchasers may be required to register and accede to specific standards regarding how their prices and conditions are set and disclosed, and to register and document the number and volume of transactions.

Participation in these markets is basically voluntary, and may sometimes be costly in terms of permit

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30 At present, all but two of the countries that have adopted a broad range of access-oriented ABS legislation are developing countries.

31 Although these markets do not eliminate abuses, they provide a level of transparency that may help. The production and distribution of diamonds is largely consolidated in the hands of a few key players, and concentrated in traditional diamond trading centers. At one time, it was thought that over 80% of the world's rough diamonds passed through a single company (the DTC, a subsidiary of De Beers.) *See* http://en.wikipedia.org/wiki/Diamond

32 Examples of commodity exchanges include the Commodity Exchange Hannover, Chicago Board of Trade, Euronext.liffe (Europe), Intercontinental Exchange (Atlanta), London Metal Exchange, Shanghai Metal Exchange, The National Commodities and Derivatives Exchange (Mumbai), Tokyo Commodity Exchange, Winnipeg Commodity Exchange and the Bolsa Nacional Agropecuaria (Colombia).

33 *See*, e.g., the Chicago Climate Exchange and the European Climate Exchange, described in websites at https://www.theice.com/about_futures.jhtml. This is only one example in an explosively burgeoning market. This mention is simply by example, and should not be taken as a recommendation of this system.

and reporting requirements. A variety of incentives encourage participation in exchanges of this type, affecting different types of participants. Sellers, for example, find access to a wider variety of buyers and a transparent market so that they can be assured of getting a fair market rate for their produce. Buyers find a single source for their purchasing activities. Most important to both, the system encourages *investors*, whose objectives are speculation and market-based profit. Through commodities exchanges, investors have access to the regulated "futures market" through which they trade in options (a kind of investment in future production). For the investor, the futures market offers the chance to speculate (invest based on the possibility of larger profits that would be available through normal interest and development), while for the underlying parties it operates to increase the availability of funds throughout the growing or production period.

4.1.2.3 Certifying a specific item – "passports," verifications and assays

A third type of registration/certificate system focuses on providing more permanent identification (a "passport," in a way) for a particular item or commodity. This type of system generally has one of two objectives, either

- to provide a basis for tracking substances of concern that are used in industry and elsewhere and overseeing the protection of the public and handlers from known risks of these substances; or

- to provide evidence of the authenticity, content, purity or condition of the item.

[a.] "Passports" for the movement of goods or individual items

A government may have many different reasons for creating a documentary tracking mechanism for moveable items. Where the goods are dangerous in some way, for example, the government may need to control the manner in which they are transported, stored, or managed; or may simply need to know where they are located (for purposes of updating area emergency plans). Some other goods are not harmful in themselves, but have been identified as the most concrete element of an industry or activity that must be controlled. In essence, the law has determined that stricter control of the goods will cause stricter control on the industry or activity underlying those goods.

Hazardous material permits:

The most common "passport" system is used for harmful items that may be transferred or used only with permission. For example, businesses that generate hazardous wastes are often required to label those materials, and create (and register) a permanent certificate that follows the waste from the moment of its creation (the moment it becomes a waste) until its final disposal. This record will be required in order for the business to use or dispose of these materials, and it provides a basis for financial responsibility even after the wastes have been disposed of in an appropriate way, in the event that the materials harm anyone or the waste disposal is ultimately breached or otherwise violated. These systems are found in a great many countries,[34] and are also mandated in international law, with regard to the transboundary movement of hazardous wastes.[35]

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[34] For a detailed discussion of the certificate system applicable to hazardous wastes in the U.S., *see* Machlin, J. and T. Young, 1988 (updated annually), *Managing Environmental Risk* (Thompson-West, Eagan MN) at Chapter 4 ("The Resource Conservation and Responsibility Act"). The act discussed therein is part of the Solid Waste Disposal Act, located at 42 US Code §§ 6400 *et seq.* Other examples of similar systems exist in many countries. *See*, e.g., BRAZIL, CONAMA Resolution No. 23 (in translation), 12 December 1996 (referring to national and subnational laws controlling hazardous waste and its disposal); CHILE: "Ley de Bases del Medio Ambiente" (Law on Environmental Requirements), tit. II, para. 2, art. 10(ń) (1994); MEXICO, "Reglamento de la Ley General de Equilibrio Ecológico y Protección al Medio Ambiente en Materia de Residuos Peligrosos" (Regulations to the General Law of Ecological Equilibrium and Environmental Protection on the Matter of Hazardous Wastes), 25 Nov 1988; NETHERLANDS, Disposal of White and Brown Goods Decree (in translation), 1999; EU Council Directive 75/442/EEC, on waste 15 July 1975, articles 9-11.

[35] National permit requirements are generally recognized (and some elements required) in international law in the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (Basel, 1989); and in regional implementing instruments such as the Bamako Convention on the Ban of the Import Into Africa and the Control of Transboundary Movement and Management of Hazardous Wastes Within Africa (OAU, 1991).

These systems can be very detailed, because their primary purpose is to make it impossible (hopefully) for one to transport or dispose of hazardous substances without complying with both the certificate process and with the underlying rules for ensuring that transport and disposal of hazardous wastes are safe, and protect people and the environment. As a consequence, these systems are typically set up so that the generator of the waste is responsible for packaging and labeling it for transport, and for creating the certificate that travels with the waste. Copies of the certificate are filed with relevant agencies, both by the generator and by the transporter or disposer of the waste. In addition, the contents of barrels, tanks and other packages in transit or after disposal may be inspected and tested at any time. If they are not covered by a certificate, or if the certificate is erroneous, the generator and others in the transport and disposal chain may be penalized. Even if there is no error in the documentation, however, where the waste is extremely hazardous, the generator, transporters and disposal facilities may continue to be liable, in case the disposal containment is breached or insufficient and the waste causes harm.

Hazardous materials transport and disposal systems are usually mandated by very stringent laws, so that the failure to comply with permit requirements is a criminal act, punishable by fines and even imprisonment. The system's design, however, can make it largely self-enforcing. Very often, the permit system imposes the same level of criminal penalty on all persons in the chain of waste disposal, from the original facility that created the waste through all transporters and storage facility to the ultimate disposer. If any of these parties has accepted waste without appropriate documentation, they may be civilly and criminally liable. Waste disposal and storage facilities, for example, face a relatively high risk of future detailed scrutiny by government, "watchdog" NGOs and other individuals. All companies that transport hazardous materials and companies that operate hazardous waste disposal sites may be liable to pay extremely large judgments, fines and penalties *unless* they can prove that they have complied with hazardous waste management laws. In many cases, this potential liability is not limited by normal statutes of limitations. Hence, they (and all entities in the chain) have a strong incentive to make certain that they can document compliance with hazardous waste laws (and certificate requirements). The companies become the primary mechanism for overseeing the general use of certificates.

Permits for international movement of endangered species (CITES):

As another relevant example, the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)[36] creates the framework for an integrated network of national laws requiring a similar kind of passport for the movement of specimens of endangered species.[37] The objective behind CITES is not to protect the public from the species, but rather to control commercial trade that is endangering species survival. In essence, the CITES Parties concluded that the cross-border movement of specimens is an appropriate "choke point" through which commercial trade activities that are endangering species can be controlled. Through CITES controls, countries can alter the market structure of such trade, because the CITES permit system is integrated into the national system that controls natural resource uses in the source country (scientific and management authorities), the systems that control international trade more generally (customs), as well as market systems in recipient countries.

The CITES system requires a person internationally moving specimens of a listed species to get separate permits for each specimen (or group of specimens of the same species).[38] It actually requires a "double permit" process, in which the person moving a specimen must usually get a permit from both the

[36] Washington, D.C. (1973).

[37] The basic CITES permit framework is detailed in the Convention at Articles III through X.

[38] Recently, some countries (especially the United States) are allowing multiple species to be listed on the same permit. This shorthand approach is not actually authorized under CITES; however, no challenges have been made in COP or other formal processes.

country of export and the country of import.[39] In general, CITES primary problems at present are consequences of its success. Gaps in border control are one such problem (given that the CITES controls have successfully limited or curtailed trade, creating a stronger impetus for involvement of the criminal element). Another is the problem of identification of controlled specimens and their parts and derivatives. With thousands of species currently listed for control under CITES, and given that border control officers have other tasks in addition to controlling movement of illegal species, customs and other officials may not be able to address the full range of these responsibilities.

As further discussed below, the CITES system is heavily dependent on the permit itself (the paper copy) in order for goods to pass national boundaries in most countries. CITES is still grappling with the possibility that formal documents will be issued on the basis of falsified verifications, as well as the possibility that the formal documents themselves will be counterfeited or altered.[40] Similar problems may also arise in hazardous waste control systems, although in countries with broadly accessible high-speed internet access (North America, Western Europe and some parts of Asia), many of these problems can be addressed by maintaining a secure electronic registry of the permits, which can be accessed by officials and members of the public to determine if the permit is valid.

CITES has frequently been cited as a possible example of a system on which the ABS framework can be modeled. There are, however, a great many essential differences between the CITES system and the particular needs of the ABS framework.[41] For example, CITES involves a one-time action (import of a particular item across a national border), after which the permit terminates.[42] If it is later necessary to export/move the item out of the country, new permits will have to be obtained to address the new movement. Consequently, CITES does not include any control on post-transfer use of the specimen. Although in some cases the importer may be asked his reasons for importing the specimen, there is nothing in the CITES or most countries' implementing laws that limits the importer's actions after the specimen has been legally imported, including selling or transferring it to others.[43]

Even if not a prototype for the CSOLP system, CITES does offer an example of the level of specificity needed in developing a standardized control mechanism that is to be applied on a rigorously consistent basis by all countries. It specifies in detail the characteristics that all countries' laws must embody, such as the existence of one or more scientific authorities and a "management authority" and the basic standard on which decisions must be based. It leaves to the Parties the task of choosing the authorities and making the scientific, technical and administrative choices regarding the manner in which the basic standards are reflected in (and proven under) national law. Although the scope of the CITES decision is much narrower than the ABS decision (whether the import or expert could be detrimental to the species, how to certify that the

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39 In some situations (movement of specimens of species on Appendix III, as set forth in Article V) only the export permit is required.

40 In COPs 11, 12 and 13, CITES Parties formally discussed the growing problem of falsified documentation.

41 A detailed list of these differences was provided by José Carlos Fernández Ugalde in his 2004 presentation entitled "El papel de los Certificados de Legal Procedencia en la política global de recursos genéticos: Consideraciones prácticas y económicas" (The Certificate of Legal Provenance in Global Genetic Resources Policy: Practical and Economic Considerations) in the SPDA Workshop on Certificates of Origin and CITES. ("Taller Sobre Certificados de Origen y CITES" (IUCN, INRENA, INE, SPDA – Lima, Nov. 2003), to be posted online at http://www.iucn.org/themes/law/abs01.html (site being revised at time of writing)).

42 It has been stated that Canadian law requires the importer to retain the permit and use it to document the legal ownership of the specimen throughout its later life. However, for all CITES purposes, the permit ceases upon use or within six months of issuance (whichever happens first). The author has been unable to obtain copies of any Canadian law as so described. It would be interesting to review it to see how this law addresses difficult questions such as the offspring of the controlled specimen, etc.

43 One other important distinction between the CITES system and the ABS regime relates to the pre-existing legal situation. Nearly every Party to CITES had already enacted substantial laws and administrative systems dealing with wildlife protection, market control, and international movement of goods and persons. The challenge for CITES Parties was simply to add or adjust these laws to take into account more specific CITES requirements. By contrast, virtually no country controlled or recognized any controllable interest in genetic resources prior to the CBD, and that is essentially true to this day (with fewer than two dozen countries that have adopted substantive laws on ABS.

capture/collection of the specimen occurred in compliance with applicable national laws and regulations) and involves a more limited regulatory time period (the one-time import/export of that specimen), CITES provisions about the national implementation framework are more than ten times as long as the CBD provisions addressing its ABS framework.[44] COP decisions, guidance documents and other officially recognized analyses directly deciding on elements of necessary implementation number hundreds of pages.

[b.] Certifying the content and/or purity of particular items

Another "passport" type of certificate focuses more on the transmission of information than on enabling movement in trade. "Certificates of authenticity" and assay reports may be used, for example, where one owns an item whose value depends on whether it is "genuine" (an antique, for example), or on its composition (e.g., whether it is made of gold or some other substance and how "pure" the gold is).[45] One might take the item to a qualified expert or an "assay" office, where its validity or the contents/purity can be verified. An assay may also be sought where an individual has found valuable metals (or other commodities of interest) on his property.

After the official evaluation, the item may be certified. In some cases, this certification is in the form of a letter from the expert regarding the item. Where called upon to confirm the purity of an item made of precious metal, the assayer may stamp the item with a "hallmark" or other identification of its contents. The owner of property containing precious metal deposits may also get an "assay certificate" to demonstrate the percentage of precious metals found in his samples and/or an inspector's/engineer's certificate that the ores have come from the property.

