

Regulating bioprospecting and protecting indigenous peoples knowledge in the Andean Community: Decision 391 and its overall impacts in the Andean region ⁽¹⁾

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Acronyms

ABS	Access and Benefit Sharing
CBD	Convention on Biological Diversity
CIAT	Centro Internacional para la Agricultura Tropical
CIP	Centro Internacional de la Papa
CITES	Convention for the International Trade in Endangered Species
COICA	Coordinadora de las Organizaciones Indígenas
ELC IUCN	Environmental Law Centre of the World Conservation Union
FAO	United Nations Food and Agriculture Organization
ICBG	International Cooperative Biodiversity Group
INDECOPI	Instituto Nacional de Defensa de la Competencia y la Propiedad Intelectual
IPR	Intellectual Property Rights
MTAs	Material Transfer Agreements
NBS	National Biodiversity Strategy (of Colombia)
PBR	Plant Breeders Rights
PROMUDEH	Ministerio de Desarrollo Humano y de la Mujer (Perú)
SETAI	Secretaría Técnica de Asuntos Indígenas del PROMUDEH (Perú)
SPDA	Sociedad Peruana de Derecho Ambiental (Peruvian Society for Environmental Law)
TCA	Tratado de Cooperación Amazónica (Amazon Co-operation Treaty)
TRIPs	Agreement on Trade Related Aspects of Intellectual Property Rights
UNCTAD	United Nations Conference on Trade and Development
UPOV	Convention of the International Union for the Protection of New Varieties of Plants
USAID	United States Agency for International Development
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation

Introduction

Since the *Convention on Biological Diversity* (CDB) entered into force in December 1993, national and international discussions regarding bioprospecting (access to genetic resources and benefit sharing - ABS), indigenous peoples knowledge and intellectual property, as they relate to biodiversity, have intensified and produced a wide range of political, ideological and legal positions.

In this general context, *Decision 391 of the Andean Community on a Common Regime on Access to Genetic Resources* has, without any doubt, become an important landmark for international law and policy development regarding access to genetic resources and the protection of indigenous peoples knowledge, as well as intellectual property¹.

Decision 391, establishes a legal framework for bioprospecting in the Andean Region that seeks to ensure that the benefits derived from ABS related activities are shared with the countries where genetic resources and biologically derived materials are collected.

When the idea for a regional regime on access was first discussed in October 1993 more or less, Decision 391 - approved almost three years later in 1996 - has continued to influence numerous ABS regulatory processes world-wide and become a very useful instrument to identify key policy and legal issues related to bioprospecting².

The Andean regime was developed in a context where CBD ABS principles were the main available guidelines to orient national policy and regulatory processes. Comparative law and legal doctrine offered little assistance on the subject³. Equally relevant, was the fact that, at the time, tensions between “biodiversity rich” but technologically poor countries and industrialised but “biodiversity poor” nations were probably at their peak. Expectations on high economic benefits and returns associated to bioprospecting and overall inequities in technological and genetic resources flows, the way the intellectual property system operated and the manner in which economic benefits resulting from these flows were distributed between developed and developing countries, also influenced national and regional policies.

The purpose of this paper is threefold: to review the genesis and *rationale* of Decision 391, assess its implementation process in the Andean Region as well as some of its derived issues such as traditional

¹ The *Andean Community of Nations* (previously the *Andean Pact* or *Cartagena Accord*) is a sub-regional social, political and economic integration treaty, adopted in 1969 and whose Member States are Venezuela, Colombia, Ecuador, Peru and Bolivia. Binding legislation does not require Congress approval (unless stated otherwise) and is mainly passed through Decisions approved by the Executive branches of governments. Common Regimes establish minimum legal standards that must be met and implemented by Member States.

² To a considerable extent, Decision 391 is based on legal elements suggested in a technical report (*Towards a Legal Framework to Regulate Access to Genetic Resources in the Andean Pact: Possible Elements for an Andean Pact Decision on Access to Genetic Resources*) prepared for the Andean Community by the *Environmental Law Centre of the World Conservation Union* (ELC-IUCN) and *Peruvian Society for Environmental Law* (SPDA) in late 1994. From a review of ABS legislation in Costa Rica, Brasil and the Philippines and draft proposals from the *Organisation of African Unity* (53 nations), Nicaragua, among others, numerous elements and issues raised in the report and subsequently addressed by Decision 391 are also part of these regulatory instruments and proposals. The notion of a *regional* approach to ABS is also an influence of Decision 391.

³ Although literature on policy and legal aspects of ABS can be traced back to the late 70's, and particularly the 80's with the influential work of people like Pat Mooney (*The Law of the Seed: Another Development and Plant Genetic Resources. Development Dialogue* 1-2 (1983)) and Jack Kloppenburg (*First the Seed: The Political Economy of Plant Biotechnology, 1492-2000*. New York. Cambridge University Press. 1998), papers produced by the *United Nations Food and Agriculture Organisation* (FAO) and to soft law instruments produced thereafter (FAO Undertaking, Codes of Conduct), specific Legal Doctrine and Comparative Law on the subject was still scarce during the early 90's.

knowledge and intellectual property and, most importantly, evaluate its overall impacts and implications on bioprospecting activities four years after its formal adoption in 1996. Additionally, recommendations are presented at the end of the text specifically, but not exclusively, for national decision makers in order to, assist in the implementation process and also in eventual modifications to Decision 391.

This paper is based on the premise that bioprospecting, if addressed in a strategically, planned, medium term perspective, could provide biodiversity rich countries with a wide range of benefits which could stimulate development and strengthening of scientific and research capacities, offer important business opportunities, provide indigenous communities with an adequate compensation for the use of their resources and knowledge, enable the development of research partnerships, provide national scientists with training and equipment, provide economic benefits for all partners, among other possibilities.

1. The policy and legal background for Decision 391.

ABS issues were first raised in the Andean Community during the negotiations of a regional system for the protection of plant breeders rights (*Decision 345 on a Common Regime on Plant Breeders Rights*, enacted in October 21, 1993). In 1992, partly due to commercial interests from the cut flower industry of Colombia and the influence and subsequent technical assistance by the *International Union for the Protection of New Varieties of Plants* (UPOV), the Andean Community began a process to develop a regional UPOV-like mechanism to promote and protect plant breeders rights.

In a context of intellectual property rights (IPR) deliberations, it was the first time that at the regional and national level, private rights (plant breeders rights or PBR) over components of biodiversity were under consideration. Timing also coincided with parallel negotiations to modify the regional Industrial Property regime (Decision 344) and, in particular, extend the scope of patent protection over biodiversity components, specifically over biotechnological products and processes for which protection was limited at the time⁴.

With the CBD article 15 (*Access to Genetic Resources*) and ABS issues in the spotlight, some participants in the process for developing Decision 345, a) questioned the need for a PBR system in the region, b) argued as to whom would become the main beneficiaries of such a system, c) inquired on what impacts might it have with regards to biodiversity conservation and d) proposed that ABS issues be included in discussions, taking into account that plant breeding activities in the region (or abroad) would almost surely access and make use of Members States' rich genetic diversity to develop plant varieties and enhance breeding processes⁵. These concerns resulted in Decision 345 incorporating a Third Transitory Disposition which called for the establishment of a *Common Regime on Access to Genetic Resources* by the end of 1994.

The fact that Member States shared common biodiversity within their territories, also contributed to consider the development of a *common* regional policy to regulate access to genetic resources. Forming a "cartel like" bloc⁶ where countries would design a system to co-operate and ensure that all benefited alike

⁴ *Decision 344 of the Andean Pact on a Common Regime on Industrial Property* was adopted during a meeting of the *Commission of the Cartagena Accord* in Bogotá, Colombia on October 21, 1993.

⁵ The *National Biodiversity Strategy* (NBS) of Colombia, who had been publicly discussing many of these issues in Colombia for many months and SPDA, who had been participating in Decision 345 negotiations, formally expressed many of these concerns to the Andean Pact Board. The NBS of Colombia and SPDA presented the Andean Pact with comments and proposals regarding the need to link the plant breeders rights system with regulations on access to genetic resources. Thus, trying to ensure that access to genetic resources from Member States for breeding purposes were subject to CBD principles (including prior informed consent and mutually agreed terms).

⁶ For further analysis of the cartel notion see: Vogel, Joseph. *Bioprospecting* (Case Study 6). In: *Biopolicy Journal*, Vol. 2, Paper 5 (pya 7005), 1997. Online journal <http://www.bdt.org/bioline/py>

from access to and use of genetic resources, seemed the best alternative to prevent Member States from initiating a price war over mostly shared resources and thus undermine common interests⁷.

Certainly the entry into force of the CBD and general enthusiasm with regards to its potential, also played a pivotal role in stimulating the formation of a political scenario supportive of novel regulatory initiatives to implement its ABS provisions.

In this favourable context, and with the legal mandate pending from Decision 345, the Andean Pact requested technical assistance from the *Environmental Law Centre of IUCN* to promote a regional process to develop an ABS regulatory framework and provide it with basic legal elements for such a framework⁸.

1.1. Legal status of genetic resources, restrictions to access and protection of indigenous peoples knowledge.

Four critical but interrelated issues were at the core of initial discussions of Decision 391. Firstly, whether the regime should address biodiversity conservation and protection measures and only thereafter ABS issues. Secondly, what was the legal status of genetic resources in the region and, therefore, the rights and role of the State. Thirdly, whether the system should focus on strict control of access to and use of genetic resources (and how to achieve this) or rather regulate more flexibly an ongoing flow of these resources. Finally, the issue of indigenous peoples rights over their knowledge, innovations and practices related to biodiversity and whether and how would an ABS address it was also a critical discussion point.

Many participants proposed that the regime should focus on conservation of resources and the protection of traditional knowledge and, only then, address how and whom may access resources. Others suggested that the regional regime was in essence, a system to regulate genetic resources flows (trade) and that conservation issues and indigenous peoples knowledge issues, although very important should not be at the central core of the system. There were other regulations (many already in force) which could deal with conservation issues (per se).

⁷ In as much Amazonian countries like Brasil, Suriname and Guyana were not members of the Andean Community, certainly limited possibilities for the effectiveness of a "cartel like" approach. This was particularly the case of Brasil whose Federal Government (through an *Inter-ministerial Group on Access to Genetic Resources*) was taking a more cautious approach to regulating access to genetic resources and assessing its potential impacts on scientific and technological developments in the country. It should be pointed out that the Brazilian Congress was also developing its own ABS proposal very much in line with Decision 391 provisions. (Personal conversation with Marcio Miranda, *Chefe do DPD do Empresa Brasileira do Pesquisa Agropecuaria in 1996*). On June 29, 2000 de Brazilian Government enacted Medida Provisoria No. 2052 to regulate access to genetic resources. This regulation which is in practice a Law, establishes the legal framework on ABS in Brasil.. In theory it should be further regulated before the end of 2000.

