

ICTSD Project on Genetic Resources



Thinking Outside the Box Innovative Options for an Operational Regime on Access and Benefit Sharing



By Manuel Ruiz Muller, Peruvian Society for Environmental Law



International Centre for Trade
and Sustainable Development

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ABBREVIATIONS AND ACRONYMS

ABS	Access and Benefit Sharing
WG-ABS	<i>Ad Hoc</i> Open Ended Working Group on Access to Genetic Resources and Benefit Sharing
COP	Conference of the Parties
CBD	Convention on Biological Diversity
GRULAC	Latin American and Caribbean Group
IGC	Intergovernmental Committee on Genetic Resources and Intellectual Property, Traditional Knowledge and Folklore
IP	Intellectual Property
IPLC	Indigenous people and local communities
IR	International Regime on Access to Genetic Resources and the fair and Equitable Sharing of Benefits Arising from their Utilization
LMMC	Group of Like Minded Mega Diverse Countries
TK	Traditional Knowledge
WIPO	World Intellectual Property Organization

FOREWORD

Loss of biological diversity - understood as our biosphere's total endowment of living organisms, their genetic variation and functions and the ecosystems of which they are a part of - stands, alongside climate change, as one of the most pressing and daunting global challenges of our times. The increasingly rapid and massive rates of deterioration and loss of environmental resources and functions have brought an acute awareness of the urgent need for effective policies and mechanisms to ensure these valuable resources are used sustainably; this is an imperative beyond moral and ethical concerns that cannot be further postponed as societies become clearer about biodiversity's critical role in human well-being, global economic development and poverty reduction.

Diversity in nature is the key to the natural regulation of global climate and the equilibrium in the gaseous composition of our atmosphere. This diversity is the essence of healthy soils; it allows for natural regeneration and recycling of nutrients, and the maintenance of a biological balance between destructive and useful plants and organisms. It enables the existence of waterways, watersheds and aquifers and allows marine life and environments to thrive. Furthermore, diversity in natural resources forms the cornerstone of strategic and pivotal industries in critical areas of economic activity for the provision of food, health, energy and fuels, clothing, and shelter. In addition, biodiversity has proven to be critical in advancements on waste treatment, environmental services and the venturing into the new frontiers of nanotechnology, and geoengineering.

Diversity of living organisms is dwindling at a much faster pace than generally realized. Not only species are disappearing, we now know for certain that their genetic richness and functions are also dramatically affected by changes in ecosystems. Even though alterations to our natural stock through either innate biophysical causes (such as natural processes and disasters) or human activity has been a characteristic of the world throughout its existence, destruction and change now occurs on a much greater magnitude and scale, and in exceptional ways. Propelled by an explosion in economic activity, ever-increasing demand and global integration of economies, impacts on diversity of living organisms are also more rapid and of major reach across ecosystems and regions.

In order to better grasp the enormity of the problem and our passion for it at ICTSD, allow me to quote one of the pioneers of our understanding of the diversity of life, Professor E.O. Wilson from Harvard University, when he states: "Almost all current biodiversity analysts agree that the extinction of species is proceeding at one hundred to 10,000 times the pre-human rate, while the rate of origin of new species is decreasing. [...] Each species is the repository of an immense amount of genetic information. The number of genes range from about 1,000 in bacteria and 10,000 in some fungi to 400,000 or more in many flowering plants and a few animals. A typical mammal such as the house mouse (*Mus musculus*) has about 100,000 genes. This full complement is found in each of its myriad cells, organized from four strings of DNA, each of which comprises about a billion nucleotide pairs..."

Concluded at the earth summit (1992), the United Nations Convention on Biological Diversity (CBD) acknowledges this important reality when underlining the "intrinsic ecological, genetic, social, economic, scientific, educational, cultural, recreational and aesthetic value" of biodiversity. Unlike former and other multilateral environmental agreements, it addresses global biodiversity as a whole rather than limiting itself to certain ecosystems, species, or forms of biological diversity.

Premised on a global strategy for sustainable development, the CBD recognizes the sovereign rights of States over their natural resources and pursues three objectives: 1) the conservation of biological diversity, 2) the sustainable use of its components and 3) the fair and equitable sharing of the benefits arising out of the utilization of genetic resources and associated traditional knowledge.

The realization of these objectives has faced immense challenges. The third objective in particular - fair and equitable sharing of benefits arising out of the use of genetic resources - has proven difficult to implement in an effective manner, as the use of genetic resources is increasingly linked with international trade. Users of genetic resources, such as individuals and firms that develop innovative applications based on such resources, often are located outside the country of origin of these resources.

In addition, only relatively recently have countries, mostly developing ones, started to implement domestic rules that provide for access and benefit sharing. In contrast, many developed countries - where pharmaceutical, biotechnological and agricultural companies, have their headquarters - have not put in place corresponding regulations in order to ensure benefit sharing.

In this context, well known cases of misappropriation of genetic resources and associated traditional knowledge during the past two decades have crystallized the tensions between CBD objectives of promoting the fair and equitable sharing of benefits and the types of incentives established by trade and intellectual property rules, in particular those of the World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). While measures such as the disclosure of origin requirement, certificates of compliance and geographical indications related to trade in genetic resources and associated traditional knowledge have been introduced in domestic legislations in recent years to prevent such misappropriation, they still raise critical questions for all the actors involved.

Against this backdrop, following protracted negotiations and a critical political underwriting of all UN members at the 2002 Johannesburg Summit on Sustainable Development, the CBD Conference of the Parties (COP) mandated, in 2004, the Working Group on access and benefit sharing (ABS) to negotiate an international regime (IR) on ABS. The aim of the IR is focussed on adopting an instrument(s) to effectively implement the objectives of the convention and its relevant provisions (Article 15 on access to genetic resources and Article 8(j) on traditional knowledge). In 2008, the COP instructed the Working Group to finalize the negotiation of the IR before its tenth meeting, in 2010, in Japan.

The negotiations of the IR took place amid an extraordinarily complex global landscape where a profusion of fora - such as the WTO, the World Intellectual Property Organization (WIPO), the Food and Agricultural Organization (FAO) and the Union for International Protection of New Varieties of Plants (UPOV) - address issues relating to the sustainable use of genetic resources according to their respective mandates. While countries reaffirm the need to ensure consistency between deliberations and outcomes in these different fora, they tend to disagree on how such consistency is to be achieved.

At the WTO, an increasingly large number of countries are arguing that in order to ensure there is consistency between the specific provisions of the CBD and the patent provisions under the TRIPS agreement, an amendment to TRIPS should be introduced. This proposed adjustment would require the disclosure of origin of genetic resources in patent applications as evidence of 'prior informed consent' and 'equitable benefit sharing'.

Countries that oppose such measure at the WTO favour discussions at the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) of WIPO, which was established in 2001. After several years of deliberations with little progress in terms of norm-setting, the IGC was finally provided in 2009 with an explicit mandate to undertake “text-based negotiations with the objective of reaching agreement on a text of an international legal instrument (or instruments) which will ensure the effective protection of genetic resources, traditional knowledge and the protection of traditional cultural expressions.”

Countries which oppose discussions on intellectual property aspects in the context of the negotiations of the IR often invoke this new IGC mandate arguing that WIPO is the appropriate forum to address these aspects.

Despite these ‘forum-shifting’ strategies and the fact that few tangible advances have ultimately been made in several of these fora, the terms of the debate have significantly evolved in recent years. Many developing countries, now better aware of the multifaceted relevance of their biodiversity, are factoring its valuation into their economic strategies. Furthermore, all stakeholders have also come to recognize the complexity of the issues at hand and that there is no single ‘magic’ solution that would ensure effective ‘equitable benefit sharing’; but rather a variety of complementary measures to be pursued at the national, regional and international levels. Drawing lessons from national and regional experiences on ABS implementation can benefit international discussions. Virtually all countries agree on the need to diffuse potential tensions between the biodiversity, trade and intellectual property regimes, though disagreements persist on the most appropriate means to do so.