Both of these certificates have two components - the registration of the individual (assayer or engineer) giving the certificate and the certificate of the item inspected. The verification of the former is through the agency or organization performing the certification, and its strength will depend on what level of information and evaluation was applied before granting or denying the certificate. If registration can be obtained solely by the payment of fees, without any check of the individual's qualifications, then the credibility of the second certificate (the assay certificate or mine inspection) will be compromised.

The incentives to participate in this system are relatively obvious. One who owns or seeks to purchase a particular item or commodity may need some assurance of its authenticity. He will be willing to pay for this, where there is a sizeable difference in value between an authentic product and a fake (or a product that has not been tested and later proves to be different than advertised). The seller will get a better price for a genuine item than one which "might be genuine," and the assayer receives a fee for providing this service. Nearly all authentication and assay contracts, however, note that the work of the assayer depends on the cooperation of the owner of the samples, to provide true samples, and correct information about their origin. It is generally impossible to provide a usable authentication or assayer's certificate where the owner of the property, or the product developer, does not provide full information about the material.

Governmentally, the system's needs are relatively simple. It must be based on a uniform set of standards by which all assay results can be comparable to one another, and usually also a system for the qualification of assayers or other experts (as discussed in a later section of this chapter). In a few cases, such as hallmarking of precious metals, the desire for trans-

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[44] The CITES regulation of transboundary movement is 2800 words long, contained in 70+ sentences, comprising eight full articles of the convention; CBD ABS (including every provision that discusses access or benefit sharing or their component parts) consists of 275 words, in seven sentences, scattered throughout the convention.

[45] The term "assay" simply means "a procedure through which the concentration (contents, quantity, purity or potency) of a component part of a mixture is determined." (Webster's New Collegiate Dictionary 1980, G&C Merriam, Springfield, MA). Hence, a system that creates and uses an assay certificate may apply to any item or substance for which one needs to obtain external verification of its composition and purity.

boundary comparability has led to the development of international rules, systems and standards.[46]

The primary limitation of this system, however, is in its legal effectiveness. In general, these systems depend on expert verification (as discussed below) regarding a specific item. When the expert is not present, it might be possible to alter that verification or simply to change items and claim that the new item is the one that was verified. Usually, for legal purposes, authentications and assays constitute a short-term contract between the expert and the individual(s) asking for the authentication. They apply only at the time they are undertaken, and cannot be used later for a subsequent sale of the same property.

One critical problem with this kind of system is the lack of an integrated self-correcting/self-policing mechanism. Assayers and other commodity certifiers are individual experts, providing an analysis of a particular item. The only guarantee of the veracity of the assayer's certificate is to take the material to a second assayer. In most cases, assays are not registered (there is no central database of assays) because the contents of the assay is thought to be confidential – between the assayer and his client.[47] Consequently, there is little opportunity for oversight. If an assay certificate or other certificate of authenticity is given falsely, its inaccuracy may not be discovered. When/if it is discovered, the "victim" of the misrepresentation may not feel any incentive to report this fact to the proper authorities, and financial or time constraints may prevent him from taking other action (seeking damages from the assayer).

[c.] Bioassays

Although at first glance the concept of authentication and assay certificates seems very different from anything being considered for the CSOLP, the technical mechanism discussed in connection with the oversight objective of the CSOLP is essentially a kind of "bioassay." In this connection, however, bioassay information is to be used for oversight or enforcement purposes. Hence, the person obtaining the assay would not be seeking to value a specific item, but rather to confirm very specific information regarding the product. In addition, because they need to be used in courts, the bioassay must verify information normally provided by the owner or developer of the item to be assayed. The court would expect the assay to identify the specific species/subspecies/varieties used in the development or production of a particular product, and presumably to confirm their source or possible sources.

As noted in other chapters of this book, the capacity of bioassays to provide enforcement evidence is improving. New and developing techniques may help the CSOLP get past the current impossibility of determining source by examining the final product.

4.1.2.4 Registration for governmental controls and assessments

A very common kind of registry involves requiring registration as a means of imposing specific kinds of government requirements. Examples of this kind of certificate system are numerous. For purposes of discussion, this chapter will consider three: the registration of motor vehicles, the control of the traffic in goods at national borders (customs controls), and the national registries of taxpayers and voters.

Registration of motor vehicles:

Vehicle registration systems enable government to track motor vehicles – increasingly a primary identifier of human actors in many modern societies.[48] Where effectively enforced, these systems enable government officials to regularly ensure that motor vehicles are safe and within operating requirements, to keep control on drivers, to impose taxes and other fees for highway maintenance and other costs, and to keep records of changes in ownership of property of significant value.

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46 *See*, e.g., Convention on the Control and Marking of Articles of Precious Metals, Vienna, 1972, amended 1988 (additional amendments currently under discussion).

47 In some cases, assayers are (practically and legally) required to maintain a personal registry of the certificates they have given.

48 Virtually all countries require vehicle registration, hence this article will not attempt to provide a list of vehicle registration statutes or examples.

Incentives for registration include, for example, the desire to protect oneself from temporary loss of the vehicle, which may be impounded by any public officer, if it is driven on public roads without proper registration, and the fines and impound fees that might be charged. More important, this registration system also provides the vehicle owner with legal protection. By recording changes of registration, buyers and sellers can protect themselves from legal claims and liabilities. In addition, the motor vehicle registry is closely linked to a related certificate system for the registration of persons licensed to drive. An unlicensed driver may also face impoundment of the vehicle (no matter who actually owns it) at the time he is discovered to be driving without a license, and any person driving an unregistered vehicle may face penalties that could include suspension or revocation of his driving license.

Customs:

Customs certificates and declarations (some of which must be prepared long before the actual movement of property) are designed to serve a variety of government objectives.[49] Customs filing and approval systems create a record of the transportation of goods across national borders. As such they provide a basis for imposing customs duties and other taxes, and can sometimes provide formal confirmation that goods have been legally imported. They also regulate the entry of controlled substances and give border authorities a very broad mandate for regular and random searches of luggage and containers crossing borders. The incentive for participating in customs systems is primarily legal mandate. Where customs controls are effective,[50] two factors are commonly found, which can be presumed to have a significant impact on that effectiveness.

First, there are particular, unavoidable "choke points" at which most cross-border movement can be specifically overseen. Since the law regulates the moment of border crossing (rather than creating an ongoing requirement), where choke points are controlled (and constitute the primary or only opportunities for entry into a country) it is possible to control virtually all cross-border traffic with a relatively small number of officials.

Second, there is a substantial fine that can be easily assessed against any person who fails to report or disclose *any* goods that must be reported at customs. Even though customs officials open only a small percentage of baggage or cargo, the random nature of customs searches coupled with the high levels of penalty cause most persons to comply with disclosure.

Tax, voter and draft registration:

In most countries, one or more carefully developed and implemented registries exists for the purposes of assessing and collecting taxes, verifying each voter's qualification, and (often) registering young adults for military service. The objective of this type of registration, from the governmental perspective, is information – it is essential for taxing agencies, election overseers, and the military to have complete and up-to-date information about the country's citizens and taxpayers.

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[49] Owing to the intensive global meeting schedule, participants in ABS discussions and development are becoming all too familiar with the operation of national customs legislation (controlling the transboundary movement of property and goods), which exists in every country. At the international level, conservation regimes have used customs-based systems (i) to control the movement of endangered species and thereby help to curtail the loss of species caused by commercial trade in wildlife and wildlife products (described above); and (ii) to control and track international movement in substances of environmental concern, including genetically modified organisms (Cartagena Protocol to the CBD, Nairobi, 2000) and hazardous wastes (Basel Convention, cited above at note 33).

[50] Customs controls are at their most effective in developed countries. They can also be particularly useful and effective in the control of specific kinds of trade from developing countries – that is, control of the "casual" movement (smuggling) of goods that are illegal or subject to high fees or duties, for which there is a large market in developing countries. Many proposed customs and border controls in developing countries have proven difficult or impossible, where national borders are frequently crossed on foot or by many less controlled roads. Often these controls are developed in an effort to utilize existing customs networks to serve environmental and conservation purposes. *See* discussions in EAC Secretariat, 2002, Freeing Cross-border Trade in Agricultural Products (EAC, Arusha); and *see* Schei, P.J., 1996, *Proceedings of/Conclusions and Recommendations from the UN/Norway Conference on Alien Species,* Trondheim, Norway; and GEF Evaluation Office, 2005, *Evaluation of GEF Support for Biosafety Implementation,* (GEF, Washington, DC), at chapter 8 and elsewhere (considering difficulties in controlling casual transboundary movement of GMO products).

The mechanism of these registration systems is relatively simple. Usually, everyone above a certain age is required to register. In some cases (tax registration), this requirement applies regardless of one's citizenship or residency status. In many countries, however, enforcement of these requirements does not occur through regular screening, but through other incentives to comply.

While similar in many ways, these systems are very different with regard to incentives for participation. In the case of voter registration, the primary incentive is direct – one cannot vote without registration, and unregistered persons may be unable to participate in civic meetings, hold local offices, or exercise other civil rights. Hence, the incentive of voter registration is that the individual wants to be a registered voter. Because this status is desirable, many countries have grafted other requirements into voting registration. For example, the registration form may ask for additional information which the government is interested in, to be included in governmental databases.[51]

Registration for purposes of taxation and military service, however, is quite different. Given a choice, many people would prefer not to pay taxes or engage in mandatory military service. For this reason, where possible, governments attempt to make this kind of registration automatic, although this is not always possible.[52] Persons who obtain work permits or register in the social security system may be automatically added to the list of registered voters, for example. Young adults may be automatically registered for the draft through their schools.

Even for these omnibus systems, however, some other factors may provide an incentive for people who have been left outside of the system to register. The tax rolls are frequently integrated into a complex web of business relationships. One must register in order to be employed in many countries, and usually this registration is directly recorded in the tax roles. However, it is also usually integrated into the employee benefits system, so that an employer may not obtain tax credits for payment of employment benefits such as sick leave, health insurance or social security, unless the employee is registered as a taxpayer.

4.1.2.5 Registration of specialized experts

Yet another kind of certificate system relates to the provision of expert services. In many cases, the person who requires such services is not technically qualified to evaluate the competence of the expert. A mis-step (hiring an expert based on his demeanor or verbal skills) may mean that the purchased advice will be deficient (incorrect, low quality, unhelpful or un-credible). Often, the end result is simply less value for money, but in some cases, the expert's qualifications can be more essential. One urgently needing the services of a heart surgeon, a defense attorney, a property assessor, a toxicologist or even an auto mechanic, for example, will typically not want to obtain substandard services. In fact, he will usually want the very best possible assistance or advice. However, unless he is also fully qualified in the experts' field and specialty, he will not have the relevant technical knowledge to enable him to competently evaluate the qualifications and performance of those experts.

Official registries of qualified experts may serve many purposes and operate in many different ways. In many instances, they may serve simply as a record of basic qualification (a list of certified experts with no evaluative element). Expert registries can go far beyond these basic "listing" systems, however. For example, some kinds of services are limited by law, and may *only* be provided by licensed professionals. The range of such services is very broad, running from medical doctors to court recorders.

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51 In some countries the reverse process is happening. Where voters are losing interest in participating in democratic governance (and the number of voter registrations or renewals is declining), governments have chosen to link voting registration to other activities. In California, for example, one may register to vote on the same form that one uses to obtain or renew a driver's license. Since this practice began there has been an increase in the rate of voter registration or renewals.

52 Various kinds of tax registration or certificates may be required before a person can become employed, transfer property, undertake business operations, or engage in market transactions. In some cases, such as inheritance tax, registration occurs when the heirs begin the legal process of transferring the deceased person's property.

One type of certified professional services which is particularly relevant to the ABS situation is the system that controls the authentication or notarization of official documents and contracts. Many transactions and government filings require "contractual formalities," including the verification of the identity of the persons signing the document. A special legally authorized person (sometimes called a "notary public") must provide this verification. In most countries, the law requires that these designated service providers must be specially trained, authorized and even bonded, to ensure that they properly verify and confirm the identity or other issues that they attest to. A notary is bound by a formal oath and may be criminally liable if he files an "acknowledgement" falsely or without the requisite care.[53] It is reasonable to expect that the CSOLP may have elements that must be officially verified in some fashion.

Although many expert systems are backed up by criminal law (penalties for providing services without a license), only limited governmental resources at most are available for "spot checking" and other direct enforcement. Consequently, the discovery of unlicensed service providers almost always occurs as a result of malpractice. If the unlicensed professional provides high-quality un-challengeable service, his work is not likely to be investigated, and his lack of a license may never be punished. This means that the system waits until someone is injured or some violation has occurred, before finding and punishing the unqualified service provider. And most important, at this point, it is often too late to prevent harm or to find a financially solvent party to pay the costs of damages.