Although the *Amazon Co-operation Treaty* (TCA) incorporates all Amazonian countries, its regulatory powers are very limited and, therefore, no binding legislation (such as Decision 391) can be enacted. A few years later however, it remains to be assessed whether in fact a more general, non binding framework for ABS under the TCA, could be designed to serve a more effective role in the region or if co-operation mechanisms among the TCA and Andean Community could also help to serve this purpose.

⁸ Starting in early 1994, the ELC-IUCN and SPDA organised a regional process which, in general terms, consisted of an initial experts meeting in Lima to discuss a first basic draft (May 1994); distribution of a consolidated text among leading experts; a regional workshop in Villa de Leyva, Colombia (August 1994) to further work on the text and the final submission of a technical report to the Andean Pact (October 1994). This would be part of a non-governmental discussion phase which would provide a political and governmental stage with inputs for the development of what later would become Decision 391. The governmental discussions consisted of six Expert Meetings and a final text being adopted in July 1996. For further details of this process, see: Caillaux, Jorge, Ruiz, Manuel and Tobin, Brendan. 1999. *El Régimen Andino de Acceso a los Recursos Genéticos. Lecciones y experiencias*. WRI, SPDA, Lima, Perú.

1.2 A few critical issues in developing Decision 391.

- **The North / South debate.**

The high profile of Decision 391 negotiations and the continued direct and indirect participation, input and differing views from a wide array of public and private institutions, experts, indigenous peoples organisations, NGO, intergovernmental organisations, etc. in regional discussions, served to polarise much of the debates. These discussions centered themselves on an evident, but maybe overly simplistic perception of an inevitable North / South conflict of interests. This subsequently steered discussions towards the need for a system to strictly control the flow of genetic resources from the region to industrialised countries.

The concept of “biopiracy” (see Box No. 2) also played an important and catalytic effect during this process. As a result, Decision 391 reflects a clear policy option and statement oriented at ensuring control of genetic resources by Member States and preventing this kind of modern piracy. Furthermore, this statement also includes indigenous peoples knowledge and intellectual property rights issues as part of the general concerns over ABS.

- **Data and information limitations.**

At the time of Decision 391’s development there was limited hard data and information available on the global genetic resources (and derived products) trade and market. Who was using what resources, what bioprospecting projects were underway in the region, what kind of partnerships were being undertaken between public and private institutions, where were genetic resources mostly obtained from, what were the actual economic incentives for bioprospecting, how where indigenous peoples participating in bioprospecting projects, among other key questions, were being answered based on mostly anecdotal and not fully verified information.

During the regulatory process, this particular constraint limited experts abilities to carry out sound calculations on potential economic value of genetic resources and their markets. Naturally, this resulted in over estimations and expectations with regards to bioprospecting becoming a key driving force for conservation and sustainable use of biodiversity in the region and, especially, as a source of monetary benefits for countries.

2. A critical overview of Decision 391

2.1 General orientation

As has been already pointed out, Decision 391 seeks to ensure that access to and use of genetic resources from the Andean region is controlled to the greatest extent possible. The State, as a key actor in the administrative process and leading party to the main access contract, bears the responsibility to ensure this orientation is fulfilled.

Nowhere are the strict control oriented aspects of Decision 391 more evident than in the case of its general scope and definition of access (as encompassing *all* activities which require access to and use of biological materials) and the legal treatment given to *ex situ* conservation and research institutions (see Section 6).

In this regard, the problems that are faced have to do, among other factors, with a common procedure for different types of bioprospecting activities. It seems quite clear, that in practice, marine bioprospecting is

different from microbial bioprospecting, and that the search for new genes in agro-biodiversity is also different from the search for novel bio-chemicals or genetic resources for pharmaceutical purposes. Even taxonomic research, more and more based on genetic analysis, would probably require specific, differentiated rules. Unless a regulatory regime is flexible enough to accommodate these different forms of research, common regulations will probably fail to be efficiently and effectively implemented.

2.2 Objectives.

According to its objectives (article 2), Decision 391 regulates access to genetic resources of Member States (and their derived products) with a view to a) establish conditions for a just and equitable participation in the benefits generated from access, b) establish the basis for the recognition and valuation of genetic resources and their derived products as well as of their intangible components, particularly in the case of indigenous communities, c) promote the conservation and sustainable use of biodiversity, d) promote the development and enhancement of local, national and regional scientific, technical and technological capacities and e) strengthen the negotiating capacities of Member States.

The critical question is then: do Decision 391 provisions actually promote the achievement of these objectives. *A priori* and in the light of the current stage of its implementation process (see section 2.5) it could be argued that Decision 391 has not yet fulfilled its role in meeting these objectives. Various reasons for this will be suggested throughout this paper.

The fact that almost four years after its entry into force, Decision 391 has not been implemented in Ecuador, Peru and Bolivia⁹ and that in the case of Colombia and Venezuela its application in a couple of cases has been subject to controversy, initially demonstrates that, in general terms, its overall objectives are still to be achieved (see Section 2.5).

2.3 Access procedure and constraints

The general situation presented in Sections 2.1 and 2.2 relate to specific features of Decision 391. In terms of the access procedure in general (see Box No. 1) it has been frequently suggested that Decision 391 presents conceptual and practical challenges. Complexity of this procedure, particularly considering the contractual negotiating process as applied to all types of bioprospecting activities and the number of contracts which could be required in particular, could certainly have a bearing on the viability of promoting research and development projects.

To an important extent, this characteristic is in turn related to the role of the State (the National Competent Authority) as a dominant actor of the access procedure in its effort to exercise its sovereign rights and through them, ensure maximum control over its resources. Parties other than the State, only have free contractual possibilities (accessory contracts) within the limits of an administrative procedure and conditioned to a State negotiated and approved access contract. These accessory contracts (see Box No. 1) allow negotiations with regards the biological resource which contains genetic resources over which only the State has rights.

Transaction costs could furthermore become a burden for implementation in the light of the model / referential access contract proposed in Resolution 415 of the Andean Pact, adopted on July 22, 1996. For example, this model (point d (4)) of Resolution 415 proposes that an applicant should commit not to

⁹ Peru and Ecuador began national processes to develop implementing legislation as early as 1997. In October 1999, the Peruvian Government published in the Official Gazette the first draft access proposal to implement Decision 391. To date, the processes to develop implementing legislation, are still under way. Bolivia on the other hand, presents a very *sui generis* situation: although it adopted Supreme Decree 24676, to regulate Decision 391 on June 21, 1997, this regulation has in turn not been fully implemented by the national authority.

transfer to third parties, genetic material which has been obtained, without the consent of the national authority. In a scenario where a few years later after materials were obtained and samples or extracts need to be transferred to a company for further analysis, what would happen if the national authority decides *not* to allow for this transfer or unnecessarily delays its response? Should a negative response preclude further research and investment?. Contractually, and a perfectly legitimate option for the State, it would certainly seem so. Point d (9) is also revealing as it establishes that the applicant will need to request the national authority an authorisation for the removal and transport of the collected samples outside the collecting site. It would seem rather obvious that most if not all research will be carried out *outside* collecting sites or areas. Point e (5) on the other hand, proposes that an economic guarantee is established to indemnify the State in case of non compliance with convened commitments and obligations. This last condition, has probably influenced the regulatory process in Ecuador where a recent draft regulation to implement Decision 391 established that applicants should leave a deposit of 100% of the total project budget as an economic guarantee.

These conditions do not seem an ideal incentive for potential collaboration and bioprospecting to take place.

Box No. 1 General summary of the access procedure in Decision 391

Step 1. Review general minimum conditions for access (article 17) to be included in application and / or access contract¹⁰.

Conditions could include: terms of transfer of materials to third parties (see final paragraph of Section 2.3 above), submission of research results, support to conservation and sustainable use of biodiversity research, participation of Member State nationals in research activities, among others.

Step 2. Submit an access application to the national competent authority (article 26).

Step 3. Celebrate an accessory contract (between applicant and *ex situ* conservation centre; owner or possessor of land where biological resource is located; owner or possessor of the biological resource or the national support institution) (article 41), and / or an accessory contract (or Annex) between applicant and provider of the intangible component (knowledge, whether from an indigenous community or not) (article 35).

Step 4. Access contract is celebrated between the National Competent Authority and the access applicant. All other contracts are subject to the results of the negotiations of the access contract (article 32). The State will take into account the interests of the providers of the biological resources and the intangible component (article 34). All accessory contracts will only enter into effect once the access contract has been signed (article 42).

Access by research and *ex situ* centres

Step 5. If bioprospecting is to be carried out by universities or recognised research institutions and researchers and they involve multiple access activities, a framework access agreement must be celebrated with the National Competent Authority (article 36).

Step 6. If *ex situ* centres or other institutions seek to carry out access related activities they must celebrate an access contract with the National Competent Authority. The National Competent Authority may celebrate access contracts with third parties who seek to access resources deposited in these centres of which Member States are countries of origin (article 37).

Step 7. The National Competent Authority may celebrate deposit, administration and inter-mediation contracts with universities or recognised research institutions and researchers (Fifth Complementary Disposition).

2.4 The role of the State: the law on paper and practical realities

The CBD rightly points out in article 15(1) that States, in recognition of their sovereign rights over their natural resources in general, are entitled to regulate access to genetic resources. Indeed, sovereign rights of the Modern State provides it with the foundations for its regulatory powers within its jurisdiction.

Latin – Roman legal tradition in Andean Community countries has also influenced Constitutional provisions regarding access to and use of natural resources: more specifically, it is generally understood

¹⁰ Through Resolution 414 of July 22, 1996 the Andean Pact adopted a referential model / standard *application* for access to genetic resources.

that natural resources (including non renewable ones such as minerals and petroleum, and renewable ones such as timber and fisheries and, especially in their wild and non-domesticated conditions), are under State control or domain.

In accordance to Member States national Constitutions, article 6 of Decision 391 has recognised that “...*genetic resources or their derived products of which Member States are countries of origin, are goods or patrimony of the Nation or State of each Member State...*”. Theoretical discussions can be undertaken with regards to the exact legal meaning of this provision. Valid arguments can be made as to suggest that it does not necessarily mean that the State has *property* rights over genetic resources but rather, a regulatory power which must ensure that these resources are used in accordance with the national interest. However, the *ratio legis* of this article, as expressed during Decision 391 drafting, is that basically, the State has and retains property rights over genetic resources in all circumstances. Furthermore, the second part of article 6 determines that these resources are non-transferable, not subject to confiscation, seizure or prescription and are independent from the legal regime applicable to biological resources which contain them.

Article 6 makes a distinction between the legal status of genetic resources (under State domain) from the legal status of biological resources in which the former are physically found. In this regard, biological resources and genetic resources do not have the same legal condition nor are subject to the same legal treatment in all cases. This is an important conceptual distinction which has an obvious bearing on the access procedures and contract negotiations (see Box No. 1). It would also seem that, even in the case of domestic, non-wild biological resources, the State will have rights over their genetic constitution.