Since its establishment in 1996, the International Centre for Trade and Sustainable Development (ICTSD) has been working on these issues from various angles and perspectives, following and participating in the process that brought upon the system in place today: from Rio to Johannesburg, from Bonn to Geneva. As a non-partisan actor, it has generated sound and novel analysis on viable and sustainable policy options and convened exchange between a wide range of stakeholders from developing and developed countries alike.

In 2009, the German Development Agency (GTZ) and ICTSD undertook a collaborative initiative to create regional platforms for interactive and generative dialogue among key actors. The collaboration focused on problem-solving and consensus-building in regards to biodiversity issues with a high priority in development and environmental policies in Central and South America. As part of this project, in coordination with local partners, ICTSD and GTZ jointly organised two regional dialogues in Costa Rica and Peru bringing together international experts to explore concerns, knowledge gaps and priority areas for action at the political and technical level on the interface between intellectual property rights and the sustainable use of biological resources.

Almost two decades after the conclusion of the CBD a number of countries have made critical advances in design and implementation of domestic mechanisms that address these concerns. To bring their view to the international level and to analyse their experiences will be critical for the successful conclusion of multilateral processes. As we now move towards the Tenth Conference of the Parties (COP 10) to the CBD in Nagoya in October 2010, there is indeed an urgent need for deepening efforts to provide sound analysis on pressing systemic challenges and flaws, domestic and regional experiences, needs and abilities, and potential political and technical solutions.

This issue paper - published by *ICTSD's project on Genetic Resources* - is one of several outcomes generated during the 2009-2010 dialogue series; it builds on, and is complemented by, ICTSD work through its various related projects. The paper challenges some of the basic assumptions underlying the negotiating process for an international regime and, more importantly, provides an alternative approach to designing an international policy and legal framework on ABS. The paper claims that the intangible nature of genetic resources - regularly unaccounted for in debates - is the main cause of the ongoing difficulties faced by the international process and individual countries in terms of developing concepts and finally implementing respective measures. In that regard, the paper provides approaches for "thinking outside the box." By offering such "food for thought" at a stage in which negotiations gain momentum, we aim to inform involved stakeholders, so as to enable them to consider options and approaches that will ensure the efficiency and effectiveness of the new regime.

We hope that you will find this paper stimulating and useful for your work.



Ricardo Meléndez-Ortiz
Chief Executive, ICTSD

EXECUTIVE SUMMARY

The ongoing discussions on the Draft Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization has highlighted a series of complexities both at the technical and political level which will require further careful negotiations. The existing draft text of the Protocol still reflects contentious areas regarding issues such as: compliance with access and benefit sharing (ABS) measures, protection of traditional knowledge, and the recognition of disclosure and certificates of origin. This research paper explores the current situation of ABS debates within the WG-ABS on the Protocol and, more importantly, offers an alternative approach to designing an international policy and legal framework on ABS. It argues that the central problem which ABS frameworks confront refers to the policy and legal treatment given to subject matter at hand: genetic resources. The paper explores the idea that genetic resources need to be understood as coded genetic information - *natural* information - for which economics offer a set of well developed and tested principles to ensure appropriate regulatory frameworks. It further asserts that the regularly unaccounted intangible nature of genetic resources in debates is the main cause for the ongoing difficulties that countries - and the international process on ABS in general - face in terms of conceptual developments and, especially, implementation. When this status is recognized, a wholly new and redirected process will be required if benefit sharing objectives of the Convention on Biological Diversity (CBD) are to be realized. This will imply consideration to geographical distribution of species, databases (i.e. iBOL), certificates of origin, and most critically, a reassessment of the concept and implications of sovereignty in the context of genetic resources and ABS debates in general.

The paper finally proposes a “roadmap” and critical characteristics of a “new protocol” that would take account of the conclusions of the author and ensure a viable international ABS regime.

NOTE BY THE AUTHOR

At the time of writing this paper, the *Ad Hoc* Open Ended Working Group on Access to Genetic Resources and Benefit Sharing (WG-ABS) had met in Cali, Colombia (March 2010) and developed a Draft Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization. A Resumed Ninth Meeting of the *Ad Hoc* Open Ended Working Group on ABS is to be held in Montreal (July 10-16) A summarized version of the Draft Protocol is contained in Box No. 2 (below).

INTRODUCTION

Negotiations on access to genetic resources and fair and equitable benefit sharing (ABS) under the Convention on Biological Diversity (CBD) process, have gained political momentum, with countries hoping to agree on an International Regime (now a Protocol)¹ on Access to Genetic Resources and Benefit Sharing (IR) by the end of 2010, during the CBD Tenth Conference of the Parties (COP 10) to be held in Nagoya, Japan.²

Negotiations of the Protocol on ABS were formally launched in 2004, during COP 7, upon the initiative of and drive by developing countries and the Group of Like Minded Mega Diverse Countries (LMMC) in particular.³ The Protocol process is, in brief, a reflection of the call by countries to design an international instrument which addresses areas of ABS which cannot be regulated solely through national laws and regulations but require multilateral action. Countries which have developed their ABS frameworks have argued that if no multilateral action is taken, their possibilities of effectively realizing benefit sharing objectives are dramatically undermined.

This paper argues that as much as a Protocol may be required and necessary, there are some flaws and erroneous assumptions in the technical (scientific) and legal foundations of the ABS debate. These are permeating and being reflected in the process and content of the proposed Protocol. More specifically, the paper suggests that the manner in which certain concepts such as “sovereignty”, “scope”, “access”, “genetic resources”, “benefit sharing”, “control”, and “tracking”, are understood and interpreted, may significantly impact the effectiveness of the Protocol. The informed interpretation of these concepts and sound understanding of the implications, are key to ensuring viable policy and legal frameworks - both in the form of the Protocol and future implementation efforts.

The paper begins with a review of the background and history of the Protocols’ negotiations and their current status. Section two addresses the key question of whether or not an international regime or legal framework on ABS is actually needed, recognizing that progress in the policy and negotiating process is inevitably at a point of “no return”. Section three identifies some of the key areas in ABS which may require the adoption of international measures. This section also suggests that an “international regime” *per se*, may not signify a single legally binding instrument, but consist of a series of interconnected and complementary measures which give form to an ABS international architecture so to speak. Section four then analyses how some of the more critical assumptions in the access to genetic resources debate (reflected in papers, laws, policies and regulations) are undermining the realization of the CBD benefit sharing objective and principles, and affecting the interests of developing countries in particular. Finally, section five proposes some radical shifts in thinking about ABS and the Protocol in particular, suggesting the need to look at genetic resources from a more economic and informational perspective in order to develop a truly operational, international benefit sharing mechanism.

The overall goal of the paper is to offer negotiators and all actors involved in ABS frameworks development and implementation, some useful policy, legal and economic inputs and insights. Given the timeframe set by the Contracting Parties for the Protocol process (approval at COP 10 later in 2010), reverting the dynamics of the Protocol negotiating process may be an impossible task, but re-directing some of its orientations may still be an open option.

1. BACKGROUND: A BRIEF HISTORY OF THE NEGOTIATIONS OF THE PROTOCOL ON ABS

Countries' calls for the development of international measures to ensure the realization of the CBD benefit sharing principles, are based on the recognition of national ABS legislations' limitations in securing a) that genetic resources are not illegally used, in particular in foreign jurisdictions b) that the genetic patrimony of countries and related traditional knowledge (TK) of indigenous people and local communities (IPLC) is not subject to privatization through the use of intellectual property, and c) that user countries also support efforts and adopt measures to ensure that these interests are met.⁴

These concerns are also based on an undeniable "feeling" of historical disenfranchisement caused by biodiversity poor but technologically advanced Northern countries appropriating the natural wealth and assets of the South. Though this is a rather simplistic way of framing the ABS debate, it does summarize frustrations and claims from poorer, less developed but biodiversity endowed societies. Box 1 below, further specifies some of these differences and contrasts which have resulted in the current policy situation.