4.1.2.6 "Voluntary" and non-governmental certification of products and processes

Another more recently developed kind of certificate/registry system is found in programs for the certification of products or companies relating to issues of "social responsibility" and other issues of consumer concern. Voluntary standards and certification systems are gaining increasing attention as possible tools for achieving a variety of objectives, including responsible hiring and employment practices; cultural protection; social welfare; biodiversity conservation; protection of species and ecosystems; equity and livelihood improvement; and sustainability.[54]

Historically, voluntary product certification has developed organically, as needed to serve many needs. For example, initial product certification was created to ensure that physical standards (precision in size, shape and composition of produced goods) were complied with. This kind of certification supported the growth of industrial processes based on the manufacture of "interchangeable parts." Later, standards for certification were developed to address other needs, including safety certification of electrical and other consumer goods, content certification of vitamins and other kinds of products, and quality certification of products and services. All of these kinds of certification are based on standards and testing – an entity seeking certification either provides samples for testing, or provides test results demonstrating compliance. These certification systems have generally been self-generating and self-supporting. If certified products are later shown not to meet the standards (i.e., do not fit the uses they are certified for) the users will know this and can bring suit or take action based on false certification.[55] All other producers that use the same certification standards have an interest in making sure that the

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[53] The system for providing "documentary formalities" to ensure the validity of documents varies among countries. Although in many countries a "notary public" is a low-level functionary, as described in the text, in others the term "notary" may to refer to a different type of professional with much broader responsibilities. For a larger discussion of the various kinds of formal attestation used in international transactions, *see* Nanda, V.P. *et al.*, (treatise now a database, updated July 2006), The Law of Transnational Business Transactions at Chapter 4. (Transnational Contract Law II.); Schlesinger, R., 1968, 2 *Formation of Contracts: A Study of the Common Core of Legal Systems* 1652 (New York).

[54] For a general discussion of these tools and the manner in which they have been applied to environmental and sustainability issues, *see* Young, T., 2004, *An Examination of Environmental Uses of Certification Systems and Standards Development.* (IUCN PPG, publication forthcoming).

[55] Recently, however, examples of the non-self-policing conformity standards (and the problems arising from the lack of oversight) have become more prominent, for example, where it is found that an airline crash was caused by faulty parts or the use of less durable materials. Inspection of the parts by the airplane manufacturer or re-conditioner has not proven sufficient to identify these deficiencies. In such cases, the only remedy is to sue the parts manufacturer for damages – cold comfort to the families who have lost relatives in such incidents.

standard and certificate are respected. Hence, oversight bodies (standards boards) are typically either government agencies, or broadly funded by the industries served.

Another traditional kind of certification relates to the composition and production of food products – particularly foods meeting religious standards (e.g., kosher, and halal). Many products certified through this kind of system may not be objectively confirmable through testing of the product itself. However, many people rely on this kind of certification as a critical element of their religious and cultural observances. These certification systems necessarily require regular inspection and oversight of the processes of production. This kind of system has more recently been adapted to the concepts of "organic" or "eco" foods.

More recently, registry systems are increasingly considered to be a possible way of linking social objectives to business markets. Paragraph 17 of the WSSD Plan of Implementation calls on governments to "enhance corporate environmental and social responsibility and accountability" by, inter alia "encourag[ing] industry to improve social and environmental performance through voluntary initiatives, including environmental management systems, codes of conduct, certification and public reporting on environmental and social issues." This clarion call reflects an enormous groundswell of recognition of the potential effectiveness of "soft law" processes through non-governmental organizations (NGOs and commercial entities) to achieve social and environmentally desired objectives where governments and more formal systems cannot (whether due to legal limitations on governmental activity, shortages of capacity or funding, or other factors).[56]

To date, however, such systems have shown only limited results. Some of the most effective systems are those relating to the certification of forest and marine products – both of which ultimately result in consumer products that are easily identified. If forest-product certification (or marine-product certification) is generally accepted and supported by consumers, it will be relatively easy for each consumer to know in general whether each product he purchases contains wood or other forest products (or fish or other marine products) and to look for a certificate or labeling.[57]

In general, systems for certification of social responsibility and sustainable development can function effectively only where three factors work in combination:

- The system must inexorably ensure that the benefits tied to certification are available *only* to those companies and products that meet the certification standards;

- The benefits must be real (for example, where the benefit is increased price or market share, consumers or other market participants must have an actual preference for certified products for which they are willing to pay a premium or change their purchasing practices);[58] and

- There must be some means of confirmation and enforcement – to ensure that certification is not used falsely. This factor is frequently satisfied through a combination of a non-governmental

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[56] ISO SAG, 2004, and *see*, e.g., the (ISO) Stockholm Conference on Social Responsibility (sponsored by ISO and the Swedish Institute for Standards, 20-23 June 2004). Discussed in detail in Young, T. *An Examination of Environmental Uses of Certification Systems and Standards Development* (2004, publication forthcoming).

[57] Unfortunately, at present consumer acceptance of forest and marine product certification is stymied by the plethora of different certification systems governing these products. One can clearly recognize that a product is made of wood, but upon turning it over, might see any one of dozens of different certification labels. Consumers who care must undertake additional research to find out which labels are based on the kinds of standards the consumer wishes to support. *See* UNECE, "Forest Certification Updated for the UNECE Region," (2002) available online at http://www.unece.org/trade/timber/Welcome.html; FAO, Proceedings of FAO/GTZ/ITTO seminar "Building Confidence among Forest Certification Supporters" (2001); and Gunneberg, B., "Current Status and Experience of Co-operation and Efforts toward Mutual Recognition" (FAO 2001) both available online at http://www.fao.org/forestry/foris/webview/forestry2/

[58] These market factors may be of many kinds. Some key targets of certification might be bilateral environmental donor agencies, lenders and investors, as well as the ultimate purchasers of consumer products. *See* "An Examination of Environmental Certification..." (note 54) at page 17.

registry (of those qualified to label their products, or whose operations are certified) and governmental oversight and enforcement of basic laws on misrepresentation and those protecting consumers from false statements about the products they purchase.

Some of the most recent situations in which voluntary certification has been applied in social responsibility contexts involve a different combination of governmental and private action. For example, the Republic of South Africa has enacted a number of laws that require rather high levels of positive social action by companies.[59] Companies have discretion regarding the specific nature of such actions, on which their business or operational licenses depend.

4.1.2.7 Certificate systems that create valuable rights

One final type of certificate system that must be considered is the creation of valuable or tradable rights on the basis of a closed permit system. This concept is already functional in some countries in the form of "tradable development rights" and tradable air emissions credits.[60] In addition, conservation economics theorists are discussing its possible use in contexts such as protected areas, and wetlands.[61]

To provide just one example, in some countries, a company seeking permission to operate must meet air pollution standards, and in this process receives a specific permit specifying the annual volume of air emissions that can be allowed from its facilities. If the company later finds ways of reducing those emissions, it can receive a certificate that allows them to obtain value from the reduction, either by using the "saved" emission rights in another facility (making that facility larger than its existing air rights would allow), or by trading (selling) those rights to another company. In the latter instance, the government still maintains oversight, since emission rights transaction must be recorded in order for the buyer to be able to utilize the acquired credits. The system supports air pollution goals by providing that any use of credits will include a percentage reduction in the total amount of emissions involved, so that if for example a company cuts emissions at facility 1 to 200 tons below the permitted level, it will be allowed to develop additional operations that emit not more than 150 tons of the same pollutants within the same air quality region.[62]

While not precisely relevant to ABS, this system is important in its design element - the certificate system actually created a valuable and tradable commodity, literally "out of thin air." Arguably, to the extent that these credits have value, it is because (1) the permit system is fully enforced by governmental agencies and inspections; and (2) it is virtually impossible to evade such inspections (an operating facility is difficult to hide) so that the system is also completely pervasive. In such a case, commercial entities take advantage of any opportunity to lower their costs of compliance with air requirements.

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59 *See*, generally, Rockey, V., 2001, *The CSI Handbook* (2001. Trialogue.) Confirmed through personal communication, Paul Kapelus, African Institute for Corporate Citizenship, May 2004.

60 A variety of such systems exist. *See*, for example, Johl, C., 1997, "Designing Environmental Policies for India: The Use of Market Incentives to Combat Pollution" 9 Geo. Int'l Envtl. L. Rev. at page 707; Johnson, S. and D.M. Pekelney, "Economic Assessment of the Regional Clean Air Incentives Market" 72 *Land Econ*. 281 (1996). The most developed example is found in the U.S. Clean Air Act, 42 US Code §§ 7401, *et seq.*, variously implemented by separate administrative structures at the state level in all 50 states.

61 This kind of "environmental trading" system is currently receiving much attention as a possible mechanism for conservation. *See* Bishop, J. *et al.*, 2005, *Biodiversity Offsets: Views, Experience and the Business Case* (IUCN Economics, Gland/Cambridge). Although the economic and practical benefits of offsets are currently heavily skewed toward business participants, discussions in forums like the CBD suggest that significant changes and development will occur relating to this issue in the future, after which it may have a major positive impact on conservation. Without waiting to resolve the underlying conundrums (such as whether offsets result in set-asides of only the least accessible, attractive or threatened lands), offset systems are already in existence in some developed countries, and under the Kyoto Protocol.

62 The figures are simply provided for ease of understanding. The actual system is relatively complex, well beyond anything that should be discussed in the chapter.

4.2 Applying the lessons from other certificate and registry systems to CSOLP development

The lessons from these various types of certificate and registry systems can be very important for the process of developing a CSOLP. Of course, until the specific contents and mechanisms of the international regime on ABS have been decided, it would be impossible to choose any particular example as an obvious basis or specific roadmap for a CSOLP. However, these systems demonstrate that it will not be sufficient to simply list the information that should be included in the certificate or the processes for which the certificate would be required. Rather, it is necessary to consider the entire framework of information, action and oversight of which the CSOLP will be a part – a system which includes commercial and other actions and laws, far beyond the confines of ABS and IPR laws and institutions. The following discussion briefly applies some of the basic lessons learned in Part I to some facets of the ABS regime, depending on how that regime is conceived and implemented. It focuses on current proposals for CSOLP use, but also offers some additional ideas about how a CSOLP might be used.

4.2.1 Registry of genetic resource rights and transfers

To many people discussing the CSOLP idea, ABS certificate systems are expected to serve as basic registries of ownership of a new kind of property interest – genetic resources.[63] In this case, the grant of such a certificate would confirm two things: First, that the agency owns or is authorized to transfer the specified rights to use the particular genetic resources (and has complied with all requirements related to that transfer); and second, that the recipient has done or committed to do all other acts necessary to acquire such rights. In this case, the certificate system must be directed at clarifying the nature of the property right involved (what is a "genetic resource" and how is it owned?) as well as specifying the actions needed to qualify an applicant for a certificate of the right to use GR.

Basic components of a registry system:
In this aspect, the CSOLP will be similar to national property registries and the process of recording property transactions, as discussed. Applying the lessons of these registry systems to the CSOLP proposals as a registry of GR transactions, the challenges are:

- Creating a system in which both the user and the source have a direct interest in ensuring that the CSOLP is obtained and filed, and ensuring that this interlinkage cannot be avoided and is sufficiently valuable to outweigh the cost of obtaining a CSOLP (and the risks of providing the CSOLP information to a public database); and

- Finding a way to ensure that costs of accessing and obtaining a systematic report of all database information is not a bar to providers seeking to use the registry to monitor the status of transferred genetic resources.

Enforcing registration mandates:
The registry approach to CSOLP may also utilize elements of the mandatory registration systems (vehicle registration, customs control and tax/draft registries) which operate primarily through legal mandates. Here the primary question is one of the costs and opportunities for enforcement. In all such systems, two obvious systemic factors are necessary:

- A clear possibility of apprehension, whether through "choke points," (customs systems) or through an enforcement network; and

- An objective basis for officials to determine whether the apprehended person is violating the law.

[63] The impact of this heretofore undiscussed fact is further examined in Book 5 in this Series – Young, T., Covering ABS: Addressing the Need for Sectoral, Geographical, Legal and International Integration in Implementing the ABS Regime (IUCN, ABS Series).

Thus, for example, an observable fact (the possession of controlled substances, driving a vehicle on public streets, or being above the legal age) can be linked to the presence or absence of the relevant document or registration. Lacking the documents, the individual is cited. If he has some explanation or justification, he must "save it for the court."

However, there is another, less obvious requirement that is critical to the success of mandatory permit or registration systems – *the choke points and mandatory enforcement must be directly and irrevocably linked to the violation itself.* For example, in most countries (except perhaps small islands), it is not appropriate to rely on customs controls as the primary or only method of policing vehicle registration requirements. One may violate that law (drive an unlicensed vehicle) for his entire life without ever passing customs controls. People passing through customs may not be driving any vehicle or may simply avoid driving an unlicensed one. Even if bringing such a vehicle into the country, they may claim that they do not intend to drive it on public roads, so that no registration may be needed. While it is easy to identify choke points at random, it will be important in creating the CSOLP that both the choke point and the facts of the violation are not directly relevant to ABS compliance.[64]

Verification elements of a registry:
Finally, a registry of genetic resource transactions will have to be based on validated data, because it will require the provision of two kinds of information – scientific information regarding the genetic materials and their source, and non-scientific information regarding the status of government approvals and contractual rights granted in another country. Without these, the certificate will provide no assurance to the parties (whoever draws the certificate can say whatever he wants), or in the alternative, it will require any agency or individual relying on the CSOLP to verify the statements in the certificate. Lessons from verification systems suggest that if the certificate calls for external verification, it will be necessary to

- establish uniform and detailed standards on which the verification can be based; and
- develop some system for ensuring (without waiting for discovery of wrongdoing) that those providing verification (bioassays, and confirmation of legal status) operate within the standards.