Members States have legitimately chosen a legal option (to separate the status of biological and genetic resources) based on a series of considerations. Some of these include: a) a strong emphasis of the principles of permanent sovereignty, national patrimony and goods of the Nation, b) a market structure in which procurement and distribution mechanisms are still weak and therefore State intervention is required, c) a public choice to ensure that through the State and its direct participation in monetary benefits, the public interest can best be served, among others¹¹.

This situation contrasts quite dramatically with the situation of countries with a Common Law tradition (i.e. the US) where all natural resources (in most circumstances) will pertain to the owner of the land in which they are located¹².

Although for Andean countries, Decision 391 provides with a sound conceptual approach to defining different regimes for both biological and genetic resources, attending to the actual physical nature of genetic resources as a source of coded information, some practical constraints of applying the patrimony or property of the Nation or State theories become apparent.

Firstly and from a more formal perspective, this implies a series of different contracts to be negotiated which, in itself, and more so considering the State is involved, poses strong limitations (i.e. time, costs, bureaucracy, institutional capacities) for research and academic institutions in particular involved in bioprospect projects..

Secondly, if only the State has rights over genetic resources (from where the bulk potential benefits can be obtained in a negotiation), what real incentive is there for the owner, possessor or administrator of the

¹¹ For further discussion on these issues see: Rosell, Monica. *Access to Genetic Resources: A Critical Approach to Decision 391: Common Regime on Access to Genetic Resources of the Commission of the Cartagena Agreement*. Review of European Community & International Environmental Law. Vol. 6, Issue 3, London, 1997.

¹² For a comparative analysis of these different regimes see: Bass, Susan. And Ruiz, Manuel (Editors). 2000. *Protecting Biodiversity. National Laws Regulating Access to Genetic Resources in the Americas*. IDRC, Ottawa, Canada.

biological resource or land, to actually conserve his resources. Basically, what will be negotiated through an accessory contract is a payment for the provision of specimens or parts thereof. Article 34 does indicate that "... *access contracts will take into account the interests of the [physical] providers of the genetic resources ...*" but in the context of Member States governmental structures, it seems highly unlikely that benefits will in fact accrue back to these providers as compensation for their conservation effort and therefore act as an effective incentive.

Thirdly, and borrowing some simple ideas of Economy of Information Theory, the appropriation of genetic information presents a serious problem with regards to the question: how can property powers over genetic information be assigned and fully exercised? Unless protected by a form of intellectual property¹³, all genetic information contained within the biodiversity richness of a country presents itself as a *non rival* and *non exclusive* good in the sense that the use by one person does not limit possibilities of use by others. Additionally, it remains very costly to exclude others from its use. This aspect, relates very closely to the practicalities of physically restricting access to genetic resources. If genetic resources were essentially conceived as information, countries would need to develop an informational rights system which in some way ensures that use of it, is subject to certain restrictions and benefits can be captured. Decision 391 presents a critical problem regarding the nature and essence of genetic resources (i.e. from size to informational features to their almost infinite availability) *vis a vis*, the practical possibilities of applying and, especially, enforcing property or domain rights over them.

Finally, a point should be made even if it is not mentioned in political discussions, precisely because of its political implications and "incorrectness". But it is really at the core of the problems related to the ABS debates. Unlike any other natural resource, anyone, at any place and at any time can fairly simply obtain samples of biological material with potentially valuable genetic resources. Unless continued and large supplies of materials are required for research and development processes, access to and use of these resources can go unnoticed. Based on the very real premise that it is impossible to physically control most movements of biological materials, regulations in this regard should acknowledge this fact and be developed to act as an incentive for interested parties to comply rather than take easier options such as seeking access elsewhere, obtaining materials from other sources such as botanical gardens or, in the worst of cases, bypassing national regulations. The key in this regard is to ensure that the overall costs of complying with ABS rules are lower than the costs resulting from obviating legal rules so as not to create a perverse incentive. In this sense, Decision 391 could eventually act as a disincentive to interested parties, with the unwanted effect that this might generate in potential bioprospecting investors.

2.5 The process to implement Decision 391

Adopted on July 2, 1996, almost two years or so after the idea of developing a regional ABS regulation was first discussed, Decision 391 still stands as a fairly new and innovative legal instrument in the region. Although general expectations among experts and negotiators at the time regarding the common regimes' potential was very understandable, some analysts called for caution and agreed that in a context of evolving technologies and still limited North / South inter-institutional arrangements and co-operation, an uncertain demand or, more specifically, a poorly understood and assessed market for genetic resources, and generally under funded and limited scientific and technical capacities in the region, it would be the implementation stages which would ultimately prove the testing ground for the regimes' effectiveness and efficiency to address ABS issues in a regional context.

¹³ Genetic information (reflected in biotechnological products or processes) can at present be protected basically through patents. Even if existing in nature and "simply" isolated through a novel procedure, genes and their sequences or, if contained in a product, can be subject to patents in many countries. Arguably, there is a level of human intervention which enables this isolation and presentation of the genetic information in a new format or context (a new product). This foot note will not go into the details of the "discoveries", "patents", TRIPs discussions: the point to make is that through some sort human activity, genes are characterised and genetic information is deciphered even if only partially.

Information regarding *all* bioprospecting (and related) activities in member States is very much dispersed and has not been fully compiled or systematised to date. There are only a few relatively well documented cases regarding the implementation of Decision 391¹⁴.

- **Some practical cases.**

Probably the first documented case of bioprospecting where Decision 391 was applied, involved *Andes Pharmaceuticals Inc.* from the USA. In early 1997, Andes requested access to genetic resources in Colombia. The Ministry of the Environment (the national authority in Colombia) denied the application (Resolution 1030, November 14, 1997) on the grounds that it did not comply with Decision 391 formal and substantial technical, legal and scientific conditions. Official governmental arguments to deny the application differed from those of other sectors who have analysed the application and official response by the Ministry. In any case, most agree on the overall denial of Andes' application by the Government.

The Peruvian *International Co-operative Biodiversity Group Project Peru* (ICBG), an international bioprospecting effort funded by the *National Institute of Health*, the *National Science Foundation*, *USAID* and the *National Cancer Institute*, was initially negotiated in December 1993, well before Decision 391 entered into force although almost at the same time the CBD became binding to Contracting Parties. In 1996, parties to the ICBG (*Washington University*, the *National Natural History Museum of Peru*, *Peruvian University Cayetano Heredia*, the *National Confederation of Amazonian Nationalities of Peru* and *Searle & Co.*) finally reached an agreement which was based to an important extent on the CBD and draft Decision 391 principles which at the time were under negotiation. In this case, two salient features of this case were that the USA hadn't ratified the CBD and, nevertheless, its general ABS principles were taken into account as part of the negotiation process. Secondly, *Searle & Co.* agreed to a "know how" licence agreement by which indigenous Aguaruna communities of the Alto Marañon in the Peruvian Amazon provided them with knowledge (whether or not in the public domain) related to medicinal plants in exchange for benefits from and restrictions to the use of this knowledge¹⁵. This case has strongly influenced the Peruvian draft proposal for the protection of indigenous collective knowledge (see Section 3). It was basically used as a practical model from which key issues and problems could be conceptually analysed.

Venezuela, following the approach of Colombia, has chosen to apply Decision 391 directly, with no secondary legislation. In late 1999, the Ministry of the Environment of Venezuela (the national competent authority) celebrated an access contract with the *Eidgenossische Technische Hochschule* of Zurich, Switzerland in order for bioprospecting activities to take place in the Alto Orinoco, on Yanomani lands. The Yanomanis were not included in the negotiations although many medicinal plants in the region are well known and permanently utilised by them. According to widely disseminated information in the media, the contract establishes a very questionable compensation for indigenous communities who participate in the project¹⁶. Some information reveals that the Yanomanis will receive 30% of the total costs of the contract. It is not clear what this 30% figure actually entails. Although the exclusion of the Yanomanis from the negotiations is certainly unacceptable from a moral, cultural and even legal point of view, what remains as very interesting for the purpose of this paper, are the various and often conflicting interpretations given to the application of Decision 391. Whilst the government considers it has proceeded correctly and legally, many NGO and experts think otherwise.

¹⁴ The *Regional Office for South America of IUCN* is currently undertaking a project to determine the number and main features of all bioprospecting projects in South America (not only within Andean Community countries). The information and data will be available towards the end of the year or early 2001.

¹⁵ For further details of this project see: Tobin, Brendan. *Know-how licences: recognising indigenous rights over collective knowledge*. Bulletin of the *Working Group on Traditional Resource Rights*, 4, 1997, pp. 17 - 18.

¹⁶ See for example an article which appeared in newspaper *El Nacional* on January 26, 1999 entitled "El Ministerio del Ambiente Autorizó a Universidad de Suiza a Usar Recursos Genéticos de las Tierras Yanomani".

It is worth to note that in terms of the “cartel like” approach, at least in the specific cases of bioprospecting applications in Colombia and Venezuela, no evidence exists to suggest that national authorities took into account regional interests (for benefit sharing purposes) or even communicated with other Member States national competent authorities (see Section 3).

- **Regulatory initiatives.**

Bolivia rapidly adopted the *Reglamento de la Decisión 391 Régimen Común de Acceso a Recursos Genéticos* (Supreme Decree 24676, June 21, 1997) which is implementing legislation to Decision 391. However, almost three years later, this specific complementary regulation has not yet served its purpose of supporting effective implementation of Decision 391. Recently, through GEF / UNDP support, Bolivia undertook a national planning process which included a review to Decision 391, the Reglamento and discussions on how best to ensure implementation of both these norms. The technical assistance was provided by the *Royal Botanic Gardens Kew* whose *Convention and Policy Section* staff have participated in developing institutional and national ABS policies and regulations world-wide. The situation in Bolivia proves an important point with regards to Decision 391: the fact that there is secondary and complementary legislation, is not the only or most important condition to ensure an adequate implementation of the Common Regime. As discussed below, there are other factors which play a more influential role during this process.

Ecuador and Peru have also undertaken national processes to develop secondary and complementary implementing legislation. Ecuador has recently finalised the review of a draft proposal whilst Peru, as an annex to the *Proposal for a Regime for the Protection of Collective Knowledge of Indigenous Peoples*, published in the Official Gazette on October 21, 1999 (Documento de Trabajo 003-1999) for comment its own draft regulation to implement Decision 391. The regulatory exercises in Peru and Ecuador were particularly interesting in that they demonstrated the strict boundaries set by Decision 391 and the limited possibilities for, at the national level, setting less rigid provisions on ABS.

Law 5468 (*Biological Diversity Law*) of Venezuela, incorporates a chapter on access to genetic resources. However, when reviewing its articles (72 through 78), these are mainly a repetition of provisions contained in Decision 391. Hence, this Law is not truly implementing legislation as such.