Table 1: A Summary of the Tension - A Typical Constellation

Reactive Position	Demandeur Position
Biodiversity poor	Biodiversity rich
Former colonial powers	Former colonies
Technologically advanced (especially in the biotechnological sector)	Limited technological capacities
Continued public and private investment in research and development (R&D)	Continued cuts in research (almost no R&D nor basic research)
Poses the most important <i>ex situ</i> collections	Traditionally providers of samples and materials for <i>ex situ</i> collections
Intensive use of intellectual property tools (patents in particular)	Very limited use of intellectual property
Few indigenous people	High concentrations of indigenous people in biodiversity hotspots
Highly industrialized	Less or least developed
Mostly reactive to proposals from the South	Have ABS and TK frameworks in place and promote both the ABS IR and TK protection processes (<i>demandeurs</i> in essence)

Note: This is only a referential description with limited variables, but which helps understand the underlying tensions in ABS debates and negotiations. For example, China, India and Brazil, megadiverse countries, have progressed substantially in developing their biotechnological capacities over the past decade or more. Furthermore, in terms of agricultural genetic resources, interdependence between the North and South is much more critical policy wise and economically. These are just two points which could be raised.

As an initial response to these concerns, COP 5 of the CBD (Nairobi, 2000) established an *Ad Hoc* Open Ended Working Group on ABS which developed the Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits, approved by Decision VI/24 during COP 6.⁵

In parallel to the Working Group activities, the LMMC group was formed in February,

2002, and its constitutional mandate, the Cancun Declaration, called for the "...creation of an international regime to promote and safeguard the fair and equitable sharing of benefits arising from the use of biodiversity and its components". This was the first formal statement by a group of countries, recognizing the need for an international regime (expressed as a binding instrument) addressing ABS and implicitly, acknowledging the limitations of the

Bonn Guidelines, in part due to their voluntary, soft law nature.⁶

During the World Summit on Sustainable Development (Johannesburg, August-September 2002), the LMMC achieved an important success when achieving the incorporation of a reference to the need for international measures on ABS in the Johannesburg Plan of Implementation.⁷ Paragraph 44(o) of the Plan of Action refers to “*Negotiate within the framework of the Convention on Biological Diversity, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources*”.

Later in October 2002, the LMMC met again in Cusco, Peru, and reiterated their call for the development of an international regime on ABS, and specifically urged the CBD COP to “... *initiate without delay, the negotiations within the*

framework of the Convention, of an international regime to promote and safeguard the equitable sharing of benefits arising out of the utilization of genetic resources, called for in the World Summit on Sustainable Development”.⁸

As a direct result of the pressure from and influence and arguments by the LMMC, the *Ad Hoc* Open Ended Working Group on ABS recommended COP that due consideration be given to the proposal for the development of an international regime on ABS.⁹ The Seventh Conference of the Parties (Kuala Lumpur, 2004) formally launched a process to negotiate an international ABS regime. The Conference mandated the *Ad Hoc* Open Ended Working Group to develop and negotiate the regime, according to a series of guiding principles and terms of reference. This became, not without controversy,¹⁰ the starting point for discussions on binding multilateral measures to ensure the realization of the CBD’s ABS principles.

Box 1: Draft Protocol on ABS and its Main Structure and General Content: As of WG-ABS 9 (Cali, Colombia, March 2010)

Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity

Preamble

Objective: ensuring benefit sharing, contributing to biodiversity conservation and sustainable use of its components.

Use of Terms: Only two: Conference of the Parties, Regional Economic Integration Organization.

Scope: covers genetic resources within the scope of the CBD and traditional knowledge.

Fair and equitable benefit sharing: all benefits will be equitably shared, including from utilization of derivatives

Access to genetic resources: recognizes sovereignty; clear, flexible rules; a certificate or permit to confirm PIC; information sharing; etc.

Access to traditional knowledge associated to genetic resources: measures shall be taken to ensure PIC for access to and use of traditional knowledge.

Consideration to research and emergency situations: facilitate and encourage biodiversity research and give due consideration to ABS in the case of emergency situations.

Contribution to conservation and sustainable use: direct benefits to conservation of biodiversity.

Box 1: *Continued*

Transboundary cooperation: cooperate in the case of shared genetic resources and traditional knowledge.

Traditional knowledge associated with genetic resources: respect community protocols, customary law; development of PIC and MAT principles; model contractual clauses; etc.

National focal points and competent authorities: formally designate national competent authorities.

Clearing house and information sharing: create an ABS Clearing House Mechanism with relevant data and information, including related to indigenous people TK.

Compliance with national legislation on access: develop appropriate user measures and ensure that genetic resources used in foreign jurisdictions have been obtained and accessed legally.

Monitoring and tracking: monitor uses of genetic resources and derivatives; monitoring flows at different check points, including IP offices and others, through the internationally recognized certificate of compliance.

Compliance with mutually agreed terms: mutually agreed terms should consider jurisdictional matters, alternatives for dispute settlement, applicable law, among others and facilitate cooperation among Parties and access to justice.

Model contract clauses: Parties shall develop model contract clauses.

Codes of conduct and best practices: Parties shall develop codes of conduct and best practice standards.

Awareness rising: Parties shall adopt measures to raise awareness about the importance of genetic resources and the Protocol.

Capacity: Parties shall cooperate in capacity building, including of indigenous people and in development of infrastructure to make technology transfer possible.

Technology transfer: Parties shall cooperate in research programs, especially in biotechnological activities as a means to facilitate and promote benefit sharing.

Financial mechanism and resources: Financial resources for implementing the Protocol will be provided by the GEF.

Institutional arrangements (secretariat, subsidiary bodies, entry into force, reservations, etc.): Establishes the architecture and institutional structure of the Protocol.

Annex I: Monetary and Non Monetary Benefits

Annex II: List of Typical Uses of Genetic Resources.

Note: There are many more issues to be discussed during the Resumed Ninth Meeting of the *Ad Hoc* Open Ended Working Group on ABS to be held in Montreal (July 10-16). This box is a summarized version of some of the key issues still under discussion.

It should be noted that COP 7 also instructed the *Ad Hoc* Open Ended Working Group to consider collaborating with the Working Group on Article 8(j), mainly regarding traditional knowledge (TK), when discussing the international regime.¹¹ As a result, TK has now also been consolidated as a key component of the draft Protocol. This specific inclusion is however, not without its critics. Indeed, given the drive in the World Intellectual Property Organization's (WIPO) Intergovernmental Committee on Genetic Resources and Intellectual Property, Traditional Knowledge and Folklore (IGC), and the ongoing negotiations of an international regime for the protection of TK within this framework, there are valid concerns that overlap uncoordinated progress in different forums and parallel activities may actually harm efforts to negotiate and develop a sound and viable regime for the legal protection of TK at the international level.¹²

Some objective indicators point to considerable progress and advance made in the international discussion on access and benefit sharing. For instance, since 1993, ABS policy, laws and regulations, non binding instruments (codes of conduct, guidelines, etc.) and literature have multiplied dramatically. There are also many examples of implemented domestic ABS laws while further policies are under way.¹³ Secondly, many

institutions (from companies to museums and *ex situ* collections) have adopted comprehensive policies regarding activities that may have a relation to accessing and using genetic resources. Finally, literature and research regarding ABS and related issues (TK, IP, biotechnology, etc.) are now abundant and widely available also to the greater public in developing countries. Also, many more institutions (including NGOs) have engaged actively in debates regarding ABS both at the national and international levels and are key actors in ongoing processes.

