

Brazil's Practical Experience with Access and Benefit Sharing and the Protection of Traditional Knowledge

ICTSD Project on Genetic Resources

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The use of genetic resources and associated traditional knowledge (ATK) has been characterized by lack of regulation and unfair benefit sharing. This picture began to change only in 1993, when the Convention on Biological Diversity (CBD) came into force recognizing national sovereignty over genetic resources and the need for benefit sharing as a fair return for the asymmetries between users and providers of biodiversity. The CBD also obliges its members to respect indigenous peoples' and traditional communities' rights related to the use of their traditional knowledge subject to national legislation.

Access to genetic resources and benefit sharing (ABS) is a recent theme with a new perspective that is still little practiced. So far, few countries have developed specific laws and policies on ABS.¹ Brazil has made some progress on ABS, although its experience is still recent, and therefore incomplete. Before ABS legislation, negotiations about bioprospection were treated with deep suspicion, raising questions and heated public debates. Lack of clarity about who the beneficiaries should be, the legitimacy of stakeholders to negotiate contracts, the level of confidentiality of the contracts, and the role of state and private actors in these activities gave rise to uncertainty that discouraged sustainable business around biodiversity.

ABS Legislation in Brazil: Achievements and Prospects

In the 1990s, several ABS bills were tabled in the Senate and the House of Representatives by the legislative and the executive powers. It should be highlighted that these included the Project of Law n° 306/1995 authored by Senator Marina Silva, the first initiative that enabled discussion and public hearings on ABS, and the Project of Law n° 4751/1998, accompanied by the Proposal for Constitutional Amendment n° 618/1998, prepared by an interministerial ABS working group coordinated by the Ministry of Environment.

This legislative process, however, did not give rise to the ABS legal and institutional framework currently in force in Brazil. It was only after the disclosure and negative impact of the negotiation of an agreement between a social organization and a multinational company, parallel to the ongoing legislative process in the House of Representatives, that the federal government decided to issue the Provisional Act² 2052/2000, the first ABS law in Brazil.

¹ Convention on Biological Diversity-CBD (2010). *ABS Measures Database: List of Countries and Regions with measures*. Montreal, URL <http://www.cbd.int/abs/measures/groups.shtml>; accessed May 2010.

Carrizosa, S. (2004). "Diversity of Policies in Place and in Progress" in *Assessing Biodiversity and Sharing the Benefits: Lessons from Implementing the Convention on Biological Diversity*. Carrizosa, S.; Brush, S.B.; Wright, B.D. & McGuire, P.E.

² Provisional acts consist of a specific type of legislation, stipulated by the Constitution of Brazil, whose creation and enactment are independent of the legislative power.



After a few adjustments, this bill reached its final form - MP 2186-16 - and began to be implemented in April 2002 with the creation of the Department of Genetic Heritage (DPG), a division of the Ministry of Environment, and the first meeting of the Genetic Heritage Management Council (CGEN), a collegiate government body, formed by 19 ministries and federal institutions, with rule-making and deliberative functions. DPG has the administrative function of receiving and processing all access requests. The access authorizations and additional normative acts are issued by CGEN. Meetings are held monthly, and CGEN is regulated according to its bylaws.

Since then Brazil has developed a minimal and stable institutional structure concerned with ABS management, with a technical expertise on the subject. This allowed the creation of spaces for pluralistic, thorough discussion and documentation and, chiefly, has enabled the experience of managing the complex world of access to and use of genetic resources. At the same time, there is much criticism on this legislation related to the lack of civil society participation in CGEN, the excessive control over non-commercial research, and transaction costs generated by the instruments established to ensure benefit sharing - the contract between provider and user - and to ensure the rights of indigenous peoples and traditional communities - the prior informed consent.

Currently there is collective agreement on the need for a new legal framework to address ABS in Brazil. Effective management of genetic resources demands innovative and less bureaucratic approaches and ways to effectively direct the benefits gained to conservation of biodiversity. A new legal framework, however, requires a comprehensive negotiation process and eventual consensus between the various stakeholders involved. Thus far, the subject has not been a political priority to the executive and the legislative powers, and there are no expectations of change in the short term.