- **Final considerations on the implementation process.**

At the 15th *Global Biodiversity Forum* held in Nairobi, Kenya in May, 2000 and during the session on ABS, some participants suggested that assessing Decision 391 and its impacts proved to be a futile effort at this time in as much as it is still not fully implemented in the region. However, it is important to consider that a critical and fundamental task for analysts is to, precisely, evaluate the reasons *why* Decision 391 is not yet implemented and point out the direct and underlying causes for the delay in the implementation phase. In the case of Decision 391, reasons for non implementation have little to do with the fact that Member States have not enacted secondary or implementing legislation. Rather, there are major policy concerns, practical difficulties, legal uncertainties, differing interpretations, institutional limitations, data and informational gaps, among others, which severely limit at present possibilities of Decision 391 to become an effective and efficient legal instrument for countries.

The very detailed nature of the common regime in terms of procedures and even detailed terms (procedural periods) for these, pose another challenge. Decision 391 leaves little space for complementary regulations to make it more flexible according to national needs and the nature and characteristics of specific bioprospecting activities. As a common regime, and based on the considerations mentioned in Section 1, particularly with regard to a regional common approach, the *rationale* of legislators was to

establish a system within which countries would be subject to a very specific and detailed ABS legal framework to limit Member States possibilities of developing more flexible approaches and maybe undermining regional interests, over national considerations (shared resources).

What remains to be further explored among Member States, are the exact co-operation mechanisms which, for example, ensure that the (monetary and non-monetary) benefits derived from access to and use of genetic resources of which more than one Member State is country of origin, will be shared. Although at the core of the common regime, to date this co-operation has been very limited or non-existent. Most of the documented cases and situations seem to be addressed from a national perspective.

Articles 48 and 49 of Decision 391 call upon Member States to notify each other when access applications are submitted, contracts are negotiated, authorisations are given or any bilateral or multilateral negotiations are undertaken with regards to ABS activities. More specifically, the Second Final Disposition establishes that “...in the negotiations of the terms of access contracts over genetic resources or their derivatives of which more than one Member State is country of origin [...] the National Competent Authority will take into account the interests of the other Member States, who will be able to present their points of view and information they deem relevant”. However, how will this become operational and not unduly complicate a negotiation process under way or add unnecessary burdens, remains to be seen. This is a particular issue which the *Andean Committee on Genetic Resources*, legally constituted by article 51, might want to address at its first meeting. One of the roles of the Committee is to provide with advice and recommendations for a better implementation of Decision 391 (article 51(a)).

3. The access regime, intellectual property systems and indigenous knowledge: inevitable conflict or a chance to conciliate interests ?

Almost unanimously, participants in the process of developing Decision 391 recognised that access to biological and genetic resources is, in many instances, closely related to how indigenous peoples study, use and enhance them and to the application of intellectual property rights (basically patents and plant breeders rights) over products and processes, directly or indirectly, derived from these resources. The interrelation between access to genetic resources, intellectual property rights and indigenous peoples knowledge, innovations and practices are certainly complex.

Already, article 16(5) of the CBD for example, points out that Contracting Parties recognise that “...patents and other intellectual property rights may have an influence on the implementation of this Convention ...”. On the other hand, the concept of “biopiracy” (see Box No. 2) has been widely used to highlight how through access to biological and genetic resources and through the IPR system, the knowledge, innovations and practices of indigenous peoples can be unlawfully or illegally used and exclusive rights granted to transnational corporate interests. New plant varieties and biotechnological products and processes protected by IPR *incorporate* (or are based on) knowledge, innovations and practices without the knowledge or consent of indigenous peoples, without a due compensation and, in general, with little if any consideration for their interests.

Although it is hard in some cases to ascertain the (quantitative and qualitative) extent, degree, level and way in which knowledge innovation and practices are in fact used or incorporated into IPR protected inventions, it seems clear that there is a use of traditional knowledge at some point during the research and development process in many of these protected inventions. Going back in history, the use of quinine, curare, Pau d’Arco, Sangre de Grado, ginseng, and many other medicinal plants for instance, was first identified as being part of indigenous peoples cultures in different parts of the world. Nowadays, the use of ethnobotanical information (widely available in books and databases throughout the world) for

example, is certainly a means by which previously “unknown” uses and properties of medicinal plants can be used in modern societies for the development of new drugs.

Article 8(j) of the CBD offers an initial legal basis on which mechanisms to protect indigenous peoples interests can be developed. Article 8(j) establishes that subject to their national legislation (an unfortunate qualifier) Parties shall “...*respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilisation of such knowledge, innovations and practices*”.

Even if it might be extreme to argue that in *all* cases IPR systems are unsuitable to protect *all* indigenous peoples interests, it seems clear that patents and plant breeders rights in particular are not the ideal instruments through which indigenous peoples might protect their knowledge, innovations and practices¹⁷. Reasons vary and include the level of novelty required to protect an invention, the way in which innovation is generated within indigenous peoples (collectively but also individually), the complexity of administrative procedures to achieve patent or PBR protection, costs of requesting and enforcing patent or PBR protection, among others.

¹⁷ It should be noted that the concepts of “knowledge”, “innovations” and “practices”, although used very loosely to refer to indigenous peoples intellectual effort and output, imply different aspects of this effort and probably have different implications particularly from a legal point of view and, more so, when undertaking regulatory efforts. This is furthermore relevant as legal frameworks need to be very clear with respect to the object they are seeking to regulate and protect. Knowledge seems to be clearly an intangible element which can certainly be reflected in innovations (if these were limited to tangible products i.e. a traditional medicine) and practices (if these were also circumscribed to a tangible, materialised process or procedure i.e. how to prepare a traditional potion). Other analysts strongly suggest that knowledge, innovations and practices, and resources on which they are based, become a single entity, an intangible and tangible component which cannot be separated and which have to be protected as a whole. In any case, experts and policy makers will need to theorise on how these concepts are defined in a specific protection regime, whether at the national or international level. See: Ruiz, Manuel. *Protecting Indigenous Peoples Knowledge: A Policy and Legal Perspective from Peru*. Policy and Environmental Law Series. Peruvian Society for Environmental Law. No. 3, May 1999, Lima, Peru.

Box No. 2 Biopiracy in the region.

“Biopiracy” is a very effective political concept to illustrate instances where biological materials and indigenous peoples knowledge are used and commercialised (or subject to some form of IPR) without consent of national authorities or communities nor an adequate compensation. From a strictly legal perspective, it does need further analysis to become conceptually sound. It is a very useful concept however, particularly to highlight the extremely disadvantaged situation indigenous communities have to face with regards to the commercial and industrial use of resources found on their land and which they have conserved, nurtured, further developed and domesticated and studied over long periods of time. It is also useful to stress - in a more political concept - how the North has come about to dominate the South in the “bioresources market” through the use of its biological resources.

a) The Quinoa Patent

In April 1994, a patent was awarded in the US (Patent No. 5304718) for *Cytoplasmic Male Sterile Quinoa*. According to the patent document, “*the cytoplasm conferring the property of male sterility is derived from the Apelawa variety of quinoa*”, a variety long used by Andean farmers. Indeed a first reaction, it seems ludicrous that researchers could obtain rights over certain characteristics of an *Apelawa* variety used for centuries by Andean Farmers, furthermore when literature was available at the time regarding reported sterile male quinoa lines. Certainly a case where the biopiracy concept applies neatly. However, upon further research and reviews on the case (which made headlines throughout the world) it was found that the sterility itself was found in *Apelawan* varieties growing in the US and that this sterility is in fact not found in Andean varieties. In this particular case, it had been transferred from weed species growing in nearby vicinities. However, and due to concerns by exporters in Bolivia (*Asociación Nacional de Productores de Quinua*) on the potential impact of the patent for their future production and exports to the US, a campaign was initiated and ended in 1998 when Colorado State University dropped the patent.

b) The Ayahuasca Patent

A more controversial patent was US Patent No. 5751 awarded to Loren Miller of the US in 1986 for a claimed new and novel variety of *Banisteriopsis caapi* (cv), “Da Vine” or Ayahuasca, in indigenous cultures of the Amazon. This plant is cultivated and used by indigenous communities for religious and medicinal ceremonies throughout the Amazon. In March 1999 a Request for Reexamination was filed by COICA and the Centre for International Environmental Law (CIEL) to the US Trademark and Patent Office based on the argument of prior art. The request also challenged the varieties novelty and its variations were widely known in scientific literature. The request also alleges that the patent is contrary to the public policy and morality clauses of the Patent Act due to the sacred nature of “Da Vine”. The patent was annulled shortly after.

Under article 7 of Decision 391, Member States (according to this regulation and their national legislation) “...recognise and value the rights and decision making powers of indigenous, afro-american and local communities over their traditional knowledge, innovations and practices associated to genetic resources and derived products”. The decision making power is really a formal and express recognition by the State of powers indigenous peoples and communities have always had in theory but which, for a number of reasons, has hardly ever been exercised. Its explicit recognition is very important from a policy perspective. More interestingly, although subject to the national legislation qualifier and to the need for further specific content development, it recognises indigenous peoples *rights* over knowledge, innovations and practices.

But Decision 391 goes a little further. Article 35 provides with formal agreements, covenants, contracts, letters of intent, or any other instrument through which parties formalise obligations and commitments, as

the legal instruments for indigenous peoples to ensure their knowledge, innovations and practices are used subject to their consent and to benefit sharing conditions¹⁸.

Decision 391 certainly recognised the critical importance of the IPR and indigenous traditional knowledge issue and, in response to Member States concerns, the Eighth Transitory Disposition determines that upon the submission by Andean countries of national reports, the Andean Community (Secretariat) will prepare a proposal for the “...*establishment of a special regime or harmonisation regulation oriented to strengthen the protection of indigenous, afro-american and local communities traditional knowledge, innovations and practices in accordance with article 7 of this Decision, ILO Convention 169 and the CBD*”. This commitment is still pending since 1996.

All Member States have initiated and continue undergoing (with different levels of progress) national processes to assess and, eventually, develop special legal mechanisms to protect indigenous peoples knowledge, to implement article 8(j) of the CBD and not the least, to balance a situation where certain type of intellectual innovation is protected through IPR and another, just as valuable and important, remains unprotected and subsequently uncompensated nor rewarded for its use in any equitable form.

Peru has taken important steps in the development of a national policy and legal instruments to protect indigenous peoples knowledge associated to biodiversity. Following the final stages of Decision 391 negotiations and as a reflection of the Peruvian Government commitment towards the issue, article 63 of Legislative Decree 823, the Industrial Property Law, which entered into force in April 1996, established that “... *through a Supreme Decree approved by the Ministry of Industry, Tourism, Integration and International Trade Negotiation a special regime for the protection and register of native and campesino [peasant] communities will be established*”. This provision (and indeed Decision 391 and the CBD) triggered the national policy process regarding indigenous peoples knowledge.