In terms of lessons learned, however, most if not all ABS legal and institutional frameworks have been ineffective in achieving the key goal set by the CBD: sharing fairly and equitably the benefits from the use of genetic resources. All countries and regions face similar problems in terms of implementation of their ABS frameworks. These problems relate to complex ABS procedures, weak national ABS authorities, unknown demand and markets for genetic resources, increasing concerns by the national research community, etc. At least two reasons have been given for these common shortcomings in ABS regimes: the control oriented and restrictive nature of most of these laws and institutional settings and the very similar structure and content of ABS frameworks in most countries and regions (thus similar problems).¹⁴

2. REFOCUSING THE DEBATE: IN SEARCH OF VIABLE PATHWAYS

Excessive expectations are being placed on the emerging Protocol. It is being perceived as the critical instrument which will solve most of the problems related to ABS. There is an extended belief that IP disclosure issues, TK interests, compliance needs, enforcement aspects, scope and coverage considerations and other variables, will be technically and appropriately addressed. This is not necessarily the case. A brief overview of the emerging protocol, reveals that many of its provisions continue an almost two decade long tradition of incorporating ABS measures which have, in practice, been marginally effective at best.¹⁵

On the other hand, it can validly be argued that an international regime on ABS is *already* in place and has been for a while, and what is required is to find ways in which this existing regime and its different tools and mechanisms, are made operational. An “international regime” can roughly be defined as the existing set of international policies, norms and instruments which regulate a certain issue, in this case, genetic resources and ABS in particular. A rapid review of these policies, norms and instruments would include:

- The CBD and its ABS guiding, albeit binding principles,
- The FAO International Treaty on Plant Genetic Resources for Food and Agriculture,
- The Bonn Guidelines on ABS,
- Regional ABS policies and norms (Andean Community Decision 391, OAU Model Law on Access to and Use of Biological Resources, etc.),
- Institutional codes of conduct, guidelines, principles on ABS,
- COP Decisions, SBSTTA (Subsidiary Body on Scientific, Technical and technological

Advice of the CBD) and Expert Panel recommendations,

- Regional agreements and declarations,
- Standard Material Transfer Agreements,
- Other more specific instruments or tools.

In this regard, the immediate and obvious questions is why this existing ABS framework or system (which also includes all existing national ABS laws and regulation), is not operating effectively and to the satisfaction of most countries. Furthermore, what exactly is another international instrument going to add to make this system operational? Where does its value really lie?

In order to add something to the existing framework, and to be effective and have a truly international dimension, an IR needs to focus very specifically on those key issues which cannot be addressed through national ABS legislation and which need invariably multilaterally agreed measures. And there appears to be only one key area which indeed requires international measures and agreement to support the realization of the CBD objectives: the so called user measures.

To provide a brief background, countries providing genetic resources have experimented over time designing and, rather unsuccessfully, implementing their *national* ABS laws and regulations, with national actions and measures at the forefront of these efforts. But countries receiving and using these same resources have not developed measures to support providing countries efforts, for example in terms of assisting with compliance with ABS conditions in their jurisdictions or monitoring the flows of resources. “User country measures” have therefore emerged as necessary to contribute in this regards.¹⁶

3. USER MEASURES: AREAS FOR INTERNATIONAL AGREEMENT

It is generally accepted that there are shared but differentiated responsibilities in regards to the realization of the CBD's objectives.¹⁷ Experience to date has demonstrated that stand alone national ABS legislation can hardly ensure that the benefit sharing objectives of the CBD are materialized and effectively accrue to countries of origin and their IPLCs.

As a result of this situation, it has been suggested over time throughout the CBD process, that countries which are traditionally "users" of genetic resources should adopt measures to support effective realization of its benefit sharing objective as well.¹⁸ Most ABS legislation in place to date is in countries which have traditionally been exporters or providers of genetic resources. However, the CBD explicitly indicates that Contracting Parties in general, both users and providers, should adopt policy, legal, administrative or other measures to support realization of its objectives.¹⁹

This has been interpreted to mean that, given the different role and responsibilities of countries (as users or providers), different types of measures should be adopted to satisfy each others' interests. Thus, user countries could, for example, ensure that access contract terms are effectively met, or contribute more actively to monitoring how resources are used in their jurisdiction or modify their IP laws and regulations to accommodate disclosure requirements (see point 3.1 below). These are measures which seek to safeguard the interests of countries which are providing genetic resources or materials. User measures may similarly extend to TK and related aspects.

3.1 Disclosure of Origin and Legal Provenance in IP Regimes

The requirement for disclosure of origin and legal provenance has been expressed in many ways and in different forums over time.²⁰ The requirement seeks to ensure the identification of the *geographical* origin or source of a specific resource and, secondly, seeks to assist in the

*verification that ABS conditions have been met.*²¹ The disclosure of origin and legal provenance concept and principle were first reflected in a regulation for the protection of plant breeders right (PBR) in 1996 in Peru.²² This PBR regime is in turn, based on the principles of the UPOV Convention.²³

However, it is Andean Decision 391 on a Common Regime on Access to Genetic Resources (1996) and Decision 486 on a Common Regime on Industrial Property, which truly developed the principles of disclosure.²⁴ These can be summarized as follows: firstly, the granting of intellectual property rights (IPRs) in general is subject to respecting biodiversity conservation and sustainable use legislation; secondly, the processing of a patent application in the areas of biodiversity related innovations, is subject to the applicant providing evidence regarding the origin and legal provenance of materials used to produce the innovation; finally, if it is proven that components or the innovation itself were obtained without complying with these requirements, the patent can be annulled.

It should be noted, that in the specific case of Peru, adoption of laws for the implementation of the Peru-US Free Trade Agreement, have recently generated discussions regarding possible modifications to Andean Community (AC) legislation on intellectual property, specifically the patent and PBR regime and their disclosure provisions.²⁵

At present, processes and legislation expressing disclosure have multiplied around the world, albeit not without debate and sometimes opposing views. The Andean Community, Brazil, Costa Rica, India, Panama, to name a few, have incorporated disclosure requirements either in the IPR or biodiversity or genetic resources laws. Disclosure provisions even exist in some European countries, namely Switzerland and Norway.

In general terms, the implementation of the disclosure requirement in countries that have adopted and incorporated it in their legislation

is still in its initial stages. In this context, IP authorities (including patent examiners) have started to raise questions regarding some of the practical implications of the requirement.²⁶ Some of these include concerns regarding the type of sanction or measure to be adopted for not disclosing origin during the application procedure or once the patent is granted. Or which is the most appropriate moment for the authority to verify the requirement. Or even what exactly does disclosure apply to? These are only a couple of the practical complexities that need additional reflection and thought and maybe legal adjustments.

Other questions that continually emerge - among patent examiners in particular - include:

- Is the sanction of annulment of a patent too severe - especially when a right is granted to an inventor who may have acted in good faith?
- Is annulment also too severe in that it eliminates the possibility for benefits to effectively generate and be shared?
- Can an examiner determine if an invention requires an access contract or other?
- Would it be more convenient to seek sanctions *outside* the system of intellectual property for non compliance (i.e. civil sanctions)?
- In which cases (which inventions) should intellectual property authorities/examiners demand disclosure?
- Would *voluntary* disclosure mechanisms be more practical?

Ultimately, the key issue is determining non-equivocally *when* and *under what circumstance* (for what invention or claim) should disclosure of origin and legal provenance (or the certificate of origin) be required.

The draft Protocol on ABS calls upon Parties to adopt, modify or develop national laws or regulations (in the IP or biodiversity fields) which include disclosure of origin and legal provenance.