As noted above, even in more conventional transactions and certification, the notarization and verification of documents, and possibilities of falsification are typically seen as the primary weakness in transactional and property registries, including international systems such as the CITES register of permits. Authorization and registration of experts and professional service providers are not self-enforcing systems, and must be addressed.

4.2.2 Integration of the CSOLP into the genetic resource market

The primary group of suggestions for the CSOLP envisions it as a tool within the more general commercial markets involving products of the utilization of genetic resources. These proposals (including the proposals for patent-application disclosures and other kinds of "disclosure of origin") recognize that commercial entities are more attuned to commercial requirements and laws, and that environmental laws are most effective when they are directly integrated into laws governing commercial operations.

Environmental requirements can be integrated into markets in many ways. For example, the air emissions permit system's effectiveness is not a function of the contents or testability of the certificate (although these factors are important), or of the requirement that all facilities obtain a permit. Rather it depends on the integration of the permit into the body of commercial law affecting industrial facilities. It is not possible to operate a facility without a permit, nor to hide a facility from normal view. No rational purchaser of an industrial facility (or of shares in a company that

[64] Of course, it is common for customs officers to confirm the registration status of all vehicles that are brought into or taken out of the country. However, this is not the primary mechanism for enforcing vehicle ID requirements.

owns a facility) would agree to the purchase unless he is certain that the relevant permit exists in good standing. The system of permits/documentation for the movement and disposal of hazardous materials operates in the same way – it is in the best interests of all persons along the chain to require proof that documentation has been prepared and is correct and official.

"Optional" provisions, too, can be effective if they are integrated into markets. Stock and commodity markets and other protections from market abuses are often completely optional, in the sense that the parties may still engage in essentially similar kinds of commerce, even if they choose not to participate in the formal market. However, the protections and access provided by the formal market are commercially attractive to the parties. Markets that flourish outside of formally controlled systems usually do so either (i) through the mutual consent of both buyer and seller, or (ii) due to pressure from one side of the transaction, where that party is so strongly in control of the transaction that persons on the other side have no choice. It is generally felt that governmental intervention (by creating a formal and transparent market and protecting those who prefer to utilize it from undue pressure) is a duty owed by the sovereign to its citizens.[65]

A CSOLP could be developed in a manner of a closed-market regulatory system. With fewer than 250 countries in the world, and a relatively small number of companies working commercially in some key genetic resource fields, a separate formal market could be developed, offering certainty and security for all parties to the ABS arrangement. This approach might offer ways to address the need for transparency, standards of valuation, and a registry providing open information regarding each participant's record of compliance with their respective responsibilities under ABS arrangements. Market regulation systems often focus on the parties themselves, certifying them to participate in the regulated transactions (membership serving as certification), and requiring various disclosures and reports as conditions of such certification. Both the membership roles (including the public components of the reports and disclosures), as well as documentation of the regulated transactions, may be retained in accessible/searchable registries. These provisions can be integrated with other systems, similar to the general regulatory certificate systems currently used for dangerous goods or other governmental assessments.

4.3 Mechanics of developing a certificate system

A systematic consideration of certificate and registry systems indicates that they share some very specific characteristics, at the level of agreed policy and legal implementation. Whichever type of system is used, these characteristics are the factors that determine whether and to what extent a certificate system can be functional and valuable:

- Clear and agreed decisions about: what the document certifies, and how it will be used;
- Objective standards including identification of performances or conditions that are necessary and sufficient for the certificate to be granted;
- Legal procedures defining the point at which the contents and issuance of the certificate can no longer be challenged;
- Clear indicators that enable the certificate to reliably communicate to third parties when and how the certificate was granted;
- Primary logistics (the nature of the certificate itself) and some means by which such third parties can verify its validity.

The following discussion considers these factors, in terms of the needs of the ABS system and proposals for a CSOLP.

[65] Uncontrolled and abusive markets still exist, even in the most developed and intensively regulated commercial systems. Market abuses in the agricultural sector of the United States, for example, are documented in Schlosser, E., *Fast Food Nation*, at chapters 5 and 7 (Penguin, 2002).

4.3.1 Exact rights that are to be covered by the certificate

Prior to 1992, the words "genetic resources" did not have any legal meaning, nor did they describe any legally recognized property interest. Given the minimalist approach of the CBD in using, discussing and defining this term, the exact nature of "genetic resources" is still not entirely clear. Hence, clarifying this concept, and also developing practical concepts for its implementation remain the primary threshold needs of the international negotiations. This decision will be a critical prerequisite to any decision regarding the coverage of the certificate as well,[66] since the validity and effectiveness of a CSOLP system will turn on how it addresses the particular property or right which is defined by the international regime. In particular, the challenge of this element will be to determine how these particular items or rights can be consistently identified, and how any tracing or registry can effectively control regulated actions involving them.

Even after the meaning of "genetic resources" is agreed, however, the exact nature of the certificate – e.g., "What (specifically) will be certified?" – will remain as the primary question to be decided by the CSOLP. Numerous CSOLP discussions already have begun, based on particular assumptions about the nature of the right to be described in the certificate. In some proposals, the certificate is to address the "genetic resources" themselves. These approaches generally assume that the CSOLP will apply to physical samples collected and taken from the source country.[67] In other analyses, the certificate will be proof of a right to use particular resources and information (e.g., the genetic information and biochemical formulas of the species or variety).[68]

To a large extent, the selection of what to certify depends on the role that certification serves in the ABS regime. Obviously, the certificate will not be a complete answer to the complex problem of regulating ABS, but must be a tool for accomplishing, documenting or permitting key activities at a key point or points in the process.

For example, certifying the provenance of collected material would be an appropriate approach to the objective of regularizing actions of bioprospectors. One key reason to create a certificate that focused on collection in the source country would be to give the certified collector a basis for defending himself against lawsuits by NGOs, traditional communities and others who claim that the bioprospector violated the source country's laws. Issuance of the certificate may also cut off the source country's future ability to claim that the bioprospector's actions were illegal and to use that illegality as a basis for invalidating the user's rights in the genetic resources of the collected material.

Notably, however, a certificate that focuses on in-country collected material would be difficult to apply to users who obtain extracts, progeny or other products of multiplication of the original sample, nor would it be useful in addressing resources that were not collected using ABS permissions. For this purpose, a certificate that addresses the user's right to use genetic resources might be preferred.

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66 As further discussed in Books 2 and 5 of this Series, clarification of the exact nature of "genetic resources" will in turn enable agreement on consistent understandings of "access to genetic resources" and "utilization of genetic resources," as well as determining if there is a need for a term such as "derivative" or whether any use of the genetic information (including in the development of synthetic copies and products) is included within the notion of "utilization of genetic resources."

67 Various presentations and discussions on this issue were offered in a "Roundtable on the Practicality, Feasibility and Costs of a Certificate of Origin" (9-10 November 2004), however, no record of the proceedings, discussions or presentations in this meeting is available online.

68 This approach has been discussed in a variety of papers, as summarized in Book 2 of this Series, Tvedt, M.W. and T. Young, *Beyond Access* (full citation in endnote 4).

4.3.2 Purpose and use: What the certificate can prove

No matter how it is configured, the certificate cannot be a complete shield for or against its holder. Like any other kind of property, genetic resources may spawn a variety of legal claims. The certificate can only be a protection against a few types of claims. Hence, a key factor in the CSOLP will be its selection of the kinds of protection it does and does not offer to both the issuer and the applicant. For example, it may be necessary to provide options regarding the scope of each certificate, similar to the different types of property interests (full ownership, leases, easements, loan security interests, rights of entry) certified by national property registries. In addition, in practice different kinds of genetic resource utilization may require different types or levels of certificates, and may apply those certificates in different ways.

This issue, too, depends on the objectives that the CSOLP is designed to fulfill, and the specific mechanisms chosen by the regime negotiations to address this objective, and the particular points at which the certificate will be used. As shown by other certificate systems, certificates can be used at many different points in the regulated stream of activity – to validate and oversee transaction participants, document compliance with standards, verify the contents or authenticity of an item, provide a permission for an action that would otherwise be illegal and restrained, provide proof of compliance with legal requirements, certify special qualities, or qualify for a particular benefit. The CSOLP could be designed to serve any (or more than one) of these qualities.

Selection among these options depends to a large extent on the nature of right that the CSOLP holder can claim. Specifically:

- whether the certificate provides an exclusive right to use the GR of the species obtained or is simply a right to use it along with any other applicant who obtains the right to use the same species or group of species;
- whether the right applies to all possible research areas or only a specific category (pharmaceutical, agricultural);
- whether the right applies to all uses or is restricted regarding the purposes of such use (i.e. forbidding use for the development of biological weapons); and
- perhaps most important, whether the right is transferable, and if so, whether there are limits or requirements imposed on transfers.

Each of these options may limit various uses of the CSOLP, as well as its value to user, to source country or community, and to user country.

4.3.3 Compliance issues - what motivates a user to obtain a CSOLP?

As demonstrated by Part I of this Chapter, the most critical factor governing success or failure of the CSOLP (and the ABS regime entirely) relates to motivation of compliance. Even if the certificate focuses only on specimens collected within the source country, it will be nearly impossible to enforce solely through legal mandates. Beyond this, however, many users do not collect specimens in developing countries, preferring to obtain their resources in ways that are both safer and less public.[69] Moreover, there are indications that companies may be able to utilize genetic resources without having access to the specimen itself – that is, the sole inputs from the species consist of genetic sequences or biochemical formulas which can be expressed in writing or diagrams, and transferred on paper or electronically.

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[69] In some cases, the decision to stop engaging in direct on-site bioprospecting was based on concerns about potentially becoming embroiled in a claim of biopiracy or misappropriation. Companies noted that their field work was, to some extent, offered as a "reward" for laboratory researchers in their facilities, and have discontinued this practice, in favor of safer methods of obtaining genetic material – through researchers and other collections. Although it is not clear that this method avoids ABS responsibilities from a legal perspective, it clearly avoids exposure to potential claims (because the claimants will probably not know about these post-access transactions). *See* IUCN Canada, "Analysis of Claims..." (full citation in footnote 5).

As a consequence, the CSOLP development process must at least consider that it may not be possible to *compel* users to comply with the certificate requirements or any other component of ABS regulation. (As any traffic control official knows, where the law mandates an action (staying under the speed limit) that many people do not want to comply with, it is very difficult and expensive to police *everyone* or to prevent *all* or even most violations.[70])

For this reason, this chapter has earlier concluded that it will be necessary to design the system so that the user has a compelling reason to comply. Such reasons must be credible. This means, for example, that the designers should not presume that the avoidance of violation provides a reason for compliance, given that there is no clear record of any post-access apprehension of a user who has successfully been either penalized or forced to share benefits. Instead, it will be necessary to design the system to create positive benefits which are inexorably linked to compliance. A variety of such benefits have been suggested, however, at present, there is no experience which indicates a way to bind these benefits to compliance or to obtaining the CSOLP. The author is aware of four possible linkages, including two which have been regularly suggested for several years:

Requirements at the time of patenting

- In several proposals, it has been suggested that the user of genetic resources could be required to provide a valid CSOLP (or a publicly recorded disclosure of the origin or provenance of genetic resources used) at the time he applies for a patent of his product or invention.[71] Numerous points have been made suggesting reasons that this may not be an appropriate choke point at which undocumented uses or misappropriations could be apprehended.[72] It has become clear that there is a need for additional study before making this recommendation more concretely.[73] Nonetheless, a few laws have been adopted or proposed that specifically allow the voluntary disclosure of source within patent applications.[74]

For purposes of this chapter, however, the author notes that such a disclosure, even if mandatory, can be easily avoided at present, with little or no risk to the user. Patent authorities do not (cannot) routinely check all patented products to see if they appear to be based on natural biological material. This means that the only way a patent will be known to contain such material is if the applicant says so. Moreover, the question of source remains unclear. Until the international regime makes a clear decision regarding the basic concepts of "genetic resources" and origin,[75] the applicant can avoid any mention of foreign origin of the specimen or its immediate

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70 Similar experiences are found in natural resources management, where the law frequently prohibits activities such as unpermitted felling of valuable trees. As noted by forest officials in Trinidad and Tobago, the problem with such laws is that "it is not possible to post a guard around every tree." *See*, e.g., TRINIDAD AND TOBAGO, Report of the Advisory team, 1994, Evaluation and Institutional Development: Management of Commercial Forest Plantation Resources and Management in Trinidad and Tobago (FAO, Rome and Port of Spain).