Through Resolution of the Presidency of the Board INDECOPI (*the National Institute for the Defence of Competition and Intellectual Property*) No. 086-2000 - INDECOPI/DIR of August 29, 2000, Working Document 010-2000 on a *Proposal for a Regime for the Protection of Collective Knowledge of Indigenous People* was published in the Official Gazette for wide dissemination and for training purposes. This proposal is, in turn, based on a previous document also published in the gazette in 1999¹⁹ and which was subject to a wide consultation process..

This Working Document is the result of an almost three year long process where a multi-disciplinary Working Group led by INDECOPI worked towards the development of a legal instrument to protect indigenous peoples knowledge. Meetings, international seminars, workshops, consultation processes with indigenous peoples representative groups, interviews with national and international experts and presentations in international forums, were all part of an effort to, in the best participatory way possible, construct this legal proposal²⁰. Training and capacity building materials for indigenous peoples are also

¹⁸ Article 35 specifically refers to the case where access is sought for resources over which an *intangible component* is associated. In this situation an Annex (the agreement, contract, etc.) will be integrated into the access contract. This annex will be signed by the applicant and provider of the intangible component. In certain cases (subject to national legislation) the annex could be also signed by the national authority. The *intangible component* refers to *any* knowledge, innovation and practices, not necessarily nor exclusively those of indigenous peoples.

¹⁹ See: *Propuesta de Régimen de Protección de los Conocimientos Colectivos de los Pueblos Indígenas y Acceso a los Recursos Genéticos*. Working Document. El Peruano, October 21, 1999. Both this proposal and Working Document 010-2000 can be accessed at: <http://www.indecopi.gob.pe>.

²⁰ Among those consulted were: the governmental sector (i.e. *National Institute of Traditional Medicine, National Institute of Natural Resources, Ministry of Industry, Ministry of Agriculture*), the academic sector (i.e. Prof. Susette Biber Klemm from the *University of Basel*, Prof. Graham Dutfield from the *Oxford Centre for the Environment, Ethics and Society*, Prof. Abraham Vaisberg from the *Universidad Peruana Cayetano Heredia*), indigenous peoples representative organizations (i.e. ANDES, OBAAQ, AIDSESEP, CONAP) Congress representatives, NGO's (i.e. SPDA, ADN), international institutions (i.e.

being developed by the SETAI of PROMUDEH (the *Technical Secretary of Indigenous Affairs of the Ministry of Promotion of Women and Human Development*).

In simple terms, this proposal rests on three main pillars: a) the use of contracts (licences) as the legal instrument by which indigenous knowledge related to biodiversity can be negotiated by indigenous peoples themselves and through which their prior informed consent can be obtained, b) the recognition of the collective nature of indigenous knowledge (while acknowledging the fact that within communities individual intellectual efforts are also very important) and c) the possibility for knowledge in the public domain to be subject to contractual provisions upon agreement between parties. The licence referred to in point a) above is, precisely, the annex in article 35 of Decision 391 and will contain provisions regarding up front payments and eventual royalties for communities. Communities will always have a right to oppose bioprospecting or access to their knowledge. Here again an interesting conceptual and practical challenge arises if communities decide not to allow access to or use of their knowledge, with regards to resources over which only the State retains rights even if these are widely recognised as domesticated.

An important aspect of this proposal is that it is limited to indigenous peoples knowledge related to biodiversity. It implicitly excludes tangibles (i.e. a medicinal potion *per se*) from being protected. In any case, it could be also argued that ultimately, it is the knowledge which gives value to the innovation and therefore the critical element which requires attention and protection.

Whoever has access to and utilises indigenous knowledge (with their consent) has an obligation to provide the *Fund for the Development of Indigenous Peoples* (Title IX) with a minimum retribution of 0.5 % of total sales resulting from the commercialisation of products resulting from the use of this knowledge. Even in the case of knowledge which is in the public domain, applicants will be required to contribute with a maximum of 0.5% of total sales to the Fund (article 12).

Equally relevant in the proposed regime is that indigenous peoples knowledge (which is not in the public domain or undisclosed information) remains a trade secret of communities and, in this regard, the burden of proof is placed on the person or institution who unlawfully or without the consent of communities discloses and uses their knowledge to dispute any wrong doing or misuse. An administrative procedure is established for infractions to the regime (Title XI).

A national register and local registers are also incorporated as a means to prevent the loss of indigenous knowledge. This register is confidential and only accessible to communities or third parties if they have their consent. However, certain basic information can be provided to third parties in order for them to initiate contacts with communities. Article 20 establishes that upon request by communities, the information contained in the register can be used by the national authority in order to oppose the granting of patents on the grounds of the prior art or novelty requirements.

Two other important issues remain as practical challenges to be faced by the regime. On one hand, the problem of consent of communities who share similar knowledge. Article 7 and 23 address this and provide with a practical solution, which, it should be recognised, does not solve all of the problems. In order to celebrate a contract or licence agreement, the consent of all communities (who share similar knowledge) is *not* required (article 23). However, the contacted community(ies) should make the best effort to inform other communities that it is entering into negotiations and take into account their interests, particularly their spiritual and religious concerns (article 7).

This option reflects a situation where it will obviously be impossible to obtain prior consent from all communities. Indeed, this poses an additional problem of how much disruption and conflict might arise

among communities if some benefit and others don't or even if some want to participate in bioprospecting efforts and others don't. It is hoped that the *Fund for the Development of Indigenous Peoples* (Title IX), to which all communities are entitled, serves to ensure that even if communities do not participate in a specific bioprospecting project they can benefit from resources available for their use in conservation or development projects. From a more philosophical but critical perspective, one could speculate as to what effect any form of legal regime could have on indigenous cultures²¹.

Finally, another challenge to be overcome refers to whether or not the proposed regime acts as an effective incentive to promote registering of indigenous peoples knowledge and to actively empower communities to participate (or not) with their prior consent, in bioprospecting projects. Certainly, and still to be assessed, is whether the regime also creates an environment where researchers, universities and eventually companies have the incentives to enter into agreements with communities, particularly with regards to knowledge which is in the public domain.

In the case of Venezuela, the *Biological Diversity Law* (Law 5,468, of May, 2000 includes under Chapter III on the *Protection and Recognition of Traditional Knowledge of Indigenous Peoples and Communities*, specific provisions by which the State recognises their rights over their knowledge related to biodiversity and their right to collectively enjoy the benefits derived therein and, most importantly, to be compensated for their conservation of natural environments (article 84). This Law also recognises the collective nature of indigenous knowledge (article 85) and the *National Biodiversity Office* as the authority with jurisdiction over indigenous peoples knowledge issues. The Law is programmatic in nature and thus, requires further development through complementary secondary legislation.

Finally, indigenous peoples representative groups in Bolivia have also undergone a national participatory process through which they are developing a proposal for the implementation of article 8(j) of the CBD.

4. The linkage between access and the IPR regime

Decision 391 is the first binding regulation²² in the world (other than the general references of the CBD to the interrelations between biodiversity and IPRs and some FAO Resolutions) to establish a clear and unmistakable linkage between the access to genetic resources and the IPR system.

²¹ Some critics argue that "...*alternative rights regimes [for indigenous peoples] are just a more naive form of slippery slope leading inevitably to patent models and transactions ... efforts to legislate indigenous knowledge run against customary practices and threaten the survival of co-operative innovation systems*". For further analysis of this issue see: The Crucible II Group. *Seedling Solutions. Volume 1. Policy Options for Genetic Resources: People, Plants and Patents Revisited*. IDRC, IPGRI & Dag Hammarskjöld Foundation. Rome, 2000. pp.80.

²² Although this is true in a regional and international context, *strictu sensu* the first legal instrument to establish some linkage between access and IPRs was really Decreto 533 of Colombia of 1994 which regulated the plant breeders regime. Article 10 (f), regarding the application to obtain a breeders certificate establishes that the application should disclose the genetic origin of the material and paragraph (h) refers to the need to disclose geographical origin of the material used for the new variety.

But the Peruvian Supreme Decree No. 008-96-ITINCI, *Regulation for the Protection of Plant Breeders Rights* (complementary to Decision 345) of May 6, 1996 is even more specific and clear in its linkage of PBRs with ABS aspects. Article 15 (e), when referring to the application for a Plant Breeder Certificate, establishes that the application should indicate "...*the geographical origin of the plant material used as raw material by the breeder in his new variety, including, if it be the case, the document which proves the legal origin of the genetic resources contained in the variety as provided by the National Competent Authority on Genetic Resources*". Paragraph f) goes further in requiring the application to indicate "... *the genetic content and origin of the variety and include all known detail regarding the source of the genetic resources contained in the variety or for its development, as well as all information regarding knowledge related to the variety if it be the case*". This knowledge could indeed, refer to indigenous knowledge. If an application is not complete or is missing these requirements and the applicant (after he is notified) does not complete it in due time, the national patent office of INDECOPI (who are responsible for IPR and PBR issues) can declare it as abandoned.

Based on article 16(5) of the CBD and a general consensus among negotiators that mechanisms should be developed to ensure that IPRs are supportive of the CBD objectives, Decision 391 included two provisions which are of extreme importance for Member States and the region and have gone as far as to dramatically influence negotiations of the new *Andean Community Common Regime on Industrial Property*, Decision 486, adopted in September 2000 and which will replace Decision 344 as from December 2000.

The Second Complementary Disposition of Decision 391 establishes that “... *Member States will not recognise rights, including intellectual property rights, over genetic resources, derived or synthesised products and intangible associated components, obtained or developed based on access activities which do not comply with this Decision*”. Additionally, “.. *Member States are entitled to request the annulment of or present the corresponding actions in countries which might have conferred rights or protection titles*”. In principle, this provision seeks to ensure the interests of Member States as countries of origin. It is worth to note the reference to “synthesised products” which are essentially new technologies and over which Decision 391 seeks to extend its scope and have an incidence.

The Third Complementary Disposition establishes that “*National intellectual property offices shall, in cases where they have reasonable or concrete evidence that the product or processes for which protection is being requested have been obtained or developed from genetic resources or their derived products for which any of the Member States is a country of origin, require the applicants to submit the registration number of the access contract and a copy of it, as a pre-requisite for the granting of the corresponding right*”. This provision continues by establishing that IPR offices and access authorities will develop mechanisms to exchange information regarding access contracts and IPR applications.

In accordance with these Dispositions and further specifying their scope, article 26(h) of Decision 486 requires patent applications to include, if it be the case “... *copy of the access contract, when products or procedure whose protection is requested have been obtained or developed based on genetic resources or the derived product of which any of the Member State is a country of origin*”. Paragraph (i) goes on to establish that, if it be the case, a copy of the licence or authorisation for the use of indigenous knowledge will also be requested. Critical here is the “...if it be the case...” qualifier. National authorities will have to determine under what circumstances and regarding what inventions they will request these documents. Certainly this could be the case if they have evidence that a biotechnological invention has been based on genetic resources of which member States are countries of origin.