3.2 The Certificate of Origin and its Key Components

As part of the debate on disclosure, the idea of a *certificate* of origin (or legal provenance or compliance), was soon to emerge. The certificate has been proposed as an instrument (in practice a universally accepted document or bar code based tool) where origin and legal provenance of a resource can be readily and easily verified. Some have even suggested the certificate could indicate if traditional knowledge was involved in collecting activities.²⁷

The certificate should be issued by a national competent authority as part of the access to genetic resources procedure (a pre condition would be existence of an ABS law or regulation). The certificate would then indicate the origin of the specific material(s) which are being accessed and used, and additionally, certify that national ABS legal and regulatory requirements have been met.

The next issue refers to when the certificate should be required or in other words, what is the trigger for demanding the certificate. Arguably the most relevant point would be an IP (patent) procedure.

3.3 Compliance With National Legislation in Foreign Jurisdictions

One of the key concerns countries raise, is how to ensure that non compliance with national ABS measures and legislation, including obligations in access contracts, in foreign jurisdictions (where advanced R&D may take place), can be addressed in foreign courts. Public and private international law does not appropriately respond to the distinct features involved in ABS procedures and contracts. In the light of this situation, calls are being made by Contracting Parties of the CBD (especially by the Latin America and Caribbean Group (GRULAC) and the African Group) to ensure that explicit adjustments are made in foreign legislation to recognize the need and establish appropriate redress mechanisms. This has been an area of special contention as part of the ABS-WG9 debates.

3.4 Tracking and Monitoring Flows of Resources

In the specific case of plant genetic resources for food and agriculture, countries have been less demanding with regard to monitoring and tracking how genetic resources move across borders. Rather, in this case, the interdependence argument,²⁸ has helped countries reach consensus regarding the need to effectively facilitate access and not impede flows of these critically important resources.

But in the CBD context and for all non-agricultural genetic resources, countries have repeatedly expressed their concerns regarding what happens once their resources leave their national jurisdictions and how they can be monitored in a practical way, along the collection, research, development and commercialization chain.²⁹

The certificate of origin, legal provenance or compliance, have been proposed as tools that, if universally accepted, may help countries “see” how their resources are flowing and especially being used. The certificate could at the same time enable countries (through information technology and appropriate systems) to verify whether and if the contractual terms and conditions under which their resources were accessed are being met.

Others are less convinced about the feasibility of monitoring and argue that existing reporting requirements in R&D projects enable countries to achieve the above.³⁰ Yet others have suggested random audits or valuation processes under the CBD aegis to survey the extent to which access terms and conditions are effectively being complied with.³¹

4. SOME WRONG ASSUMPTIONS IN THE DEBATES REGARDING ACCESS TO GENETIC RESOURCES AND THEIR IMPLICATIONS

Having recognized the value of user measures and some of the “progress” made overall in ABS debates and processes, there are more profound and essential reasons which deem ABS laws and regulations ineffective and very limited in what they can achieve. An initial problem relates to the rarely understood concept of “genetic resources”. For the past two decades, policy makers and legislators have been focusing their regulatory efforts on controlling the flows of tangible, material expression of genetic resources. Efforts have therefore centered on regulating movement of and research in a seed, a leaf, a piece of bark, biological tissue, sap, an extract, etc.³² In these cases it is biochemical expressions in informational forms which render these elements important. Historically, the use of this concept (genetic resources) has resulted in considerable difficulties in realizing their practical usefulness when seen in a tangible form.

Doing so is, in itself, a complex task in terms of control and monitoring mechanisms. These are not timber, fish catch, minerals or hydrocarbons which can be “seen” and controlled at the borders almost physically. This becomes an even more vain effort when accepting what natural scientists have recognized all along, namely that genetic resources are *natural, coded information* which is what gives these resources their ultimate value, considering their potential for the development of useful products and services.³³ They are not tangibles (a problem in itself) but rather *intangibles*.

If genetic resources are indeed recognized as intangibles, the focus of regulatory efforts should be the economics of information. In that regard, it is important to acknowledge the differences between regulating tangible materials and intangibles such as information.³⁴ Seeking to exercise or forcing controls over information is extremely costly, in comparison to freely replicating it. The marginal cost of collecting a biological sample is negligible and this results in a much reduced capacity of the country of origin to negotiate with a user in a context where other countries of origin are

prepared to underbid. In the case of artificial information (human creations), intellectual property literature has thus long since explained the economic foundations and logic for using temporary, monopoly rights to extract rents and compensate innovators. Think about CDs, music downloading programs and computer software.³⁵ Given genetic resources are natural information; a wholly different structure should be envisioned for ABS legal frameworks - both at the national and international levels.

This problem relates to another often misunderstood albeit continuously invoked concept: “sovereignty”. Developing and mega-diverse countries in particular have for years, strongly proclaimed their sovereign rights over *their* genetic resources. Whilst sovereignty of States (or the Nation, depending on constitutional systems) over natural resources such as minerals, hydrocarbons, forests, fisheries, coastal waters, territories, wildlife, even plants, can be easily understood, the extension of sovereignty over genetic resources (as an intangible, where its value lies) poses considerable challenges in terms of public policy and regulations.

Countries claim sovereignty because they tend to consider genetic resources as unique, physical, distinct entities. They are not. They are widespread across boundaries and furthermore, the genetic structure of most organisms (at the genetic level) is hardly distinct. As a result, genetic resources and their coded information (in the form of DNA) are mostly shared. Indeed, a reduced group of countries have the privilege of maintaining this genetic reservoir in *in situ* or in their natural conditions.³⁶ But even within these countries, considerable genetic diversity is geographically shared and widely dispersed across borders. If this is the case, claiming sovereignty or more appropriately domain or property over a resource in Brazil, which is also found in Peru, Bolivia and maybe Malaysia, may be politically correct but has no legal nor practical effect when subject to closer scrutiny. In economics, seeking to extend sovereignty over information makes less sense still.³⁷

5. THINKING OUTSIDE THE BOX: AN INNOVATIVE OPTION FOR AN OPERATIONAL REGIME ON ABS³⁸

As mentioned in Section 4, one of the most dramatically overlooked issues in the debate on ABS relates to the actual nature of genetic resources. What *are* genetic resources? This paper suggests they are *natural* information, an aspect grossly overlooked in ABS policy and legal discussions and especially in laws and regulations, both nationally and internationally.³⁹ Debates have centered their attention on regulating access to and use of the tangible, visible biological materials and samples. But as soon as information is integrated into the discussions, the foundations for regulatory frameworks shift or must be reformulated altogether. As they stand at present, they have centered on genetic resources as if these were material resources such as oil, gas, water, timber, fisheries or others. Consequently, they are inapplicable to genetic information, even though it is this information with which new innovations and technologies can be created and developed.⁴⁰

One of the reasons the natural information aspect has been overlooked lies in the CBD itself. The excessive emphasis on recognizing and stressing that “... *States have sovereign rights over their own biological resources*”, and focusing on the concept of “countries of origin” as the key elements to determine who benefits from accessing and using genetic resources, have for considerable time, prevented a more scientifically and economically sound look at ABS. Negotiators and policy makers have missed critically important factors which condition the construction of a viable regime on ABS.

So what can be done or proposed at this point in time even if negotiations of the Protocol are well under way? To begin with, the process needs to “press on the brakes” and reconsider its conceptual foundations in consideration to the informational nature of genetic resources. There must be an explicit recognition within

ABS processes, that what is being discussed is in essence a regulatory framework applicable to natural information. If this is the case, economics offer abundant literature regarding protection of artificial information, which is applicable to natural, genetically derived information as well. This is critical, albeit unlikely given the dynamics and pressures on the process itself.⁴¹

Secondly, if it is acknowledged that genetic resources are shared among countries, more so at the informational level and that they are not distinct, unique units which can be found only within one jurisdiction, except in very exceptional cases, the notions of sovereignty and countries of origin, to an important degree reflecting the needs and interests in control which States may have, require reconsideration.⁴² Not doing so will result in a “price war” (excessive competition) between countries offering the *same resources*, seeking to gain the bilateral agreement or contract, pushing prices down and making it impossible to extract economic rents from these resources. In this case, the price of a sample equals the insignificant cost of collecting samples even though a future biotechnological or other products or processes may generate a considerable economic rent when IP (patents) are applied.