The logic of Brazilian ABS legislation is similar to that already established in other countries. It involves issuing permits of access to activities of scientific research or bioprospecting to user institutions. Foreign institutions aiming to access genetic resources must necessarily be associated with a Brazilian institution. Authorizations are granted only by CGEN when the purpose of access is considered to have economic potential. If the purpose is strictly scientific, authorizations are issued by two accredited institutions with faster procedures, the Brazilian Institute of Environment and Natural Resources (IBAMA), and the National Council for Scientific and Technological Development (CNPq).

One of the requirements for granting authorization of access for bioprospecting³ is the previous signature of a Contract for Use of Genetic Heritage and Benefit Sharing. This contract is the instrument to ensure that benefits from the economic exploitation of a product or developed process is fairly and equitably shared between

the contracting parties. The contract is signed by the user institution, and, according to the geographical origin of the samples of genetic resources, by the public or private landowner, or a representative of the indigenous community, and by the Brazilian governmental indigenous agency, or a representative of the local community.

The contracts become effective only after they are approved and registered with CGEN. Where the contract does not involve genetic resources from federal public areas, the Council will not evaluate whether the benefits are fair or monitor the implementation of contracts; it only checks whether the formal requirements have been met. There is also no legal obligation to revert benefits to the conservation of biodiversity as recommended by the CBD. So far, there has been no economic evaluation of the effectiveness of contracts to ensure fair and equitable sharing of benefits in Brazil.

As of March 2009 CGEN had approved and registered 22 contracts. Most of these contracts relate to bioprospection at the initial stage, conducted mainly by national public institutions. Only one of these contracts included a foreign institution. Several institutions that perform this activity have claimed great difficulty in estimating the benefits that could be generated when developing a commercial product. For this reason, many contracts stipulate that benefits will be shared, through an additive term, only if economic exploitation occurs. Some of these contracts have confidential benefit-sharing clauses requested by user institutions.

In many cases it has not been possible to sign a contract due to an inability to define or identify the landowner of certain in situ sites or even the geographical origin of the genetic resource. In other situations, the collection of genetic resources has been done in the past, without a precise identification of the geographic origin of genetic resources. These situations prevent the contract signature and, in some cases, the granting of a permit. Moreover, when the bioprospection involves genetic resources collected in different places, the processing of tens to hundreds of contracts becomes virtually impossible. These examples exemplify the failure of existing ABS law.

These imperfections have led to questions concerning the operational logic of the current law. The linkage of benefits to the holder of the area generates a high transaction cost, once it requires CGEN to monitor negotiations in which it does not participate, and there is no guarantee that the benefits revert to the conservation of biodiversity. The federal government recently prepared a new draft law on ABS in which contracts with providers of genetic resources disappear. Accordingly, when users of genetic resources are based in Brazil there would be an obligation to contribute to a public fund of benefit sharing based on a fixed percentage rate of benefits deriving from commercial sales or licensed patents. Contracts would remain only in cases where users of genetic resources are foreign institutions, and the benefit share would

³ CGEN promoted debates and consultancy to different sectors in order to establish a complementary norm capable of distinguishing bioprospection from non-commercial scientific research. Bioprospection comprises only those activities already aimed at the development of new products.

be negotiated with CGEN and directed to the public fund. Finally, this fund aims at financing actions for the conservation and sustainable use of biodiversity.

From the standpoint of benefit sharing, results obtained with current legislation have not been quantified. However, despite the recognition that legislation needs to be improved, the fact remains that Brazil has a legal framework for ABS, legal and institutional requirements for bioprospecting projects are in place, and benefits have been and continue to be shared.

Connections Between ABS and Intellectual Property Rights

The existence of a procedure to disclose origin or source or legal provenance of genetic resources and ATK in the process of granting intellectual property rights (IPRs) is a measure claimed long ago by megadiverse countries and by indigenous peoples and traditional communities. If this type of connection was implemented, especially in user countries, there would be a great boost to benefit sharing and defensive rights of indigenous peoples and traditional communities over their knowledge.

The link between the ABS and IPR laws is a legitimate mechanism to ensure that one law with less implementation capacity is driven by another one, already consolidated. In this case, the disclosure of legal provenance would require any applicant for a patent to prove that the process of innovation was undertaken in compliance with the ABS system before granting this right.