This approach is clearly an innovative mechanism to ensure that when using genetic resources (or traditional knowledge) in an invention for which IPR is requested, applicants have undergone all regulations related to ABS and indigenous knowledge protection before the rights are granted. There are some constraints though, including jurisdictional limitations (this mechanism can only be applied in Member States) and there could be practical problems in, for example, identifying the exact geographical and legal origin of genetic resources contained in a biotechnological invention for which IPR is requested.

These problems however, should certainly not be regarded as insurmountable. This mechanism, if adequately implemented, not only in Member States but throughout the world, could provide a) with a means for *all* parties to the CBD (providers and users of genetic resources alike) to promote compliance with its general ABS, technology transfer and IPR provisions, b) act as a mechanisms to safeguard the interests of mega-diverse countries which provide biotechnological sectors (in the North) with genetic resources and, most importantly c) create a system which acts as an incentive for mega-diverse countries to make their ABS regimes more flexible. If industrialised nations adopt these measures and include them in their own IPR regimes, this could pave the way to a process of mutual confidence building among those traditionally supplying resources and those using them and positively influence international negotiations, research and development initiatives and bioprospecting endeavours in general.

The region is again the source of a unique and groundbreaking Industrial Property (Decision 486) regulation whose article 3 (*Biological and Genetic Patrimony and Traditional Knowledge*), establishes that "... *Member States will make sure that protection provided through elements of industrial property [not only patents] is provided safeguarding and respecting their biological and genetic patrimony as well as the traditional knowledge of their indigenous, afro-american and local communities. In this regard, patents concerning materials obtained from this patrimony or knowledge, will be subject to those materials having been obtained in conformity with international, regional and national regulations*". Basically, what Decision 486 is proposing is that patents are available but in justice and fairness and legality, applicants must make sure they also comply with ABS and indigenous peoples knowledge regulations which could be in force, and are intrinsically related to certain type of innovation, more specifically, biotechnological products and processes.

But here again, there are experts who already, but validly, question Decision 486 as a whole²³. Indeed, their argument goes beyond the actual text of the law and focuses on the overall IPR system and TRIPs in particular, as clear mechanisms which have been imposed (fundamentally by the US) on developing countries and ultimately only favour industrialised nations. Furthermore, the important, but often sidelined moral and ethical argument against patenting of life forms, is also another valid approach to the discussion. Decision 486 falls within the scope of these arguments. But what seems quite a paradox in the Andean IPR Decision is that it contains so many explicit - and in our concept groundbreaking provisions- and self-executing articles (i.e. article 3, 26, 29) which refer to the protection of the Members States interests in genetic resources and biologically derived materials as well as to the interests of indigenous peoples. A regional, specific IPR regulation containing a single reference to ABS or indigenous peoples would have been unheard of only a couple of years ago anywhere in the world. In this regard, an important step has been taken to find ways in which IPR systems and ABS provisions and ultimately the CBD principles can establish the necessary synergies to ensure that biodiversity components are sustainably used and the benefits derived thereof equitably shared.

5. Perspectives for research and development and the *deterrence* effect in the region

Although institutional and corporate views (in the case of private biotechnology companies, pharmaceutical companies, *ex situ* conservation centres, research institutions) with regards to the effects of CBD ABS principles and specific ABS legislation on research and development processes vary considerably, the more complex policies and regulation are, the greater the disincentives for the establishment of bioprospecting alliances with national institutions. As a result, alternative options usually imply targeting other countries (where no or lesser restrictions are in place) or to seek other sources of biological and genetic materials (i.e. from *ex situ* conservation centres)²⁴.

Many of these institutions and even companies, readily acknowledge that in a context where national and regional policies and rules to access biological and genetic resources are changing dramatically with regards to prior situations, they need to adapt to this emerging scenario²⁵. However, they also point out

²³ See BIO-IPR docserver for an article prepared by Genetic Resources Action International (GRAIN) and Margarita Florez from Colombia "*Andean Community Adopts New IPR Law*". This article will be shortly posted on GRAIN's website (<http://www.grain.org>).

²⁴ For a comprehensive overview of the different positions of companies and industry in general and research institutions regarding ABS regulations, see: Ten Kate, Kerry and Laird, Sarah. 1999. *The Commercial Use of Biodiversity. Access to Genetic Resources and Benefit Sharing*. EARTHSCAN. Earthscan Publication Ltd. London.

²⁵ Some of these organisations have developed their own institutional policies to orient and guide their bioprospecting and research practices. Examples include the *Botanic Garden Policy on Access and Benefit Sharing* which includes gardens from Australia, Brazil, China, Colombia, Malaysia, Germany, Ghana, Mexico, Russian Federation, South Africa, USA and the UK in an effort to develop a common approach to ABS from the perspective of botanical gardens acting as users and providers of biological and genetic material. The *Royal Botanic Gardens Kew Policy on Access to Genetic Resources and*

that stringent regulations will not promote the necessary co-operation which is required in all bioprospecting effort. Strict and burdensome regulations imply transaction costs which will probably deter national and international bioprospecting initiatives and research activities in the region in general²⁶.

In its present form, Decision 391 does not necessarily *promote* bioprospecting²⁷, even though its objectives refer to “promotion” as a key feature of the regime. When reviewing its history, it becomes clear that the policy goal of negotiators and drafters was to establish a system to strictly control access to and use of genetic resources and ensure State participation in benefits derived thereof. The balance between regulating access and facilitating it (as provided by article 15(2) of the CBD) is probably still to be met either through continued practice during future implementation of Decision 391 or through its formal legal review.

From an overall assessment of the common regime, it is striking to note that in none of its provisions does the State (represented by the national authority) actually act as a *promoter* of inter-institutional collaboration. Here again, Decision 391 does refer in various of its provisions to “co-operation”, but its procedural complexities and limitations (i.e. number of contracts to be negotiated or level of State intervention) and its underlying *rationale* (i.e. controlling the flow of resources) certainly undermine its express objectives and goals. The lack of incentive measures plays an important role in shaping this situation.

Benefit Sharing (January, 1998) is another example. Some *International Agricultural Research Centres* of the CGIAR such as the International Potato Centre in Peru, currently have in force *Material Transfer Agreements* (MTA) as a mechanisms to regulate the use of their collections. Furthermore, they also have institutional policies on IPRs and for general use of deposited materials. The MOSAICC project (*Micro-organisms Sustainable Use and Access Regulations - International Code of Conduct*) is also developing guidelines and norms to ensure microbial collections conform to CBD principles. The *Strathclyde Institute for Drug Research* in the UK also has standard agreements which regulate how they will access resources and the benefits they will share. The *National Cancer Institute* of the USA also has an institutional policy which it implements with respect to ABS. Indeed, many institutions and companies are addressing the issue and, whether in the form of policies, non-binding regulations, (material transfer agreements) MTAs or any other instrument there seems to be a clear tendency towards incorporating ABS considerations into corporate routine practices. How these policies link to national or regional ABS policies and regulations is key in ensuring comprehensive, coherent and mutually supportive ABS systems.

²⁶ During the *XVI International Botanical Congress* held in St.Louis, USA in August, 1999, a specific session on ABS clearly reflected the views of botanists and scientists in general: although most agreed that in the context of international policy and the CBD in particular, ABS rules were now an integral and unavoidable part of the research process, they highlighted the potential risks of over regulating, restricting and probably unintentionally affecting research. To an important extent, scientists from developing countries would be affected by declining co-operation and possibilities for institutional partnerships. Furthermore, they stressed the importance of not imposing restrictions to taxonomic research as the building bloc for any (whether regional or national) biodiversity conservation or sustainable use strategy.

In this context it became clear that a delicate balance must be achieved between the legitimate right of countries to regulate and control access to their resources and the need to ensure and not unduly restrict co-operative, and, especially national research activities.

²⁷ During personal conversations with national and international researchers (from universities, botanical gardens, CIP) and representatives of the private sector (national and international companies), held between 1996 to date, all agree that as much as there is interest in continuing bioprospecting and research activities in the Andean region, in its present form, Decision 391 is not acting as an instrument to promote co-operation and collaboration and certainly does not provide with incentives to undertake these activities. The recent study by ten Kate and Laird (see Note 23) highlights some of the reactions from the private sector to ABS policies and regulations in general and would confirm this particular view.

Box No. 3 Towards a more flexible legal framework on ABS

Following, is a proposed basic and general framework with elements that could be considered when defining a legal ABS regime, whether at the national or regional level. Before defining a system, countries should assess and take into account legal and practical considerations arising of integrating the different systems already in force to access biological material and samples (i.e. scientific collecting permits, CITES procedures, etc.) or establishing the necessary linkages and complements among them. Whether the national authority is a single entity for all procedures which imply accessing biological material or genetic resources or their derivatives, or, if different procedures are developed for different types of access, its competence and jurisdiction should be clearly identified

Also critical and of great importance before defining the legal structure of a norm, is the heed to have a very clear idea of the objective and ultimate purpose of bioprospecting laws, in the context of national (or regional) research and development targets.

Step 1. Submission of an access application to a national authority.

Step 2. Submission of the access project (all agreements, covenants, letters of intent, etc. celebrated among participating institutions). Parties are free to negotiate although they will need to take into account general conditions established by the national authority (i.e. necessary participation of a national research institution in field and lab work, need for part of the research and development process to be carried out in the country if facilities and capacities are available, need for a percentage of monetary benefits arising from the commercialisation of a product to be directed to a national research and development fund, need to seek consent of indigenous peoples if field work is carried out on their lands, need to submit copies all reports to the national authority, etc.).

Notes:

- According to the type of bioprospecting activity, the access project will obviously be more or less complex. The national authority will require certain discretion when assessing applications and projects. Training and capacity building at the national level and for national authority officials is key to ensure technical soundness of decisions and overall transparency of procedures.
- Special procedures apply for *ex situ* conservation and research institutions. Field work should not be unduly restricted. Restrictions could apply at the stage when deposited materials are transferred to third parties. *Standard Material Transfer Agreements* could be an instrument to be considered for this purpose.

Step 3. National authority approves overall project after verifying that general conditions are met.

It should also be noted that for a system like this to be operational (basically in Latin American countries) it would have to be assumed that parties (individuals, institutions, the State, indigenous peoples) who have rights over biological resources are entitled to negotiate with regards to the genetic resources and information contained therein. This would not imply that they necessarily have property rights over these, but that they are legally entitled to negotiate over them. Conditions of access would then ensure that the State or Nation interests are duly taken into account and respected. Benefits for the country would thereby encompass a wide range of possibilities which could include: strengthening of national (private or public) research capacities, promotion of bioprospecting efforts throughout the country, strengthening the negotiation capacities of indigenous communities in as much as a) they are free to a decide if they want to negotiate and b) decide upon terms of the negotiation process (support by specialised institutions will probably be required), promotion of co-operative projects, continued exchange of scientific information, training of national scientists, of a national research and development capacities throughout the country etc.