Thirdly, policy and decision makers, including those drafting ABS laws and regulations, need to carefully review the abundant literature which explains the relation between information, protection and the economic and legal tools which exist already and are applicable to information. When it is accepted that genetic resources are information, the idea of creating walls, barriers or frameworks suited for tangibles, becomes obsolete and useless. Rather, looking at cartel theory and intellectual property principles may provide with some suitable options to develop appropriate and viable ABS frameworks.

Box 2: The “new” Protocol on ABS**Key elements in the “new” Protocol on ABS**

1. An internationally recognized database or information system (i.e. iBOL or any other database) with specific data regarding spatial distribution of families, genus or species.
2. An international financial mechanism (fund) to receive monies from the monetary benefits derived from products generated from access to and utilization of genetic resources.
3. Very simple, flexible almost “open” national ABS frameworks which stimulate research. They may include model standard material transfer agreements which set mainly non monetary benefits to be shared plus a specific and express obligation in regards to potential and future monetary benefits.
4. An international recognized certificate of origin which simply indicates the species (family and/or genus) from which the specimen, sample or biodiversity component was obtained regardless of the actual country of origin or source. The certificate “travels” along the research and development route.
5. An international agreement is reached to modify patent procedures to ensure the certificate is disclosed during patent application reviews. IF commercial benefits are generated by the patent, the obligation to share benefits (established contractually and recognized by Protocol signatories) is triggered and countries which conserve that specific specie in in situ conditions, share in the benefits according to spatial distribution.
6. Thirteen 13 % of the sales of the patented product are directed to the international financial mechanism (fund), which will in turn distribute these benefits, according to the spatial distribution of species indicated in the certificate. Spatial distribution refers to ecosystems where species are conserved in *in situ* conditions.

Advantages of this new Protocol on ABS

1. Access is truly facilitated (as provided by the CBD) and research promoted (no complex administrative ABS procedures).
2. True equity in sharing of benefits according to concrete conservation efforts by countries.
3. Elimination of a price war among countries.
4. Effective incentive to conserve ecosystems and species in *in situ* conditions.
5. Rents are extracted from access to and use of biodiversity.
6. Simple, cost-effective system.
7. Low probability of monetary benefits, but high returns when they do occur.
8. Countries do not renounce to their sovereignty, rather, they reaffirm it by committing to the “new” Protocol.

Source: Manuel, Ruiz, 2010 (adapted from Joe Vogel ideas and proposals).

Over the past few years, a reduced number of institutions and individuals have been pondering on the implications of accepting that genetic resources are in fact, natural information. Some proposals and ideas have also emerged in this regard. It has been suggested that what is required is a global pool of resources made available by those countries concentrating the world's biodiversity in *in situ* conditions. This has been called the "Biodiversity Cartel".⁴³ To make the Cartel operational, a system of certificates of origin (of the specie from which genetic information is extracted) is to be created, associated to the patent system. When a patent application (regarding a biodiversity related invention) is presented, the certificate

will be added to the documentation. If and when a commercial product is generated in any technological field, a percentage of the monetary benefits will be channeled to an international global fund. Benefits will then be shared equitably according to the spatial distribution of the specie (indicated in the certificate) using available data and information regarding distribution of species.⁴⁴

Indeed, thinking outside the box presents considerable challenges which need to be overcome as pressure is mounting on negotiators to deliver a Protocol on ABS which, in the light of the existing draft, contains the same flaws in approach as existing legal frameworks.⁴⁵

CONCLUSION

This paper has highlighted some of the more complex issues which surround the ongoing negotiation of the ABS Protocol and in particular, proposes an alternative view of how an effective ABS policy and framework could be designed, based on the true nature of genetic resources and technological advances.

However, there is only a slight chance that the Protocol process re directs its focus. It is very obvious that there is an urgency to conclude negotiations as soon as possible, hopefully in time for COP 10. In this context, it is not surprising that policy makers and negotiators base their activities on prevailing positions and ideas, with no chance for reviewing

“alternative” options. These may imply considerable re thinking outside the box, but as a Turkish proverb says “No matter how long you have gone down the wrong road, turn back”.

However, even in a situation where the Protocol is adopted in its current form, there may still be an opportunity to test some of the ideas and proposals explained in this paper during the process or at a later stage. The concept of genetic information and an international regime based on a “cartel” could be applied, for example to a set of resources such as microorganisms, or to resources extracted from extreme environments, or deep sea resources.

ENDNOTES

- 1 A Protocol is a legally binding, international instrument, which usually derives from an international convention or treaty and develops in further detail some of the latter provisions. Protocols usually need approval, signature, ratification or adherence in the same terms as treaties or conventions. Only contracting parties to the original convention or treaty can ratify or adhere to a protocol.
- 2 The *Ad Hoc* Open Ended Working Group on Access to Genetic Resources and Benefit Sharing (WG-ABS) met for its Ninth Session in Cali, Colombia from March 23-28. Although a draft text on an International Regime on ABS has been agreed upon, there are still many pending contentious areas which require further negotiations. One area of agreement is that a Protocol on ABS will be the resulting product of these negotiations. A resumed meeting of the WG-ABS has been convened for July, in Montreal, Canada.
- 3 The Group of Like Minded Megadiverse Countries was formed in Cancun, Mexico on February 18, 2002. The Cancun Declaration was signed by Brazil, Colombia, Costa Rica, Ecuador, India, Indonesia, Kenya, Mexico, Peru, South Africa and Venezuela. The Group was later broadened to include: Bolivia, Malaysia, South Africa and The Philippines. The LMMC sets general, common policy guidelines and positions in regards to biodiversity related issues and ABS, IP and TK in particular.
- 4 For an analysis of some of these elements see, Cabrera, Jorge (2006). *El Régimen Internacional de Acceso a Recursos Genéticos y Distribución de Beneficios. Avances, Elementos y Recomendaciones*. Unidad de Políticas, Biodiversidad y Acuerdos Internacionales. Oficina Regional para América del Sur de la UICN. Quito, Ecuador.
- 5 Decision VI/24 of COP VI, the Hague, The Netherlands, 2002, Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of their Utilization. Available at, <http://www.cbd.int/decision/cop/?id=7198>.
- 6 To some extent, notion of an “International Regime” is equivocal, as in practice, an international regime on access and benefit sharing is *already* in place. If due consideration is given to the CBD and its (ABS) principles, the FAO International Treaty, the Bonn Guidelines on ABS, a series of regional norms on ABS, numerous institutional codes of conduct and ABS guidelines, among other instruments and tools, it could be argued that a regime as such currently exists. Whether these different instruments in their interaction are effective or not, that is another matter. What the LMMC really had in mind when calling for an international regime was a specific multilateral, distinct international instrument on ABS. See for example, Ruiz, Manuel. *The International Regime on Access to Genetic Resources and benefit Sharing: In Search of the Right Path*. Policy and Environmental Law Series. Peruvian Society for Environmental Law. No. 17, January, 2006. Lima, Peru.
- 7 Available at http://www.un.org/esa/sustdev/documents/WSSD_POI_PD/English/POIChapter4.htm.
- 8 For the complete text of the Cuzco Declaration by the LMMC see, http://www.llmc.nic.in/cusco_declaration.php?Section=three.
- 9 COP Decision VII/19, Access and Benefit Sharing as Related to Genetic Resources (Kuala Lumpur, 2004), Point D. International Regime on Access to Genetic Resources, available at, <http://www.cbd.int/decision/cop/?id=7756>.
- 10 Positions have ranged from very cautious and opposed to an ABS IR altogether (US, Japan, Australia), to more moderate (EU, and with discrepancies even within its Members) to openly supportive and encouraging (GRULAC, some Asian countries and the African Group).