This is not the only argument that justifies the linkage of the systems. After the recognition of national sovereignty over genetic resources and the provision of ABS systems, it is necessary to harmonize legal systems that focus on the same objects and situations. This would ensure greater consistency and coherence between the systems and thus increase the legitimacy of patents resulting from inventive activities based on genetic resources subject to a particular sovereignty and regulated by specific laws. The need to harmonize ABS and IPR legal systems becomes more evident when analyzing the uniqueness of inventions based on genetic resources.

Whenever an inventor identifies a specific application of a functional property that is a characteristic of a genetic resource, one can distinguish between two types of merit: First, we have the functional property of the genetic resource existing in nature which is not created by the inventor, but is the result of biological evolution. Second, there is the inventive activity, the action of the intellect and the experimentation, which enables the inventor to identify a novel application for that functional property. This is what happens when a new antibiotic is identified from a microorganism. The antibiotic's property already exists in a substance synthesized and secreted by the microorganism. The merit of the inventor is to recognize and adjust it to a specific target and establish a mechanism of action for it. Such procedure allows its use for a given situation, as a treatment of skin infections, for example. This amounts to a partnership where the country of origin ensures the functional property of the genetic resource kept under its jurisdiction, providing the biochemical

apparatus for the inventor to undertake, at long last, his inventive activity. Viewed this way, the benefit sharing is imposed as a fair and ultimate retribution.

There are even cases where the disclosure of legal provenance can avoid problems of moral nature. This tends to occur when using associated traditional knowledge as intellectual contribution in new patentable technological applications. There is some knowledge that can be considered sensitive or sacred by indigenous peoples and traditional communities, who have the right to deny its use to third parties or set limits and conditions for its use. The right of communities can be effectively materialized only if during the process of granting a patent there is a requirement of previous informed consent of the community in question.

From an operational standpoint, it does not seem to be very difficult to harmonize the systems. However, there is still lack of practical experience in order to draw concrete conclusions. The ABS laws in Brazil stipulate that the granting of patents is contingent to the authorization of access to their genetic resources. Article 31 reads "... grants of industrial property rights made by the competent bodies to a process or product obtained from sample components of genetic heritage is contingent on the observance of this Provisional Act, and the applicant must inform the origin of genetic materials and associated traditional knowledge, where appropriate."

The implementation of Article 31 of the Provisional Act began in late 2006, after the issue of resolution n° 23 of CGEN. Based on this, the National Institute of Industrial Property (INPI), the Brazilian Patent Office, issued resolution no 134 with adjustments on the form and internal procedures for processing patent applications. From then on, every patent applicant has to declare, at the time of the patent application, whether or not it was obtained due to access to genetic resources or to ARK and whether it was in compliance with the law of access; and, if so, to provide the number and date of the relevant authorization.

Nevertheless, after more than a year in force, adjustments to this procedure were necessary. Some institutions were prevented from forwarding their patent applications for reasons such as regulating activities that were initiated without a proper ABS authorization or failing to adapt their designs to these rules. The impossibility of processing the patent applications nonetheless could mean a clear loss of innovation initiatives in the country. In response, in 2009, resolution no 34 of CGEN and no 207 of INPI were issued establishing new procedures. Now, requests for patents related to genetic resources and ATK must be accompanied by an additional form containing the number of the corresponding access authorization, or, when it is not the case, a declaration that there was no use of genetic resources and ATK obtained in areas under the national jurisdiction. The main adjustment was the adjustment of the period of time available for presenting the access authorization to the patent office, as there is a large time interval between the patent application and its actual granting. The submission of this form is required only for the technical examination stage, that is, after the formal preliminary examination and the publication of

the patent application. In addition, whenever the patent examiner finds any evidence of use of genetic resources, the INPI may request the applicant to send the forms within 60 days. If the forms are not submitted within this timeframe, the application is suspended. The applicant has the option to appeal at any time and submit the requested form.

The difference in procedures is that, before, the burden used to fall solely on the applicant, and the requirement was prematurely demanded. Now, the burden is shared between the applicant and the patent examiner, with the latter being in charge of formally requesting the completion of documentation under penalty of the suspension of proceedings. This reformulation solves some problems: it prevents anyone who did not respect the ABS law from being granted an unlawful patent; ensures more time for resolving pending applications; and establishes a legal situation where noncompliance with the law of access materializes in the form of false information provided by the applicant, possibly justifying patent revocation according to the rules of the intellectual property system.