At present, there are evidences that a series of bioprospecting initiatives are on hold and stand by and, in some cases, could be under way *de facto* and sidelining Decision 391. As mentioned in Section 2.4, the physical nature of biological material (and encoded information) and relative ease with which it can be

used, mobilised, replicated and even exported, certainly plays in favour of those seeking easy, unregulated and uncompensated access to potentially valuable genetic resources. Furthermore, limited systematised information about ongoing projects and geographical features of the Andean and Amazonian region especially, make it extremely difficult to assess the general situation in the field and establish control mechanisms (see footnote 13).

On a final note, though confidentiality regarding certain aspects of bioprospecting agreements is understandable from a commercial point of view, the cloud of secrecy and non-transparency which surrounds many of these agreements (or the limited access provided to these) tends to naturally fuel suspicions and negative reactions. Applications for and sometimes granting of very questionable patents (i.e. Ayahuasca, genetically modified cotton and soya, quinoa, among the most conspicuous ones) do not contribute either to reducing tensions. In this regard, making information available on the projects to be undertaken and sharing information on the general structure of it as well as who are involved, could be a means to lower these tensions surrounding bioprospecting activities.

6. International research centres: the Centro Internacional para la Agricultura Tropical (CIAT) in Colombia and the Centro Internacional de la Papa (CIP) in Peru

Ex situ conservation and research centres (botanical gardens, aquariums, nurseries, etc.) are very important actors in access related activities. These centres collect genetic resources, carry out taxonomy and other research, sometimes develop commercial products, maintain materials and, often, transfer this material to third parties. This section will not address the problem of all *ex situ* centres in the Andean Community with relation to Decision 391 but, rather, focus on how it relates to two *International Agricultural Research Centres*, CIAT in Colombia and CIP in Peru²⁸. Nevertheless, most of the arguments apply to all *ex situ* centres in the region.

During negotiations of the common regime, *ex situ* centres and particularly CIAT and CIP were perceived as unregulated filters through which genetic resources were continuously exported to industrial nations. No hard data nor information regarding the transfer of materials (i.e. their origin, destination, purpose of transfer, etc.) was available nor rigorously assessed, but the general feeling among negotiators, based on historic patterns of genetic resources flows, was that this flow of resources from *ex situ* centres should be further regulated and controlled. It is also interesting to point out that during negotiations of Decision 391, limited if any contact was made with CIAT and CIP representatives in order to receive their inputs and suggestions with regards to the proposed regime.

Two articles of Decision 391 specifically address the situation of *ex situ* centres and a couple more complement these provisions. These obviously apply to CIAT and CIP.

Article 36 of Decision 391 establishes that “...*the National Competent Authority can celebrate framework access agreements with universities, research centres or recognised researchers which allow for the execution of various projects, in accordance with Decision 391 and national legislation of each Member State*”. Under this provision, CIAT and CIP, which certainly *are* recognised research centres could decide to negotiate a framework access agreement with the national authority, although the actual terms and scope of this particular type of agreement is not defined by Decision 391. Framework access agreements would seem to refer to general and more comprehensive agreements which would allow these

²⁸ For a detailed analysis of Decision 391 and its relation with CIAT and CIP see: Ruiz, Manuel. *Los Centros Internacionales de Investigación Agrícola y los Posibles Impactos de las Políticas y Normas de Acceso a Recursos Genéticos: el Caso del CIAT y el CIP en la Región Andina*. Serie de Política y Derecho Ambiental. SPDA, No. 4, November, 1999. Lima, Perú.

centres to carry out their activities without the need for individual access contracts for each and every access related activity.

But then article 37, also establishes that “...*ex situ conservation centres and other entities which carry out activities that imply access to genetic resources or their derived products or, if it be the case, to the associated intangible component, will have to celebrate access contracts with the National Competent Authority, in accordance with this Decision*”. This article specifically refers to *ex situ* centres (i.e. CIAT and CIP). Whilst article 36 seems to suggest a more flexible regime for research centres which continuously carry out access related activities (i.e. continued field work and collecting of samples), article 37 establishes that *ex situ* centres will have to celebrate access contracts under all and each circumstance in which they are accessing genetic resources.

Article 37 goes further, and its second paragraph determines that the national authority “...*may celebrate with third parties, access contracts of which Member States are countries of origin which are deposited in these centres ...*”. Although the qualifier “may” is used, the phrase is interesting in that it reflects once again, a general orientation of the common regime where *all* possible situations in which *ex situ* centres are involved require State intervention, including transfer of materials to third parties. This situation arises from the point that was initially discussed in the paper: genetic resources are State property and, therefore, only the State has a right to negotiate them. The practical implications of this are obvious and in the case of institutions such as CIAT and CIP even more so in the case of materials of which Member States are countries of origin.

Two initial questions need to be addressed. Firstly, which one of these articles is applicable to CIAT and CIP in as much as they are both research centres *and ex situ* centres at the same time. Secondly, in the case of article 37, it would seem that the need for participation, intervention and control by the State reflects itself in two different moments: during field work (where access contracts will need to be celebrated) and during the stage when samples might be transferred to third parties. Why intervene both when collecting and transferring materials? Rather, why not develop a system by which ABS measures cover gaps and complement their institutionally regulated transfer activities?

The answers to these questions are further complicated by the fact that CIAT and CIP are developing their own institutional policies with regards to ABS. Though not necessarily comprehensive in their approach, they do reflect the concern of two very special type²⁹ of institutions and their initial steps to adapt to an evolving international ABS context³⁰ which includes the review of the *International Undertaking on Plant Genetic Resources* and its eventual adaptation to CBD ABS principles.

The First Transitory Disposition of Decision 391 calls upon entities who hold genetic resources (i.e. *ex situ* centres) of which Member States are countries of origin, to regularise their situation with the National Competent Authority. It does not specify whether this requires the celebration of an access agreement for each and every sample held or maybe a framework access agreement if article 36 is invoked.

²⁹ CIAT and CIP are special in that they hold agricultural accessions from numerous countries. Not all indicate origin of the material. Most importantly, these resources are basically used for agricultural research purposes. Considerable amounts of material (from the region and abroad) are used directly in Colombian and Peruvian national agricultural research systems and benefit national and local populations in general.

³⁰ For a complete review of CIP policies on ABS and intellectual property rights see: International Potato Centre. *Genetic Resources. Biotechnology and Intellectual Property Rights*. Office of Deputy Director General for Research. Lima, Peru, June, 1998.

7. The problem of parallel processes: CITES permits, scientific collection permits.

This very brief point, basically highlights the fact that in parallel to Decision 391, Member States have long standing legal instruments which regulate access to biological material and flora and fauna samples. These regulations norm scientific collecting of these materials and samples and questions arise as to whether in certain cases (and most importantly *which*) both Decision 391 rules and regulations for this collecting apply simultaneously or rather complement each other. From a strict interpretation of Decision 391 (and its definition of “access” and scope) it would seem that the common regime either supersedes any other system for collecting biological derived materials or is yet an *additional* legal requirement to those imposed by these traditional scientific or commercial collecting systems.

Article 14 of Decision 391 establishes that “... *as long as genetic resources contained in biological resources are not accessed ... the provisions of the regime will not affect the utilisation and free transit of these resources ...*”. It would seem that direct use of biological resources are not covered although the definition of “access” and “genetic resources” leave this possibility open.

A practical and important issue which Member States need to face refers to the fact that in many cases, some countries (i.e. Peru) are currently allowing activities for the collection of biological materials (i.e. *Sangre de Grado* or *Croton lecheri*, *Pijuayo* or *Bactris gasipaes Kunth*, *Uña de Gato* or *Uncaria tormentosa*) for commercial purposes which have little to do with research and development of genetic resources *per se*, but are rather oriented towards providing growing national and even international botanical medicine, nutraceutical and food industries with raw, unprocessed materials for the development of new products.

Indeed, at least in the case of Peru, the problem of which regulation is applicable, has been clarified by the Third Complementary Disposition of the draft access bill (August 2000) which establishes that “... *permits, authorisations and other documents issued by public entities such as INRENA, INIAS or MIPE and that allow for research, access to, transfer of or others, over biological resources, with objectives which are different from being used as a source of genetic resources, do not entitle holders of those biological resources to indirectly access genetic resources nor do they imply an access authorisation*”. The question in this case, is whether in fact companies could be accessing biological resources for their general properties as such or indirectly for properties derived from their genetic make up.

Some countries such as Ecuador, have interpreted Decision 391 and its definition of “derived products” as including these types of activities within its scope and therefore the need to apply the common regimes ABS rules. Peru on the other hand is not applying these rules to these activities but rather applying the commercial collecting permit system³¹.

Also very interestingly, in early 2000, the *Fundación Amigos para la Naturaleza* (FAN) of Bolivia and the *United States Department for Agriculture* (USDA) presented an access application to the Bolivian *Dirección General de Biodiversidad* (DGB) of the *Ministry of Sustainable Development and Planning* in order to collect, elaborate inventories, prepare a distribution atlas and deposit in national and foreign *ex situ* facilities wild peanut specimens.

This appears to be a typical conservation project for an agricultural (industrial) crop where access to genetic resources *per se* is not necessarily the main objective of the overall project although it could be

³¹ In a personal conversation with Ximena Butron, an official of the *TRAFFIC International* office in Quito, Ecuador in August, 2000, the question of whether Decision 391 scope applies to these activities (direct industrialisation of medicinal plants) was also raised.

Ecuador’s legislation includes Resolution 019 of 1997, which regulates research, collecting and export of wild flora and fauna for non-commercial purposes.

argued that peanuts are biological and genetic resources at the same time. In any case, FAN has strongly argued that all formal requirements have been fulfilled (including strict compliance with the national Reglamento and Decision 391) the *Foro Boliviano de Medio Ambiente y Desarrollo* and indigenous representatives have denounced this project as a form of biopiracy. Here again, conflicts within countries regarding exact interpretation of access rules³². FAN argues that, ultimately, and given the delay in a response by the national authority (the DGB) the message given is that no incentive is provided to those who seek to undergo and comply with formal legal procedures.

These concerns would also apply to CITES permits and whether Decision 391 can also be invoked for this specific kind of collection and export of biologically derived materials.

For these cases, it would be important to specify the relations between the different legal systems in force and their application to activities implying access to and use of biological and genetic resources. This would certainly contribute towards legal certainty³³. During the *First International Congress Fito 2000* and *First Peruvian Congress on Medicinal Plants* (September 2000) held in Lima, Peru, lack of references or even acknowledgement of Decision 391 when legal and institutional aspects were discussed in some way demonstrates not only limited awareness but maybe an explicit position with respect to this regulation by all participants (public officials, companies, indigenous representatives, scientists).