71 CBD COP Decision VI/24, UNEP/CBD/COP/6/24, para. C.1 and *see* Bonn Guidelines Art. 16(d)(ii). In para C.2, Parties were similarly urged to "encourage the disclosure of origin of relevant traditional knowledge, innovations and practices ... in applications for intellectual property rights, where the subject matter of the application concerns or makes use of such knowledge."

72 Registries have been suggested as a means to facilitate patent-based disclosure of source of traditional knowledge. This approach is examined in more detail in Mgbeoji, I. Pre-emptive Defensive Patents, Indigenous Knowledge and Biological Diversity: Expanding the Frontiers of the International Patent System for a Sustainable Environment (loose-leaf, 2001); and Patents and Plants: Rethinking the Role of International Law in Relation to the Appropriation of Traditional Knowledge of the Uses of Plants. (Dalhousie University, 2001); Lesser, W., Sustainable Use of Genetic Resources Under the Convention on Biological Diversity: Exploring Access and Benefit-sharing Issues (CAB Intl, Oxford, 1997) at p.129.

73 *See*, e.g. the Report of the 2nd Meeting of the Ad-hoc Open-ended Working Group on ABS (UNEP CBD/COP/7/6 (2003) Recommendation, para g (page 26).

74 European Commission, Directive 98/44 [on the legal protection of biotechnological inventions], Recital 27 ("if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographic origin of such material if known.") This non-binding provision underscores its completely optional nature by specifically stating that it is "without prejudice to the processing of patent applications or the validity of rights arising from granted patents." A few other countries (Sweden, Norway, Romania) have indicated that they have adopted or are in process of adopting similar voluntary disclosure provisions.

75 Questions to be addressed should include, for example, whether the person utilizing the genetic resources must list as his source the individual/institution/location from which he acquired the specific samples used, or must trace back to a "country of origin" from which someone

ancestors, simply saying that original biological samples were acquired from a collection, garden or other location within the user country, or that they were collected before the commencement of the convention.[76] Lacking scientific capability to verify the geographic origin of any specimen or genetic sequence, the patenting system again must rest on the applicant's willingness voluntarily to disclose origin.

- ***Requirements at the time of trans-border movement.*** As noted above, it is entirely possible for a biological specimen to move across boundaries before it is converted (by sale or a change in the holder's intent) into a genetic resource. Moreover, a system that depends on international movement as the choke point for regulation may be very difficult to apply to domestic utilization of genetic resources – a process that may need to be regulated or registered in order to ensure that there are no loopholes in control of trans-border situations. The challenges of selecting a border-control approach are (i) ensuring that it does not prevent other mechanisms to address users and biological specimens that do not cross national boundaries with the label "genetic resources"; and (ii) creating a reason that the person who transports a biological specimen (and those who acquire it further down the ownership chain) will want to know about and comply with restrictions in onward transfer of the material.
- ***Requirements at the time of commercialization.*** Recognizing that many kinds of utilization of genetic resources may not involve patenting, it is possible that a CSOLP could be required before any product (or category of products) that was developed utilizing genetic resources may be placed on the market in any country or imported for commercial purposes. This approach suggests a possible benefit – the right to commercialize the product – that might not exist without government approval. While this may not always result in a direct benefit to that country of import, it might constitute a partial "choke point," resulting in an overall increase in the number of benefits paid, if a large number of countries imposed the same request.[77]

- ***Requirements imposed on certain industries and users.*** Another possible approach has been suggested, based on the identification of particular user industries that are most directly involved in the utilization of genetic resources.[78] This approach has been used in law, where it is not feasible to attempt to identify particular companies, but where certain industrial categories are known to have been well involved in the activities under scrutiny.[79]

in the chain of acquisition and regeneration acquired the initial biological specimens. Another such question is when the biological sample is deemed "accessed" for these purposes. If biological specimens may be collected without triggering ABS requirements, it will be necessary to define a particular time at which those specimens convert (by virtue of use or intent) from being biological specimens to being "genetic resources." A third such point is the question of when and how the property interest in "genetic resources" came into being. As noted, there was no legal statement of this concept until 1992 when it was included in the CBD. This leaves open the question of whether and how any entity that acquired a biological sample prior to 1992 could be thought to have also acquired the right to utilize its genetic resources. It is at least arguable that material collected prior to the Convention was a "biological resource" only – and that no "genetic resource" was thereby acquired.

76 The CBD seems to exclude situations in which genetic resources were acquired prior to 1992, however, since there was no legal process for acquiring natural resources prior to the adoption of Article 15, most persons who took biological material across boundaries before 1992 would probably be considered to have a right to possess the "biological specimen," but not a right to its "genetic resources." Presumably, however, the pre-1992 exclusion would apply where one utilized genetic resources prior to that date. (This issue is discussed in greater detail in Book 5 of this Series.)

77 The author notes that such a requirement will need to be carefully created and applied to avoid conflict with restrictions imposed on governments under international trade agreements. These matters have not been comprehensively examined, as yet, however they are treated in Book 2 in this Series –Tvedt, M.W. and T. Young, *Beyond Access* (in endnote 4).

78 This proposal of Dr Morten Walløe-Tvedt was originally presented in the Norway-South Africa ABS International Expert Workshop on Access to Genetic Resources and Benefit Sharing (20-23 September 2005, Cape Town, South Africa). It has since been refined and included as part of the proposals and conclusions in Book 2 in this Series – Tvedt, M.W. and T. Young, *Beyond Access* (endnote 4).

79 *See*, for example, UNITED STATES, Comprehensive Response Compensation and Liability Act, 42 United States Code § 9611(a), creating a fund (the "Superfund") to pay for hazardous waste cleanup when the companies or individuals responsible for the original contamination are no longer available to bear this responsibility. The Superfund is capitalized by a tax on all businesses within certain operational categories (those categories which use and have used significant amounts of hazardous materials, or generated significant amounts of hazardous wastes).

As yet, none of these options have been thoroughly canvassed or developed. In all of these cases, the system will function effectively if the user is willing to disclose, regardless of whether the legal provision is "mandatory" or voluntary. Given that profit-making entities may be discouraged from taking unnecessary actions that decrease their profits, and have many potential justifications for choosing not to make disclosures under the ABS system as it currently appears, it will be necessary to find ways to tie the acquisition of a CSOLP to serious functional incentives – benefits that derive from compliance with the CSOLP requirements, that are sufficient in value and relevance that they will counterbalance the costs of ABS compliance, thereby encouraging users to seek a valid CSOLP.

4.3.4 Verification problems: Asssuring the currency and accuracy of the CSOLP

One of the assumptions underlying many of the CSOLP proposals is the idea that the certificate itself will constitute proof of the facts stated in it. Even where the proposal merely calls for a "disclosure" by the user, it is expected that some verification will occur (either by the patent officer or by forwarding the application to the relevant country to confirm its contents). It is relatively easy to see many potential challenges arising from the need for verification:

- The need for careful standardizing of the details of the certificate (so that all facts within it can be verified by objective means);
- The need to confirm the scientific factors regarding the species and its origin;
- The need to confirm the identity and authorization of all persons connected with the certificate, and the validity of all related documents;
- Questions regarding access to the database(s) in which this material is maintained;
- Concerns about the oversight and accreditation or authorization of the issuers of such certificates and other experts; and
- Documentation of the "chain of evidence" by which an expert knows that the material and documents he is certifying have not been manipulated in any way.

These verification requirements are not indications that government distrusts either its officials, its experts or the users. Rather, they are ways of protecting users from later claims of violation or "biopiracy" by proving the effectiveness and security of the certificate system. Each of these requirements presents a significant challenge, but generally they should not be insurmountable once other questions regarding the objectives, nature and scope of the CSOLP have been agreed.

There is, however, one other, more difficult, verification challenge for the CSOLP, arising from the longevity of the certificate. Once the certificate is granted, it would appear to be permanent, unless some cause for revocation is given. However, many things might change in the future, including matters as basic as the transfer of the material, a move of the user's operation to a different "user country," a change in the proposed use, or some change in the source's ABS law which alters the user's rights and with which the user refuses to comply. The certificate verification system (particularly any system for reconfirming certificate validity each time the certificate is presented by the user) cannot ignore this possibility, but at the same time must protect the user from random revocations.

4.3.5 When is the certificate "final" (unchallengeable)?

The right granted by a certificate can only be valuable only after it is clear that the decision to grant the certificate and the statements made in it are final and cannot be changed by claims or appeals of third parties. This issue arises in a variety of ways. It is useful to begin by remembering the processes of conventional property law. Once the basic formalities and searches are completed, the transaction is final, unless there is a later proof of criminal behavior (fraud or an attempt to use the transaction as a way of hiding illegally obtained money). This is possible because of the extremely objective nature of the sale process. If the seller's identity is proven, and his title to the property is unblemished, then his signature on the deed automatically transfers the property.

In transfers of GR, however, there are difficulties that must be clarified in order to enable the CSOLP to function in this way. Often, constitutional or other law gives citizens rights to challenge or overturn governmental decisions - rights that could be applied to the decision to approve an ABS transaction or to grant a CSOLP. It may be difficult for a certificate to be "final" unless the system addresses these rights of third party challenge. At the national level, this difficulty is exacerbated by the relationship between genetic resource utilization and the utilization of genetic-resource-related traditional knowledge. Until the rights of local residents and traditional knowledge holders are concretely specified (including some clear delineation of the nature and time limitations on their right to challenge a permit issuance decision), it will be difficult to verify that a permit creates a final legally certain right, in which time, money and other investment can be made.[80]

4.3.6 Balancing the needs of users, providers and regulators

The need for both sides of the ABS transaction to have appropriate legal protection and legal certainty suggest that it will be very important to carefully and clearly identify the outside limits of the scope of the CSOLP. The objective of giving legal certainty to the user of genetic resources must be balanced against the need to ensure that the source country's rights are appropriately protected and exercisable.[81] To this end, one of the most significant challenges will be to create mechanisms that can substitute for specific property identification (given that it is not possible to independently determine the source of particular specimens, genetic sequences or biochemical formulas by testing the specimens or products).

It is also notable that other parties also have an interest in (and needs regarding) the CSOLP system. One group of interested parties will be the other countries that also are countries of origin of the species covered by the permit. Although ABS provisions in the CBD are specifically limited to the "source country," there are many possible scenarios in which the exact source country cannot be discerned. Other countries of origin may wish to have access to CSOLP records to confirm that they are accurate regarding source. Similarly, holders of traditional knowledge, members of the public and NGOs may also call for transparency in these matters.

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[80] Another side of this issue, of great concern in the negotiations, is the need to know how long the certificate (and the ABS process) continues to apply. Currently, it is still not clear whether a person who obtains a user's GR-related product, and then uses that product in the development of another innovation will be required to share benefits with the source country.

[81] "Summary Analysis: Legal Certainty for Users of Genetic Resources under Existing Access and Benefit-sharing (ABS) Legislation and Policy," published as UNEP/CBD/ABS/3/INF/10 (3rd Ad-hoc Working Group on ABS, Bangkok, 2005) (reprinted in Book 5 in this Series – Young, T., *Covering ABS: Addressing the Need for Sectoral, Geographical, Legal and International Integration in the ABS Regime,* (IUCN, ABS Series)).

4.4 Conclusions: Developing and exploiting user motivations

In sum, the greatest challenge in integrating a tracking mechanism or CSOLP into the ABS regime will be the need to integrate clear commercial benefits and tie the system in with existing commercial systems in a way that creates a clear incentive for users to comply with the system requirements. Once those relationships have been created, the CSOLP can finally be configured as the tool that ties them all together.

In both the regime negotiation and national implementation, however, it will be important to avoid self-deception. Many of the supposed "benefits and incentives" that have been identified in the past as reasons to expect compliance with a CSOLP requirement have been the result of a high level of wishful thinking. Claims that a CSOLP will operate to provide a premium for holders or source countries, or legal certainty for users, or that it will facilitate trade or provide a public relations advantage in the marketing of the ultimate product are generally not supportable through logical analysis. Some of these benefits seem unlikely to exist, while the rest cannot be inexorably tied to the CSOLP.

The design challenge for proponents of the CSOLP is to create such inexorable ties, comparable to the factors that motivate compliance under other kinds of certificate, passport, or registration systems operating nationally and internationally in other sectors. Thus, an individual obtains a passport because he cannot cross national borders without one. Landowners register their purchase of land because the registration system protects them against false claims on their title. Automobile owners file a certificate when they sell their car because they will thereafter be protected if the new owner causes damage or injury with the car. A patent is filed to give the innovator affirmative protection for the value of the innovation – a protectable legal right that is useful or necessary in most negotiations for commercialization of the innovation. Customs declarations are filed without direct compulsion because the traveler knows that a certain percentage of random searches are carried out, leading to fines and jail sentences if undeclared goods or contraband are found.

In each of these instances, the protection is directly tied to the acquisition and use of the certificate or registry. One cannot obtain these benefits in any certain, legal way unless he registers, acquires the necessary certificate, or otherwise complies. Given the difficulty or impossibility of proving ABS non-compliance with scientific or analytical evidence, it appears that the motivations integrated into the ABS system will have to be oriented around the provision of benefits or desirable objectives, rather than the fear of apprehension and punishment.