- 11 Indigenous peoples and local communities (IPLCs) have been very explicit and vocal in regards to the need to address the issue of access to genetic resources in close relation to TK. Traditional knowledge and genetic resources cannot be, for IPLCs, addressed separately as they are part of a single whole. This is the holistic approach, which particularly indigenous peoples have stressed over time in a series of declarations, papers and instruments. For a comprehensive compilation of some of these declarations see, http://en.wikipedia.org/wiki/Indigenous_intellectual_property#Declarations_regarding_Indigenous_Intellectual_Property.
- 12 On October 1, 2009, the WIPO General Assembly renewed the mandate of the IGC. Among others, it specifically established: *The Committee will, during the next budgetary biennium (2010/2011), and without prejudice to the work pursued in the other fora, continue its work and undertake text-based negotiations with the objective of reaching agreement on a text of an international legal instrument (or instruments) which will ensure the effective protection of GRs, TK and TCEs.* For details of the IGC process see, www.wipo.int/tk/en/igc.
- 13 The African Union (53 States), the Andean Community (Bolivia, Colombia, Ecuador and Peru), Australia, Brazil, Costa Rica, India, Panama, The Philippines, The Seychelles and India, are a few of the better known examples of ABS frameworks in place and in force. However, national and other regional policy processes addressing ABS have multiplied throughout the world since 1993, and include initiatives in Cuba, China, Indonesia, Malaysia, Spain, and many other countries. For a review of some of these processes, see, Carrizosa, Santiago, Brush, Stephen, Wright, Brian, McGuire, Patrick. 2004. *Assessing Biodiversity and Sharing the Benefits: Lessons from Implementing the Convention on Biological Diversity*. IUCN Environmental Policy Paper No. 54. IUCN, GRCP, BMZ, Gland, Cambridge.
- 14 This feature has been widely acknowledged, especially within academic and scientific circles. Since the late 1990's, many researchers and private sector representatives have highlighted that restrictive ABS frameworks equal limited access (or worse still, illegal access) which in turn translates into zero benefits. See, Grajal, A. Biodiversity and the Nation State: Regulating Access to Genetic Resources Limits Biodiversity Research in Developing Countries. In: *Conservation Biology*, Vol. 3, No. 1, 1999. Also illustrative of the difficulties researchers have is Mansur, A. Cavalcanti, K. Xenofobia na Selva. In: *Veja*. Vol. 32, No. 33, 1999.
- 15 Though no detailed study has been made in regards, there is evidence that countries with ABS frameworks are experiencing difficulties in applying these norms and regulations. In the case of the Andean Community, see for example, Chaves, Juanita, Macías, Fernando, Torres, Ricardo. *Hacia un régimen de acceso a los recursos genéticos eficiente y aplicable para Colombia*. Programa de Investigación en Política e Investigación. Instituto de Investigación de Recursos Biológicos Alexander Von Humboldt. Bogotá, Colombia, febrero de 2004 y Ruiz, Manuel. ¿Es necesario un nuevo marco jurídico para la bioprospección en la región andina? Breve revisión crítica de la Decisión 391. Serie de Política y Derecho Ambiental. Sociedad Peruana de Derecho Ambiental. No. 14, febrero de 2003, Lima, Perú.
- 16 In the area of plant genetic resources for food and agriculture, countries are always users and providers at the same time. Interdependence has been used to describe this well recognized phenomenon. However, historically, some countries have acted more intensively as providers of genetic resources and others as users. See, Andersen, Regime. *Governing Agrobiodiversity. International Regimes, Plant Genetics and Developing Countries*. Aldershot, UK, Ashgate, 2009.

- 17 The CBD Preamble expressly recognizes the differences between developing and developed nations and calls for special provisions to meet the needs of developing countries, including through provision of new and additional financial resources and appropriate access to technologies. These may also include user measures.
- 18 The Bonn Guidelines on ABS make specific reference to the type of measures and actions countries could adopt and take, specifically in their role as users of genetic resources. These include: supporting enforcement measures, incorporating disclosure requirements in national legislation, provide information, discourage unfair trade practices, etc (see Decision VI/24).
- 19 Article 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. Such sharing shall be upon mutually agreed terms.”*
- 20 The TRIPS Agreement contains disclosure provisions as well. Article 29 (1) establishes that Member States *“...shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application”*. Disclosure is critical to ensure continued innovation and make the invention public. It guarantees transparency and legal certainty as well - two key considerations in disclosure of origin and legal provenance arguments.
- 21 For conceptual contributions on disclosure (legal nature, characteristics, trigger points, etc.) see, Chouchena-Rojas, Martha, Ruiz, Manuel, Vivas, David, Winkler, Sebastián (2005). *Disclosure Requirements: Ensuring Mutual Supportiveness Between the WTO TRIPS Agreement and the CBD*. IDDRI, CIEL, ICTSD, QUNO, IUCN. France. Likewise, a text by Professor Correa explains why it is perfectly valid and legally consistent (under TRIPS) to propose the requirement for disclosure of origin and legal provenance. Correa, Carlos. *Alcances Jurídicos de las Exigencias de Divulgación en el Sistema de Patentes y Derechos de Obtentor*. Initiative for the Prevention of Biopiracy. Year I, No. 2, August 2005, Lima, Peru.
- 22 Supreme Decree 008-96-ITINCI (1996) that regulates Andean Community Decision 345 on a Common regime on the Protection of the Rights of Breeders of New Plant Varieties (1993) establishes in Article 15 that the application to obtain a breeders certificate must contain or attach, as appropriate, *“...the geographical origin of the new protected varieties raw material including, if the case be, the document accrediting the legal provenance of genetic resources, issued by the National Competent Authority on access to genetic resources”*.
- 23 The UPOV Secretariat has reiterated its position opposing the inclusion of this requirement in plant breeders regimes on various occasions. This poses a problem for countries such as Peru which has ratified a Free Trade Agreements with the U.S.A. and has committed to adhering to the 1991 UPOV Act. In the case of Peru, where few applications for the protection of plant varieties have been presented and granted (mainly on introduced varieties such as marigold, rice and cotton), this requirement has not been required by the national IP office as yet.