8. Decision 391 in the wider international policy context: its impacts and where to now?

Decision 391 and the Philippines Executive Order 247 (*Prescribing Guidelines and Establishing a Regulatory Framework for the Bioprospecting of Biological and Genetic Resources, their By-Products and Derivatives, for Scientific and Commercial Purposes and for Other Purposes*) served as catalysts for ABS policy and regulatory processes world-wide³⁴ and as a source of legal elements and comparative regulations for these processes.

In perspective, Decision 391 certainly enabled the Andean region countries to start seriously addressing issues which were critically important for the region. Among those, intellectual property rights and biodiversity, indigenous peoples participation and intellectual property rights, how to give the concepts of prior informed consent and mutually agreed terms operational and practical significance and biosafety. For most of these issues, Member States have also started to undertake policy and regulatory processes and, indeed, in some cases, have enacted legislation or developed well advanced drafts or incorporated these issues into broader regional policy discussions (i.e. inclusion of biodiversity and access considerations into the recently approved *Decision 486 of the Andean Community on a Common Regime on Industrial Property*).

Decision 391 is at present the only *regional* approach to ABS and in this regard and even if not fully implemented, offers a unique opportunity for other mega-diverse regions to compare the advantages and

³² Press release by FAN "Alientan Biopiratería Genética en Bolivia", June, 2000.

³³ The Sixth Complementary Disposition establishes that in the case of natural protected areas, the access applicant will not only be obliged by Decision 391, but will also be required to comply with specific national legislation related to these protected areas. In this particular case, Decision 391 is very clear with regards to the legal regimes which are applicable (both those of the common regime and of national protected areas).

³⁴ By 1998, more than 50 countries had initiated ABS policy and regulatory processes, including, Nigeria, Seychelles, Mexico, Argentina, Australia, Turkey, USA, the Organisation of African Unity (53 States), Laos LDR, Indonesia, India and Fiji. See: Glowka, Lyle. 1998. *A Guide to Designing Legal Frameworks to Determine Access to Genetic Resources*. IUCN Environmental Law Centre. Environmental Law and Policy Series No. 34. Gland and Cambridge. pp.23.

disadvantages of adopting this option. Based on this approach, the *Organisation of African Unity* for example, has developed a *Draft Legislation on Community Rights and Access to Biological Resources*.

To an important extent, the common regime has also served as a case study based on which the issues it addresses can be further explored, assessed and developed. It has certainly served to raise the profile of these issues in the region (and elsewhere) and raise awareness of public officials and civil society in general. ABS related topics pose common problems to countries undertaking regulatory efforts.

Although it is hard to evaluate the exact role and influence Decision 391 has had in international forums which address ABS, such as the CBD itself, FAO meetings, the WTO and WIPO, a review of the actual discussions and the policy / technical / information papers prepared and distributed, almost always contain explicit references to Decision 391. Arguably, discussions referred to transaction costs of ABS regimes, on how to address PIC problems when indigenous communities are involved and on how to relate ABS systems to intellectual property rights regimes (see Section 4) have relied to an important extent on the Decision 391 experience.

Four years after its adoption and in the light of ongoing policy and regulatory processes world-wide, most of which incorporate common considerations and approaches to the ABS, it remains to be seen and confirmed by practice, if these efforts have undergone the necessary, comprehensive and rigorous planning processes required to achieve effectiveness and efficiency in ABS regulations. General enthusiasm on regulatory approaches could be leading to overlook key elements and practical considerations that, in the long term, might in fact undermine ABS laws. For instance, understanding and rigorously assessing (with verifiable data and information) the markets for genetic resources and their derivatives, the way research and development efforts actually work and the demands of different sectors of industry, is critical when designing laws and rules which will have a direct impact on these and their related activities. Assessing national interests in terms of technology needs, training of scientists and, in general, participating in collaborative research and development processes is another factor which requires *ex ante* rather than *ex post* analysis.

ABS regulations based on careful and participatory planning, which takes into account some of these points and undertakes this comprehensive multi-disciplinary analysis, will probably have as a result more effective laws which in turn will almost certainly improve possibilities of attracting investment in bioprospecting and reliable partners. In all cases, the national interest should be assessed in the light of practical considerations as well.

9. Conclusions

Whether through a regional legal regime (Decisions) or national regulations, incentives are key for national and foreign institutions to engage in co-operative research and development processes. A review of Decision 391 (and national secondary implementing legislation in Bolivia and drafts in (Peru and Ecuador) does not reveal incentive mechanisms (i.e. tax exemptions for national institutions who require equipment for research purposes, differentiated procedures for taxonomy purposes) but rather a strong tendency by the State to intervene, regulate and control ABS related activities.

In this regard, for the common regime to be effective, a critical question to be made is: what are the cost of implementing the system in relation to the benefits it generates? Costs in this case imply: costs of establishing and organising a national authority, training its personnel, administration of the system, monitoring activities, negotiating contracts and, in general, evaluating all costs associated to economic efficiency. This efficiency would certainly also include assessing the best mechanisms to ensure indigenous peoples groups are adequately and timely advised and informed.

Equitable bioprospecting depends on regulations (and their effectiveness) but also considerably on the capacity that national scientists and institutions have to engage with national authorities in medium or long term strategies for bioprospecting and research and development in general. Proactive approaches and a clear objective are essential to ensure that research and development initiatives are achieved. If a legal framework can reflect this, all the better.

On another note, direct participation - in terms of negotiating bioprospecting agreements - of national authorities in all and every single bioprospecting project is not absolutely necessary. National institutions such as universities and research centres (the national support institution referred to in decision 391) could represent the States or Nations interests in these negotiations. These are national institutions (i.e. universities) with impeccable reputations who are directly involved in bioprospecting efforts, know the actors, know the “business” and could fairly easily ensure that the minimum conditions which the State establishes in order to guarantee the national interest is taken into account. In this regard, another question to respond and assist in the planning process could be: what exactly and specifically is the national interest in the context of bioprospecting activities and how and by whom could it best be served (i.e. through training in molecular biology of a public or private university scientist who will then teach new techniques to colleagues and students). National interests should be seen in a wider context and not exclusively from a State oriented perspective. It is mostly a question of building confidence and being mutually supportive of initiatives.

Finally, in its current form, Decision 391 offers limited possibilities for partnerships and co-operative efforts to take place. The problem rests not so much on the fact that there is an access framework (which there should be) but how this regime is structured and designed. If - and only if - bioprospecting is to be seen as a potential tool for developing national scientific knowledge, ensuring a wide range of benefits and promoting strategic alliances among the different range of institutions, being practical and flexible is not incompatible with holding strong political and ideological beliefs oriented at securing the national interests³⁵.

10. Recommendations

The *Andean Committee on Genetic Resources* should undertake, in the light of new information and data on genetic resources markets and international policy developments, a comprehensive policy, economic and legal review of Decision 391. This review, *if* bioprospecting is to be promoted as potentially beneficial activity for the region by means of a common policy and legal framework, should consider aspects such as flexibility and overall transaction costs of the system and their impact on effective implementation.

Access procedures should be simplified and, most importantly, viewed in the context of differentiated activities and actors (i.e. agriculture bioprospecting, pharmaceutical related bioprospecting, bioprospecting by *ex situ* conservation or research centres). These procedures should be very clear and transparent and, in this regard, flexible alternatives and a degree of discretion by national authorities could serve to streamline access related activities.

³⁵ As mentioned initially, this paper would like to stress that its content will probably only be of use and be valid for those who are not fundamentally opposed to bioprospecting *per se* and who see in it, potential for building national capacities and, hopefully, as a real business opportunity to benefit all actors alike: the State, scientists, indigenous communities, companies, etc.

Most countries have in place procedures for collecting biological material for research purposes (i.e. Peruvian scientific collecting permits or even CITES permits). An access regime should be assessed in the light of existing regulations in order to avoid parallel or overlapping procedures which would lead to legal uncertainty for all (national and international) potentially interested parties.

National authorities should be clearly identified and their specific roles determined. Ideally, their role should focus on promoting partnerships, creating incentives for these partnerships, providing indigenous communities with legal / technical advice and training on ABS issues or orienting them towards institutions who can fulfil this role, maintaining information and databases updated with regards to all bioprospecting activities being undertaken in the country (and share this information with other competent authorities), oversee and monitor bioprospecting activities, among others. Furthermore, national authorities should support without unnecessarily intervening, private and even personal research initiatives and efforts³⁶.

Overall benefits derived from access to and use of genetic resources are often hard to pin point. Monetary benefits are usually the focus, particularly of the State. But benefits are usually not easy to perceive. For example, training and enhancing capacities of national scientists, development of databases, taxonomic work, biological assessment of biodiversity rich areas, preparation and publication of scientific papers and reports, participation of national scientists in work in foreign laboratories, development of strong institutional partnerships, among others, are all benefits which accrue, directly or indirectly, in the medium or long term, to the country as a whole. In this sense, the State should develop measures to ensure that these benefits are continuously generated through different projects. As mentioned in the previous point, direct participation of the national authority is not necessarily the best means through which to ensure this.

In terms of negotiating or establishing benefit sharing conditions, Andean countries and national institutions should also seek to ensure that at least part of the research and development process and training possibilities and financial resources can be targeted at fighting national / regional endemic diseases such as yellow fever, malaria, cholera and other tropical illnesses.

The process of development of new rules and provisions for the common regime or national regulatory frameworks, should take into account: evaluating international policies and instruments, specific institutional policies on ABS of institutions seeking access, possible alternative instruments to ensure sharing of benefits derived from access (i.e. national or regional mechanisms to protect native crops or land-races), measures that “user countries” could be implementing in order to ensure country of origin interest are protected, etc.

Aggressive awareness raising processes need to be undertaken by Member States of the Andean Community to explain Decision 391’s significance and the scope of its provisions. The *Andean Committee on Genetic Resources* could develop an explanatory guide or manual where common approaches are detailed and possible gaps and misconceptions or doubts be addressed for the benefit of potential bioprospectors (whether national or international institutions).

³⁶ A very illustrative case of how private initiatives should be supported and promoted is that of Dr. Manuel Sandoval, a Peruvian Phd. working as an Assistant Professor for the Center for Cardiovascular Sciences at the Albany Medical College. Dr. Sandoval travels every year to Peru, to the University of Tingo Maria in the Amazon and teaches students techniques for screening native medicinal plants from the region. He is committed to teaching students basic skills and establishing a research program, an aspect which clearly relates to bioprospecting activities. The question is then: what impacts could Decision 391 have on his activities and whether it would support and stimulate further commitments by him to spend time teaching and in turn stimulating local students to research the potential of medicinal plants in the area.

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