5 A Proposal on International Audits to Track and Monitor Flows of Genetic Resources and Verify Compliance with ABS Agreements

Manuel Ruiz Muller and Isabel Lapeña[1]

Executive summary

Tracking and monitoring of genetic resources have only recently become issues of interest in the context of discussions regarding access to these resources and benefit sharing (ABS). This chapter suggests that these systems can be analyzed from two closely related perspectives. "Tracking" is part of the process of verifying how genetic resources and their derived products flow and move along the research and development chain (including collecting and product commercialization stages). It basically addresses the "physical" movement and use of these resources. "Monitoring" on the other hand, could be understood as verifying whether institutions are using genetic resources as originally stipulated in the corresponding access agreements (including Material Transfer Agreements (MTAs)) with the country of origin or provider.

This chapter looks at a few examples of tracking and monitoring for different purposes and highlights the recurrent concern over costs. It also refers briefly to the concept of certificates of origin/legal provenance and some of the key questions which should be posed in relation to their operation.

The central proposal put forward is the possibility of establishing an international audit system for tracking and monitoring international flows of genetic resources under the Convention on Biological Diversity (CBD) and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). This system would focus on evaluating compliance with access to genetic resources agreements (or MTAs given the case).

Clearly, reporting requirements, quite standard in all projects, are insufficient to guarantee that interests of countries of origin and providers are being appropriately met. An international audit system, which selects only a limited amount of projects worldwide and evaluates their performance in relation to the use being given to genetic resources (in accordance with the corresponding contract) could serve to either dissipate or confirm a series of concerns. This chapter argues that continuous and exhaustive tracking of resources and monitoring of contracts is costly, ineffective and extremely complex from a political point of view. More targeted tracking and monitoring (agreed by all Parties to the ITPGRFA and the CBD) may be a more realistic approach. Furthermore, these audits or valuations could be applied to a wide range and broad scope of projects - whether commercially or academically oriented.

Of all the different issues addressed by the Convention on Biological Diversity (CBD), access to genetic resources and benefit sharing (ABS) has probably been – and continues to be – the most contested and disputed. Control and rights over genetic resources and their derived products, have been and remain at the core of ABS-related policy, legal and economic discussions (Caillaux 1996).

To address the issue of control of and rights in genetic

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resources, more than a dozen ABS laws have been enacted and are currently in force in different countries and regions of the world, and a similar number of drafts are at some stage of development in many others.[2] These laws and policies derive in turn from a new paradigm: regulated albeit facilitated access, *vis à vis* free access based on the common heritage of mankind principle (from the pre-CBD era).

International guidelines (Bonn Guidelines on Access to Genetic Resources and Benefit Sharing, 2002) and even a global binding agreement (FAO International Treaty on Plant Genetic Resources for Food and Agriculture, 2001), have also been developed to address and cover some aspects of ABS and a wide range of related issues. Sectoral guidelines and institutional policies of, for example, *ex-situ* centers (microbial collections, botanic gardens, etc.) are also part of this complex structure of ABS provisions worldwide. All of these legal instruments are part of the international policy and legal framework on ABS. The focus of these laws, draft laws, regulations, guidelines, and the ITPGRFA, as well as CBD Article 15 itself, is to regulate conditions under which genetic resources can be accessed from *in-situ* and *ex-situ* sources and, subsequently used for conservation and research in many areas, including for commercially intended research and development.

Without exception, a common feature among these laws and instruments is a bilateral approach to negotiating conditions on ABS. Contracts are the tool of choice to legally bind applicants and users with the country of origin (represented by a national competent authority) and/or the physical provider of genetic resources. These contracts generally include a series of obligations imposed on users of genetic resources as a means to safeguard the rights and interests of countries of origin and providers of genetic resources. In a way, this approach is a natural progression from and reaction to the pre-CBD open access/common heritage paradigm, and to the post-1992 explicit recognition of the sovereign right of countries to decide how and under what conditions their natural resources – including genetic resources – can be utilized (Glowka *et al.* 1994).

Until recently, however, the primary focus of work in this area has been on the questions of "regulation" without giving particular attention to the means of ensuring that the regulations have an impact on actual genetic resource development activities. Furthermore, over the past few years there has been growing consensus among countries (especially among the Group of Like-Minded Megadiverse Countries[3]) that, unless there is coordinated and concerted action taken by countries of origin (or countries and institutions providing genetic resources) and countries and institutions using genetic resources, the effectiveness of ABS laws and instruments and contracts in particular will be limited.[4]

As is frequently noted, it is impossible in practice to police and control physical access to genetic resources as may be the case for other natural resources such as minerals, oil or timber. Reasons for this are varied and include: size and amount of biological materials required to undertake research and development activities; existence of *ex-situ* facilities which hold important collections of genetic resources and in most cases claim property over accessions; very complex legal agreements and arrangements between researchers, universities, companies in developing and developed countries alike (many times confidential); among others. It is also extremely complicated for countries and institutions to track and monitor genetic

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2 Countries with ABS legislation in place include Bolivia, Brazil, Colombia, Costa Rica, Ecuador, India, Peru, Philippines, Nepal and Venezuela. The Organization of African Unity (formed by 53 African States) also has a model law on ABS in place. Drafts have been developed and are at different levels of political discussion in Argentina, Chile, Madagascar, Malaysia, Mexico and Nicaragua, among others. For further details *see*: Carrizosa *et al.* 2004.

3 The Group of Like Minded Megadiverse Countries was formed in February 2002 in Cancún, Mexico. The Group at present comprises: Brazil, Bolivia, China, Colombia, Costa Rica, Ecuador, India, Indonesia, Kenya, Malaysia, Mexico, Peru, Philippines, South Africa and Venezuela. Its members hold almost 75% of the world's biodiversity in situ. The Cancún Declaration recognized the need for the "creation of an international regime to effectively promote and safeguard the fair and equitable sharing of benefits arising from the use of biodiversity and its components." The Cancún Declaration became the first formal call by countries in this regard.

4 For a detailed analysis of this position *see* Barber *et al.* 2003.

resources throughout the *in-situ* collecting, research and development stages and the chain of value-adding process.

Tracking and monitoring can be understood as two closely related processes. "Tracking" refers to following the movement of genetic resources (and their derived products) along the research and development chain, while "monitoring" refers to verifying that the uses being given to these resources and products are reflected in and are permitted by the original ABS contracts (or subsequent contracts) and national laws under which research and development are undertaken. Tracking may imply identifying what institutions are actually doing research on collected genetic resources. Monitoring may imply verifying if research by these institutions is permitted in the light of obligations assumed in ABS contracts or whether research has taken a totally different route than originally planned – and whether this is provided for in the ABS contract.

Even if technically possible (for example through the use of DNA technology, fingerprinting and molecular markers or more common project result reports), tracking and monitoring require time, resources, equipment and human resources and skills which may not be currently available in most developing countries. Most importantly, there needs to be commitment by countries and institutions providing and using resources alike. And in terms of cost-benefit-analysis, it seems that at least in the case of certain types of resources (genetic resources used in plant breeding), regularly tracking and monitoring the flow of these, would not be worth the effort (Visser *et al.* 2000).

As mentioned above, tracking and monitoring are very closely related to and make sense in the context of conditions and obligations agreed upon in contracts. Contracts imply usually four phases: negotiations, celebration (signing), execution and enforcement. Of these phases, enforcing contractual obligations becomes the most critical challenge as we move upwards in the value-adding chain and as original materials get broken up and transformed into isolated genes, proteins, DNA segments, molecules, even synthetic or semi-synthetic products. What was originally agreed upon in a contract may not apply or be relevant to future situations and products generated from genetic resources. Countries of origin or providers would have a harder time in demonstrating they actually provided these elements. The jurisdiction of courts, as resources and their transformed versions pass between different countries and institutions, poses yet another complex challenge.

To help overcome this situation, and the only seemingly viable option under discussion – at this time anyhow – an international certification of origin and legal provenance regime is being advocated to prevent misappropriation of resources (and related traditional knowledge) and to assist in tracking and monitoring the flow of genetic resources (Correa 2005; Barber *et al.* 2003). These tools may help countries of origin and especially source countries actually providing genetic resources to ensure that their legal rights (including sovereignty) and economic interests in genetic resources which are moving and flowing outside national jurisdictions and removed from any real possibility of control, are effectively protected. But for this idea to develop and operate, countries using genetic resources need to adopt measures which include and recognize certificates as a requirement and condition to commercialize certain products or, in some cases, as a condition for the granting of intellectual property rights.[5] User countries would also need to establish legal provisions which sanction third party illegal use of genetic resources as a means to support source country demands. The source country's interests would be additionally safeguarded if their right to demand benefit sharing and enforce this demand were addressed by the user country's legislation.

In very simple terms, source countries (countries physically providing genetic resources) are asking the fol-

[5] Some critics argue that certificates of origin or legal provenance will, ultimately, not serve the purpose of preventing misappropriation of genetic resources and traditional knowledge (*see* Dutfield 2005). However, it should be noted that certificates are not the solution but a solution to the problem of misappropriation. They are part of a package of measures oriented at supporting tracking, monitoring, compliance and enforcement efforts.

lowing two questions: (i) how can genetic resources be tracked, traced and monitored along the value-adding chain in the research and development process? and (ii) how can countries verify compliance with originally agreed conditions and requirements in an ABS contract? [6]

5.1 Tracking and monitoring in the context of the CBD and the ITPGRFA

The CBD makes no explicit reference to tracking or monitoring the flows of genetic resources. It does, however, provide the legal foundations for developing the certification of origin and legal provenance concept and thus, indirectly, justifies the calls for tracking and monitoring by countries of origin, as a means to verify compliance with ABS agreements. This is based on the accepted international principle that countries have common but differentiated responsibilities[7] with regard to the realization of the CBD objectives, one of which is benefit sharing. One way in which these differences become clear is when countries are identified as providers and as users of genetic resources.[8]

Article 15 (7) of the CBD establishes that each Contracting Party:

> *shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources [...].*

Article 15 (7) refers to each Contracting Party taking measures to ensure benefits arising from the use of genetic resources are fairly and equitably shared. This means an obligation on countries of origin providing genetic resources and countries receiving and using them alike. All countries must contribute – in different ways and using different policy, administrative and legal tools – in order to realize the benefit-sharing objective of the CBD. It is under this framework and logic that the idea of a certificate of origin and legal provenance has been developed over the last few years.

How would a certificate of origin, source, or legal provenance operate? A country of origin or source country providing genetic resources would issue the certificate and a country accessing and/or using these resources would request that the certificate be presented and provided at certain moments during the value-adding chain, for example, during a product approval procedure or during intellectual property application processes.[9] This would enable the ABS system to guarantee that legal formalities regarding access have been met. In some cases, it may also indicate that benefit sharing has taken place and in others, that it should take place through some sort of notification system.

Most proposals to date have centered on the use of certificates in the context of linking with intellectual property instruments. For example, in the Andean Community, prior to processing a patent application (especially in the case of biologically derived inven-

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6 Though policy makers and most analysts refer to "countries of origin," its use is problematic in the context of ABS if one takes into account a potentially common situation where there is an ABS Agreement in place and countries of origin who have the species but are not the source for the actual user start demanding rights and attacking a user who has a valid contract or agreement with a single source country. This paper will not address the even more complex issue of genetic information and its probable source, which may be a country which is not even a country of origin nor a source country of the physical material.

7 The Preamble of the CBD (*see*, for example, paragraphs 15, 16 and 17) provides a set of basic principles in which explicit differences are made between developed and developing countries (including particular reference to small island states). All countries share similar responsibilities in conserving biodiversity but not all have similar capacities to conserve biodiversity and sustainably use its components.

8 All countries are providers and users of genetic resources at the same time. However, some have historically been more providers or users than others. The North-South paradigm which influenced debates during the 70s and 80s responds to this feature of biodiversity-poor but technologically rich countries from those which are biodiversity-rich but with less technological capacities.

9 Most debates regarding certificates of origin and legal provenance have taken place around the issue of modifying disclosure requirements in intellectual property (especially patent) legislation. *See* IUCN. 2005. *The Complex Road towards Hong Kong: Proposals and Ideas to Move Forward in the CBD-TRIPS Relation Debates.* Gland: IUCN.

tions), the national IP authority has the right to request that evidence is provided regarding the legal origin of biological resources or traditional knowledge which may have been used in the invention under consideration.[10] Though the mechanism is in place, there is no reliable information as to how national IPR offices are implementing these provisions. This type of approach has been incorporated into several national policy processes and is under intensive discussion in the international arena in forums such as WIPO and WTO.