- 24 Decision 391 specifically establishes in its Second Complementary Provision that Member States (of the Andean Community) “... will not recognize rights, including intellectual property rights, over genetic resources, derived or synthesised products or the intangible component, accessed or developed through an activity not in accordance with its mandates”. Its Third Complementary Provision determines that national IP offices of Member States must “... request the applicant the registration number of the access contract and a copy of it, as a pre requisite for the granting of the right ...”. Decision 486 is even more specific. Not only does it condition the granting of IP to respecting and safeguarding Member States interests in biodiversity (Article 3), but includes specific procedural provisions in this regards. Article 26 (h) establishes that the patent application should include as appropriate “... a copy of the access contract, when the product or procedure for which a patent is being requested, have been obtained or developed based on genetic resources or derived products of which Member States are countries of origin”. Article 26 (i) establishes that the patent application should also include as appropriate “... the document which provides evidence of the licence or authorization of use of traditional knowledge of indigenous communities ... when the product or procedure for which a patent is being requested, have been obtained or developed based on genetic resources or derived products of which Member States are countries of origin”. Disclosure therefore also extends to traditional knowledge. Furthermore, article 75(g) and (h) establishes that if these requirements are not met, the patent can be annulled.
- 25 For further details on this debate, see the article by Caillaux and Ruiz, presented at the recent XVII Inter-American Association of Intellectual Property (ASIPI), that took place in Lima, Peru (2009). Caillaux, Jorge, Ruiz, Manuel. 2009. *Biodiversidad, Biotecnología y Propiedad Intelectual: Algunos Retos para el Derecho*, available at the SPDA archives and soon part of the Conference publication.
- 26 This is one of the conclusions of the International Workshop on the Application of Disclosure of Origin Provisions ad Legal Provenance in Intellectual Property Legislation organized by INDECOPI, WIPO, SPDA and the Initiative for the Prevention of Biopiracy, that took place in Lima on August 13-14, 2009. The report of the workshop is available at <http://www.biopirateria.org>.
- 27 For details about the certificate formal and substantial elements see, Cunningham D., Tobin, B. and Watanabe, K. (2004), *The feasibility, practicality and cost of a certificate of origin system for genetic resources. Preliminary results of comparative analysis of tracking material in biological resource centres and of proposals for a certification scheme*. United Nations University Institute of Advanced Studies, Yokohama, Japan. Information document of the Third meeting of the *Ad Hoc* Open-ended Working Group on Access and Benefit-Sharing UNEP/CBD/WG-ABS/3/INF/5.
- 28 For a broad review of the concept of “interdependence” in plant genetic resources for food and agriculture see, Andersen. *Ibid.* at 16.
- 29 Article 12.3.b of the FAO IT establishes that access to plant genetic resources “...shall be accorded expeditiously, without the need to track individual accessions ...”.
- 30 Industry has been especially active in opposing disclosure and the idea of a certificate. See for example, WIPO/GRTKF/IC/16/INF/21 Policies, Measures and Experiences Regarding Intellectual Property and genetic resources: Submission by the Biotechnology Industry Organizations (BIO) and the International Pharmaceutical Manufacturers and Associations (IFPMA) to the IGC of WIPO, Sixteenth Session (may2-7, 2010).

- 31 For a review of the different approaches to tracking and monitoring see, Ruiz, Manuel and Lapeña, Isabel. (Eds) *A Moving Target: Genetic Resources and Options for Tracking and Monitoring their International Flows*. ABS Series No. 3. IUCN Environmental Policy and Law Paper 67/3. IUCN, SPDA, Gland, Switzerland, 2007.
- 32 The scope of most ABS laws and regulation extends not only to genetic resources *per se*, but to “derivatives” or “derived products” as well. There is no universally accepted definition to these concepts but, in general, they are considered to include almost anything which may derive from a biological source, from a grounded flour to a raw sap extracted directly from a tree bark. Andean Decision 391 for example, defines a derived product as “... *a molecule, or mixtures or combination of natural molecules, including raw extracts of alive or dead biological organisms, derived from metabolism of legal organisms*”. (Article 1 of Decision 391 of the Andean Community). The Conference of the Parties (Decision IX/12) established a Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches (which met in Namibia in 2008), presented the ABS-WG7 (2009) with recommendations regarding derivatives and derived products. In general, it was observed that derivatives are not covered by the CBD although the Bonn Guidelines do mention “derivatives” and “products”. What is important is to note that derivatives are: the result of an organisms’ metabolism, the result of a human activity using a genetic resources or information on genetic resources.
- 33 A quote by Richard Dawkins, the world known evolutionist, explains this very clearly when he affirms that genes are “pure information“. He states “*What has happened is that genetics has become a branch of information technology. It is pure information. It’s digital information. It’s precisely the kind of information which can be translated, digit by digit, byte for byte, into any other kind of information and then translated back again*”. Dawkins, Richard. *Life, A Gene Centric View*. Craig Venter & Richard Dawkins: A Conversation in Munich. (Moderator: John Brockman) Available at: <http://www.positiveatheism.org/hist/quotes/dawkins.htm>.
- 34 There is abundant academic literature explaining the economics behind the development, use and management of informational goods. For an excellent overview of these and other issues, see Birchler, Urs and Butler, Monika. 2007. *Information Economics*. Routledge, New York.
- 35 Piracy in CD’s, books, databases, software, etc. in most developing countries (and many developed countries as well) are just a few examples of the almost insurmountable difficulties in controlling flows of information. In the United Kingdom alone, back in 1999, the software industry lost more than UK Pounds 500 million to piracy and illegal reproduction. And this is a developed country with considerable enforcement of IP capacities.
- 36 The CBD refers to in situ conditions as “...*conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties*”.
- 37 See Ruiz, Manuel, Vogel Joe, Zamudio, Teodora. *Logic Should Prevail: a New Theoretical and Operational Framework for the International Regime on Access to Genetic resources and the Fair and Equitable Sharing of Benefits*. Research Document. Initiative for the Prevention of Biopiracy. Lima, Peru. Year V, No. 13, March 2010.
- 38 Professor Joe Vogel, of the University of Puerto Rico, has been proposing since as far back as 1993, that the concepts of sovereignty and country of origin, as well as the obligations

regarding mutually agreed terms and even PIC (bilateralism), have been adversaries of true equity and fairness in the distribution of benefits from access to genetic resources. This sections presents some of the ideas he has been proposing over time and only very few have noted, regardless of their conceptual and logical soundness.

- 39 Within the scientific community, the fact that genetic resources are information has been recognized decades ago. Even before Watson and Crick discovered the structure of DNA. In any case, since the 1960`s the informational nature of genetic resources has been the foundation of continued advances in genetics, genomics, proteomics, molecular biology, bioinformatics, and, ultimately, synthetic biology. As Dawkins and others, Schrodinger, has also expressed his views regarding the informational nature of genes. See, Schrodinger, Erwin. 1994. *What is Life ?*, available at http://whatislife.stanford.edu/Homepage/LOCO_files/What-is-Life.pdf. A recent text which addresses the complexities in the research and development process and analyses some of the implications of new technologies in ongoing policy debates see, Pastor, Santiago, Ruiz, Manuel. *The Development of an International Regime on Genetic Resources and Fair and Equitable Benefit Sharing in a Context of New Technological Developments*. Initiative for the Prevention of Biopiracy. Research Documents Year IV, No. 10, April, 2009. Lima, Peru. Available at <http://www.spda.org.pe>.
- 40 For experts such as Joseph Vogel, Economist and Professor of the University of Puerto Rico, the informational characteristic of genetic resources (widely recognized by scientists) has been underestimated and not taken into account in national and international policy and normative processes on ABS. Genetic resources are codified information: this is where the value and importance of genetic resources lies. As a result, this has generated inadequate legal and institutional frameworks, which have been ineffective to capture benefits derived from access to and use of genetic information. For details on this innovative yet inexplicably dismissed approach, see: Vogel, Joseph. 1994. *Genes for Sale. Privatization as a Conservation Policy*. Oxford University Press, USA.
- 41 Many international negotiations processes suffer of the principal-agent problem. Issues such as asymmetric information, representation, incentives, etc. all contribute to impeding process in the negotiations.
- 42 It is already possible to have a precise idea of how many species are distributed worldwide. GPS mechanisms, bioinformatics and newly developed tools such as the International Barcode for Life Initiative (iBOL), can serve to identify spatial distribution and help allocate benefits for conservation purposes. For details of iBOL see, Stoeckel, Mark and Hebert, Paul. Barcode of Life. In: *Scientific American*. Pgs. 82-88, October. 2008.
- 43 Vogel, Ibid. At 41.
- 44 See, Ruiz, Vogel, Zamudio, Ibid. at 36.
- 45 Contracting Parties are committed to reaching the Tenth Conference of the Parties in Nagoya, Japan in late 2010 with an agreed text, discussed in prior meetings of the *Ad Hoc* Open Ended Working Group on ABS (the last being in Cali, Colombia, in March 2010).

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