Even though the CBD does not specifically refer to tracking or monitoring of genetic resources *per se*, compliance with and enforcement of ABS contracts requires some type of mechanism which enables countries and institutions to exercise and enforce their rights. This will almost certainly require that these countries and institutions have precise information available regarding how their resources are being used and whether these uses coincide with contractual provisions originally stipulated. Tracking and monitoring could provide this type of information. Under the ITPGRFA on the other hand, and for very practical reasons, it was agreed that access should be facilitated expeditiously without the need to track individual accessions. However, there needs to be some practical way to verify what is being done with resources which have been accessed and are being used.

In the case of the ITPGRFA, which is based on a Multilateral System of [facilitated] Access and Benefit Sharing, unlike the CBD there is a specific reference to tracking. Article 12.3.b provides that access to plant genetic resources for food and agriculture (PGRFA), which are incorporated in a closed list, will be accorded expeditiously *"without the need to track individual accessions and free of charge ..."*.[11] This is an attempt to ensure the Multilateral System operates efficiently, with minimum burdens and low transaction costs associated with the movement and transfer of plant genetic resources of critical importance for food and agriculture (PGRFA).[12] The rationale behind this provision is to ensure that PGRFA continue to flow unimpaired for conservation purposes, and research and development-related activities.

Under the Multilateral System, Material Transfer Agreements (MTA) – standard contracts – are used to link providers with immediate and subsequent users of PGRFA. What article 12.3.b seems to imply is that holders of PGRFA are not required to track and monitor the flows of each and every material which has been accessed from the system. Tracking and monitoring would only be relevant – and may be needed – if there is a breach in and/or non-compliance with the terms and conditions imposed by the MTA (Moore *et al.* 2005). However, given that the ITPGRFA applies only to materials in the public domain and under the control of the State, there are many ways in which users may obtain materials from individual farmers, from non-member countries and even *ex-situ* collections. This poses a serious question in terms of incentives to comply with ITPGRFA rules and use the MTA as an instrument to define access and flow conditions.

In any case, the underlying idea is that, given the importance of interdependence between countries in regard to PGRFA, verifying movements and flows of every single seed or genetic resource used for conservation, research and breeding could seriously jeopardize these activities and, ultimately, affect food security worldwide. This implies a critical trade-off between the exercise of strong controls over access and use of genetic resources and the need to look for and ensure food security worldwide.

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[10] *See* Decision 486 of the Andean Community on a Common Regime on Industrial Property. Articles 3, 26(h), (i), 75(g)(h). Available at: http.//www.comunidadandina.org. For a conceptual analysis of this idea, *see* Correa 2005. Available at: http.//www.biopirateria.org

[11] During informal talks with some delegates and experts at ITPGRFA related meetings, they have expressed the view that this provision does not imply that source country cannot request some type of tracking to take place.

[12] For further details on the issue of transaction costs with regard to PGRFA, *see* Visser *et al.* 2000.

5.1.1 Ensuring compliance of ABS rules and principles

Tracking the flows of genetic resources could also be seen as a means of assisting in building some "teeth" into the CBD operations and the ABS international regime in particular.

In this regard, in the specific context of the ITPGRFA, countries recognized the importance of developing compliance mechanisms within the IT as a means of fulfilling the obligations and conditions set out in the standard MTA. For this purpose, the Governing Body at its first meeting will consider mechanisms and instruments to promote compliance including through monitoring and offering advice and assistance, especially to developing countries.

This will require consideration of mechanisms through which compliance of obligations of MTAs can be verified. At a minimum, this will also probably include specific reporting requirements, information exchange mechanisms regarding results of research on PGRFA obtained from the Multilateral System (through a clearing house) or through some valuation or audit mechanism (see also Chapter 2 for some initial thoughts on this idea).

In the context of the CBD, and as part of the process of negotiating an international regime on ABS, there are good reasons to speculate that compliance (in this case with ABS contracts) will become a key feature in these negotiations, just as compliance is a key component in the implementation process of the ITPGRFA.

As a background to this, paragraph (p) of point 15 of The Hague Ministerial Declaration of the Conference of the Parties of the CBD, urged governments to *"undertake adequate measures with respect to their international obligations, including through the development of mechanisms for assessment and review of implementation and the establishment of compliance regimes."* This will probably require a combination of measures including recognition of rights, definition of jurisdiction and pinpointing the location of genetic resources along the research and development process and its different contractually obliged actors.

Tracking and monitoring are not an end in themselves. They are a mechanism which could serve the specific purpose of ensuring countries of origin and providers legal interests in regard to the materials they supply, including interests related to the CBD objectives of benefit sharing.

5.2 Examples of tracking and monitoring: Alpacas, sharks and botanical research institutes

There are a few documented examples available of how countries and institutions are addressing tracking and monitoring, not so much in the area of following genetic resources *per se*, as in following the movements of certain plant and animal species (and derived materials). Technology, including microchips, the Geographical Positioning System, DNA markers, databases and the internet in general, are playing a very important role in enhancing the capacities of tracking and monitoring the movement and flows of endangered species. Having a detailed situational "picture" and a well founded, scientifically grounded, base line of data and information regarding the conservation and trade status of these species is critical in ensuring that sound policies and regulations are put into place and the appropriate control measures are imposed.

Peru is home to more than 90% of the world's alpaca (*Lama pacos*) population and a leading producer and exporter of alpaca wool (4000 tons per annum) – greatly appreciated in European, Japanese and North American fashion markets. Alpacas are also increasingly used as domestic pets in Europe and North America. Raising alpacas (vicuñas and llamas) provides the main income for small, poor rural communities living between 4,000 and 5,000 m above sea level in the Andes. Exportation of alpaca specimens is subject to strict controls and regulations in Peru - under the competence of the National Council for South American Camelids (CONACS).

To control and monitor the illegal movement and trade of alpacas across the borders with Chile and Bolivia, some of the best (genetically "clean") speci-

mens are implanted with a microchip which, with the aid of the Geographical Positioning System, enables national authorities to track and monitor their movement, especially across the Peruvian border with neighboring countries, which have also become exporters of alpaca, mostly of Peruvian origin. These microchips also enable border custom officers to undertake regular interventions to impede illegal trade in this species. According to statistics by the Ministry of Agriculture of Peru, the country has lost since 1995 almost US$ 400 million from illegal exports (contraband) of alpaca and alpaca-derived products – mostly via Chile and Bolivia.[13] The problem of illegal or very questionable exports of Andean camelids (including alpaca, llama and vicuñas) over the past few years is very complex. Specimens have been exported to the U.S., New Zealand and Australia and are now bred extensively in these countries. A recent issue is the use of camelid antibodies for pharmaceutical research and their commercial potential in this market.[14]

In another effort to monitor what is happening with specific species, the Guy Harvey Research Institute in Florida has developed cutting edge DNA-based forensic techniques and markers to identify the species level of shark carcasses, dried shark fins and other products obtained from shark fisheries. Over 100 million sharks (of all species) are killed annually, mostly for the purpose of using their fins and other parts for culinary purposes. These techniques are revolutionizing research in the international shark trade and, especially, are expected to assist authorities in identifying sharks (and shark products) protected under U.S. and CITES regulations. They are also helping in the re-evaluation of public policies and regulations related to the conservation and protection of shark species and sustainability of shark fisheries.[15] These techniques are only available in the U.S., Australia and Europe and are, albeit very precise, quite costly.

According to information on the Institute's web page, forensic analysis based on these techniques have used by the National Oceanographic and Atmospheric Administration and U.S. prosecutors as a basis for bringing suits for major CITES violations. If upheld by U.S. courts, they could offer a major breakthrough in the recognition of specimens and heretofore unrecognizable parts of specimens, for purposes of determination of the legality of their transport and trade.[16]

In contrast with these very practical examples of how technology allows for tracking resources, botanical research institutions around the world have developed their own mechanisms and regular practices under which they access biological materials and, in some cases, transfer samples to other research institutions.

In the specific case of herbarium specimens, for example, Royal Botanic Gardens Kew has developed an institutional policy which stipulates that when acquiring plant material from *in-situ* sources, Kew will work with an in-country partner (usually through a Memorandum of Understanding) and obtain prior informed consent (PIC) and relevant permits from national authorities.[17]

Herbarium materials are accessioned and sometimes also loaned to other research institutions for scientific and non-commercial research only. During the period 2002-2003 Kew accessioned (i.e. formally incorporated into collections) almost 23,000 specimens. Incoming herbarium specimens are provided with labels which incorporate basic information (location, date, scientist, partners, species, etc.) which is then electronically databased. Format and content details of labels vary around the world. In the case of Kew, and most botanical institutions around the world, existing human and economic resources are insufficient to database all individual specimens enter-

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13 For further information on this tracking and monitoring project *see* http.//www.peru.tk/modules/news/article.php/storyid=1389

14 *See* Pastor, S. and B. Fuentealba. 2005. *Camélidos, Nuevos Avances Tecnológicos y Patentes: Posibilidades y Preocupaciones para la Región Andina.* Documento de Investigación. Lima: Iniciativa para la Prevención de la Biopiratería. Año II, No. 4, Enero 2005.

15 *See* www.sciencenews.org/articles/20022012

16 *See* www.nova.edu/ocean/ghri/sharkforensics.html

17 *See* http.//www.rbgkew.org.uk

ing the collections, whether these are herbarium or living collections.

Kew may loan herbarium specimens on standard written terms, and generally prohibits commercial uses and sampling of specimens. Most loans are based on reliability and good faith in scientific partners who will receive materials for research, rather than in post-oversight mechanisms such as tracking and monitoring of each loaned specimen once they leave Kew. Kew has repeatedly expressed its concerns that any additional requirement that may be imposed in order to access biological materials will add to the already costly and timely process required to obtain permits, authorizations and PIC from national authorities – which relates directly to the costs of creating a new certification of origin/legal provenance requirement.[18]

These examples are an indication of important technological advances which may help in the process of monitoring and tracking species and their products and also in identifying how they are being utilized. Nevertheless, it remains undecided how these technologies may be applied and become operational in the context of an ABS system. On one hand, there are differences in tracking specific specimens, quite apart from the problems of identifying their progeny and products later in a research and development process. Secondly, these technologies are extremely specialized and available in very few developed countries, mainly in the U.S., Europe and Japan. Availability of these could be a problem especially if they are covered by IPR or other proprietary rights.

5.3 Certificates of origin or legal provenance: A step in the right direction in the context of the international regime on ABS?

Over the past few years, certificates of origin and legal provenance have become the subject of considerable attention by policy makers and scientists alike. Many see these certificates as a means to alleviate the current burdens and restrictions imposed by most existing ABS laws in their effort to address and solve all of the problems related to accessing and using genetic resources: regulating access as such, controlling immediate and future use of genetic resources, impeding illegal transboundary (and interinstitutional) flows of resources, safeguarding the sovereign rights of countries of origin, especially when resources are obtained from *in-situ* sources, protecting traditional knowledge related to biodiversity in some cases, among others.

Given that certificates of origin and legal provenance place a considerable part of responsibilities on the actual users of genetic resources, this may act as an incentive to reduce the rigidity and control-type approach most of the aforementioned ABS laws currently have.

Some, though, see certificates of origin as additional burdens on an already over-regulated scenario (Dutfield 2005). Since the mid-1990s, scientists from around the world have expressed their concerns that excessively zealous ABS legislation may have a negative impact on research activities, especially when these are clearly oriented towards non-commercial objectives (UNU 2005; Grajal 1999; Hoagland 1997). Though there is a blurred line sometimes between commercial and non-commercial research, it is not always possible to identify the borderline in a way that will facilitate the latter.

However, the condition for a certification regime to be successful is to ensure that user countries accept this instrument and incorporate it into the discussions of the (an) international ABS regime currently taking place (Young 2005; Ruiz Muller 2004). Certificates would need to be recognized at the international level (maybe as part of the ABS international regime) to become binding on all countries, especially those which have traditionally been perceived as users and transformers of genetic resources.

Though conceptually very appealing, even at this time there is still considerable uncertainty with regard

[18] *See* UNEP/CBD/WG-ABS/3/INF/5. 2005.

to the practical operation and implications that certificates may have (see Chapter 1, above).

It is fairly easy to imagine a certificate traveling attached (and even pinned) to a specimen, with some basic data on this specimen. Herbarium specimens (and parts thereof) usually travel and flow this way (with labels attached).[19] This is standard practice for institutional trading among botanical gardens, but may not continue where the specimens are acquired by commercial users. Even in the case of microbial culture collections, for transfers of materials, these are packed and shipped with a series of documents including shipping documents and invoice and safety information. It is much less clear how the certificate would apply to the movement of a single gene, a gene sequence, a molecule, a specific protein, etc. which is also part of a specific specimen. At the time of actual collecting (or physical access), limited, if any, information may be available regarding these specific component parts. Or the certificate of origin and legal provenance may refer to the specimen itself or a sample, individual seed or accession in some cases and not include any details regarding genetic resources *per se*.

Whatever the situation, some of the fundamental questions a certification regime would need to address include:

- What exactly is being certified (geographical origin, compliance with ABS legislation – including Prior Informed Consent and national administrative and legal measures)?

- What does the certificate apply to? A single gene in a collected specimen? A complete genome? A gene sequence? The actual specimen?

- Would these (above) be known at the time of the transfer? And if they are not, what would the certificate apply to then?

- Does the certification scheme extend to derived products (a synthetic or semi-synthetic compound)?

- When would a certificate need to be requested? Prior to initial research and development? During a specific milestone in the value-adding chain or commercialization phase?

- At what point in the research and development, value-adding chain or commercialization phase does a certificate expire? Or does it?

- What type of information is included in the certificate?

- Would a standard, uniform internet-based system be required under which certificates can also be tracked?

Each of these questions implies the need to assess a series of institutional, technological (scientific data, information and tools) and human resource capacities in order to ensure that a certification of origin and legal provenance mechanism becomes operational. This includes evaluating the incentives for different actors to accept a certification scheme (see Chapter 4 above).

[19] *See* for example the situation of INBIO and its specimen collections in Costa Rica in UNEP/CBD/WG-ABS/3/INF/5, 2005.

5.4. An international audit system for tracking and monitoring the flow and legal use of genetic resources

A major concern for countries which are Contracting Parties to the CBD and the ITPGRFA is whether and how to develop and make operational a mechanism which assists in verifying whether the ABS conditions agreed upon ("mutually agreed terms" in ABS contracts, including the standard (and special) terms in Material Transfer Agreements – MTA) are being met and complied with. Tracking and monitoring proposals become an almost natural response to assist in this effort. Voluntary and even obligatory reporting requirements in typical research projects do not seem to generate the appropriate incentive to inform on what exactly is being done with materials.

This needs to be assessed in a context where tracking every transfer and subsequent movement of every single material or resource covered by the CBD or the ITPGRFA throughout the world is a daunting task even if the technology, human and financial resources are available.[20]

Although MTAs (and ABS contracts under the CBD) impose legal obligations on parties which sign them, effective compliance with their terms (and, ultimately, possibilities for oversight and enforcement) is still limited not only by jurisdictional issues (what courts and plaintiffs would have competence in specific cases), but also due to the physical and informational nature of genetic resources and the dynamics of technologies which make use of them at different stages of the research and development process. This is particularly true in the case of genetic resources which are, in essence, coded information.[21]

To claim a breach in MTA or contract obligations in general, providing countries (or in some cases countries of origin or other institutions) require information regarding:

- what is being done with these resources and derived products (depending on scope of obligations);
- where are activities taking place;
- by whom; and
- (subsequently) whether these uses comply

with conditions set in these contractual instruments. Indeed, in any contractual relationship, a considerable level of good faith (*bona fides*) is required. However, mechanisms must also be in place to ensure an appropriate level of oversight and verification as to how parties (especially recipients and users of materials in this case) are behaving contractually and abiding by their obligations.

The biopiracy[22] phenomenon and recent documented cases of it (e.g. patents on ayahuasca, quinoa, maca, beans, etc.) have contributed to generating an understandable situation where countries of origin are requesting additional assurances that materials which

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20 Royal Botanic Gardens Kew undertook an assessment of what it would take to implement/comply with a certification of origin mechanism (which they determined would mean databasing all collections). Kew concluded that if the average 53,000 transactions a year in herbarium specimens are subject to complete databasing of accession, loans and transfers, a minimum of 3.5 new staff posts (assuming that each person could deal with a maximum of 69 accessions in a business day (seven minutes per accession)) would be required, which would be a very unlikely possibility even for Kew, one of, if not the most scientifically solid and financially stable institutions in the world.

21 *See*, Report from the Regional Biopiracy Prevention Workshop held in Bogotá, Colombia, September 1-2, 2005. Available at: http.//www.biopirateria.org

22 "Biopiracy" is not a recent phenomenon. However, it has only in the last couple of decades gained widespread recognition and been given attention from a policy and legal (even economic) perspective and been widely reported upon by institutions and the media. Biopiracy may be defined as the illegal, unlawful, unethical, unjust and even immoral use of genetic resources and traditional knowledge, particularly in cases where products which directly or indirectly make use of resources or knowledge, become patented or protected through intellectual property instruments. This definition of biopiracy is provided by Law 28216 of Peru, which creates a National Commission for the Prevention of Biopiracy (2004).

are part of the Multilateral System of facilitated access under the ITPGRFA and all materials covered by the CBD, will be utilized strictly in accordance and conformity with binding MTAs and ABS conditions and obligations set in contracts.

Although MTAs and contracts offer a first legal filter to ensure the correct and legitimate use of materials, how these are subsequently used (maybe in a transformed version i.e., as a derived product) especially in cases where resources flow to third countries, remains an explicit worry of countries which have traditionally been sources and the origin of them.[23] The issue of "derived products" or "derivatives" is a controversial one within CBD debates. Some see derivatives as too detached from the original genetic resources on which they may have been based. Others argue that, whatever the distance, these (derived) products ultimately exist because of the mere existence of the original genetic resources on which they where based – no matter the level of technology and innovation which may have been applied.

Genetic resources are in essence a "packet of informational goods" which are presented as biological material (biological tissue, a seed, a leaf, skin, an entire specimen, etc.) which, include molecules, gene sequences, DNA, RNA, proteins, enzymes, etc. Each of these elements may have a specific function and potential use and, in some cases, may be subject to specific legal rules, including intellectual property rights. Technologies nowadays enable the use of the packet as a whole or in isolation and even use of its component elements thereof (individually or in combination).[24] If semi-synthetic or synthetic products are added to this list of elements, there is yet a third set of elements which may also be subject to intellectual property regimes.

From a legal perspective, this poses a problem as rules may apply to the actual "packet" as a whole or its individual components separately. In some countries, for example, the legal status of the "packet" (i.e., biological materials) may differ from the legal status assigned to its components (i.e., genetic resources, genes, DNA).[25]

One pressing question and challenge is how to develop a cost-effective mechanism to allow for tracking and monitoring, especially of genetic resources (and derived products), which is practical and does not affect normal flows of resources on one hand, but is effective in verifying that these are being appropriately used, according to MTA and contractual obligations and satisfies the interests of providing countries, institutions and, especially, countries of origin.

An *a priori* assumption behind these ideas is that reports which are regularly required or expected in research and development projects, are not sufficient to guarantee an appropriate level of assurances regarding how resources are being utilized.

Given these circumstances, one suggestion may be the establishment of a small task force composed of expert representatives of countries with the mandate to undertake an annual international valuation or audit process which follows genetic resources which are under the Multilateral System and ABS contracts or agreements under the CBD from their sources (where they were accessed) to any phase in the research and development process. For example, this may include tracking and monitoring the movement and use of a resource obtained from an *ex-situ* centre, all the way to its incorporation into a cosmetic or pharmaceutical products or even its use in a breeding program.

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[23] The Group of Like-Minded Megadiverse Countries has been particularly vocal in expressing this concern. The Cusco Declaration of the Group (2002) reflects this concern. The report of the Open-Ended Ad Hoc Working Group on ABS (UNEP/CBD/COP/7/6 – 2003) also makes explicit reference to the need to develop and assess compliance and enforcement mechanisms (in legal regimes and contracts).

[24] Some of the most powerful scientific disciplines today, including bioinformatics, genomics and proteomics, are gradually making (genetic) *information* the most valuable good in research and development processes. Informational products – in a wide range of sectors, including medical research, agroindustry, bioremediation, to name a few – are placing new challenges on the process of developing ABS policies and laws. For further details, *see* Oldham 2004.

[25] In the Andean region, for example, Article 6 of Decision 391 (on a Common Regime on Access to Genetic Resources – in force in Bolivia, Colombia, Ecuador, Peru and Bolivia since July 1996) establishes that genetic resources are the property of the State or patrimony of the Nation, independently of the rights vested in biological materials which may contain these resources.

This may mean a random selection of a few projects based on a set of criteria and appropriate methodologies (maybe tailored to a case-by-case analysis). These may include projects or activities which imply access to Annex I materials and the celebration of MTAs and another set of projects which are based on collecting and using genetic materials of plant, animal and microbial origin for commercial and non-commercial purposes (in non-commercial areas of research). In the case of materials under the Multilateral System, maybe focus on transfers of materials made by International Agricultural Research Centers (IARC).

This task force would have the responsibility of carrying out an exhaustive and detailed assessment of a) how genetic resources move from *in-situ* or *ex-situ* sources (countries of origin or providing countries if it be the case) and b) whether contractual conditions and obligations agreed upon in MTAs or ABS contracts related to these resources, are being complied with as part of these specific projects. Possibly target six or seven sample projects (or more if there is an available and sufficient budget).

These assessments would require the consent of involved parties to the actual contracts, especially in the case of recipients.[26] This type of assessment has the potential of determining how smoothly the system is operating but could face limitations in verifying overall compliance by the different actors involved. Indeed, these valuations or audits would be operating on a sample of agreements and MTAs.

Reports by the task force could maintain the confidentiality of certain information if so required by parties. Most important, it would conclude whether or not parties (and institutions) are complying with agreed MTA standards and ABS obligations set in contracts and whether resources are being used as originally agreed. The task force could provide a detailed flow chart of the movement of resources, their eventual transformation into a derived product, their incorporation into a commercially viable product, etc. and their movement along the value-adding chain.

At each stage of this process, the task force would evaluate to what extent MTAs and ABS contracts are useful or not in *a priori* covering a range of options for (and uses of) genetic resources. The task force would also come to a preliminary (non-judicial and non-binding) determination as to whether contractual terms are being met.

In terms of a step-by-step process, the task force could report to the Governing Body or COP on each evaluated project and identify problems, gaps, shortcomings and potential measures to overcome these. All of these would relate strictly to MTAs and ABS obligations in contracts. The Governing Body and COP could then negotiate and decide on the type of measures they would like to adopt at the policy level for countries to consider as a means to support compliance and enforcement measures in general.

From a political perspective, countries of origin and parties to the ITPGRFA and the CBD in general, would have a mechanism available to address – to some degree – a valid concern of countries, that is, whether flows of materials are responding to the ITPGRFA and CBD principles and obligations, and MTA and contract conditions.

If undertaken with transparency and openness (i.e., making public results of these valuations or audits) the process would also serve to ascertain whether or not MTAs and the Multilateral System and the CBD ABS provisions (and contracts used in most, if not all, ABS laws and regulations in place worldwide) are operating as envisioned and what are the main difficulties.

From a legal point of view, this would be advancing in the effective implementation of the ITPGRFA and CBD, without individual tracking of specific resources. From a technical and economic perspective, these audits would not entail huge budgets and

[26] If a recipient was not to accept this audit process, this may serve as an indication of whether or not parties to the MTA (and the ITPGRFA and the CBD) are acting in good faith and with transparency, though not necessarily disqualifying the user/recipient for any wrongdoing.

complicated bureaucracies and have a positive impact in terms of providing the ITPGRFA and CBD with useful information regarding where gaps and problems may be arising in actual practice.

This mechanism is not designed to assist each and every country to track and monitor and verify compliance with ABS conditions. But it may help in identifying good practices, good partners and how these country providers may develop more specific measures to satisfy their interests with regard to how their resources are being utilized.

5.5 Final comments

In debates regarding ABS it is surprising how little attention is paid to a key element embedded somewhere in human nature: good faith (*bona fide*). Whether it is discussing a national law or in international negotiations (in the CBD, WIPO, WTO or FAO processes), parties and actors involved either directly or indirectly in ABS processes seem to work their positions on the assumption that everything is suspicious and everybody is acting in their own self interest. There may be some solid arguments accumulated over the years to support this attitude. However, there needs to be a reassessment of the role of all actors and an honest and transparent approach to ABS discussions comprising (a) good faith in the negotiation of an ABS international regime; (b) in the negotiation of ABS contracts; (c) in complying with CBD principles and national laws; (d) in evaluating the pros and cons of tracking and monitoring options, including the certificate of origin and legal provenance idea. This is very practical realism. No oversight, compliance or enforcement mechanism, as perfect as it may be conceived, can replace good faith and positive incentives.

As difficult as it may be, however, differences should be made regarding basic, non-commercial research and research which is oriented towards the development of commercial products. Clearly, at the outset of projects, it is sometimes very difficult to envision future circumstances and how scientific research may be more inclined towards applied uses of genetic resources. It is at this moment where good faith should enter into play and concerned actors recognize the need to change conditions originally agreed upon in ABS contracts and negotiate these new conditions with countries of origin or providers of resources. New technologies and new disciplines such as bioinformatics, proteomics and genomics are certainly powerful research tools but which make development of appropriate policies and laws ever more complex. Informational goods – directly derived from digital libraries and specific databases – are the ultimate extension in the research on biodiversity and their utilization does pose an important challenge in terms of defining policies (or not) which link them to their original, essential source: biological and genetic resources.

An international audit or valuation system or mechanism, which annually and randomly evaluates how a few specific ABS projects (concrete projects which are using genetic resources and subjecting them to research and development) may help a wide range of actors understand better what type of policy and legal tools may be more appropriate to, in the right circumstance, justify tracking and monitoring efforts. Audits should apply to all ABS projects whether they are considered basic research or are commercially oriented. These audits should also extend to activities of *ex-situ* conservation centers.

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