The connection between the laws of access and intellectual property is not intended to injure the granting of patents or inhibit technological innovation. Although the patent system is the subject of some controversy, the point that arises here is only to emphasize that if this system is appropriate in a way it converges with the ABS system, both can benefit by improving their implementation and reliability. There are no statistics on the operation of this mechanism. However, it is worth pointing out the joint pursuit made by CGEN and INPI authorities to find viable alternatives to harmonize the systems with the least possible increase in transaction costs.

Among the remaining unsettled issues of a new legal framework for access to genetic resources are the consequences of violating ABS law on any granted patents and the responsibility for applying these sanctions. This stems from the pending negotiations in the WTO and CBD, as well as from the concerns of those who fear a lack of protection for innovation products.

Protection of Associated Technical Knowledge in Brazil

The Provisional Act 2186-16/01 recognizes and protects some rights of indigenous peoples and traditional communities over their knowledge. It dictates the informed consent of the communities involved as a requirement to obtain authorization to access genetic resources within their territories or their traditional knowledge. CGEN issued resolutions that detailed the scope of prior informed consent and the process of obtaining it. One of the controversies, predating the existing law concerned the representation of the consenting community. The solution found is to define that in the process of obtaining prior informed consent, forms of social organization and political representation of traditional communities should be respected. Moreover, communities must be clearly and

in an accessible language informed about the research activities (purpose, methodology, duration, geographical area, knowledge to be accessed, budget, and potential impacts), and on the rights and responsibilities of each party, also ensuring the right to refuse the access to their knowledge during the process of consent. Prior consent, duly signed by the community, should be submitted to CGEN, along with a written report to explain the procedure adopted for obtaining informed consent, which should comprise the conditions agreed between the parties.⁴

When access to traditional knowledge has economic ends, the report about the procedure for obtaining prior informed consent should be part of an anthropological report. It should detail the forms of social organization and political representation, assess the degree of awareness of the community on the content of the proposal, and its consequences, and provide an assessment of socio-cultural impacts of the project. With this, CGEN sought to qualify the process of informed consent, ensuring that it was a process of clarification for minimizing the asymmetry of information, and then enabling a communal decision among the communities, based on complete information. There is also the provision of assistance by experts (lawyers, economists, etc.), when requested, to the communities holding genetic resources and traditional knowledge funded by institutions interested in obtaining samples and information. However, novelty and complexity regarding the issues has hindered an effective participation of the holders of areas in the negotiations.

One of the main points of discussion, both nationally and internationally, is whether the legislation should establish and ensure rights to communities over their traditional knowledge or whether it should only protect such knowledge. Some argue that the outcome being sought is the same - the preservation of the ATK, given its importance for the conservation and sustainable use of biodiversity. But it should be emphasized that the traditional knowledge is a dynamic, intangible good, produced and reproduced by societies settled in a given environment. A record of these assets can be very important, but it is only a snapshot of an ever-changing landscape. Peoples and communities have sought to associate the warrant of rights over their knowledge to the recognition and protection of their territories, claiming that it is impossible to distinguish both culture and environment.

The inclusion of traditional knowledge in the ABS system has been fundamental to give value to this kind of knowledge, and therefore to traditional cultures, from the standpoint of not only the user, but also the communities. Many communities recognize as threats to their knowledge, beyond biopiracy, the lack of interest of the younger generations to learn and use them and the defacement of the natural environment, which is the source of the resources they have knowledge about. The recent attention given to the value of knowledge is now motivating the young to defend the conservation and sustainable use of the environment they inhabit.

⁴ Azevedo, C. & Moreira, T. (2005). "A Proteção dos Conhecimentos Tradicionais Associados: desafios a enfrentar In: Cunha, M. C. Patrimônio Imaterial e Biodiversidade". *Revista do Patrimônio Histórico e Artístico Nacional* 32: 44-60.

The establishment of the rights of indigenous peoples and traditional communities over their knowledge faces further challenges. One of them is the identification of the holders of these rights: it is quite common that more than one person or community possesses the same knowledge about a particular genetic resource when they inhabit the same environment and have the cultural tradition of exchanging information, seeds, plants etc. How do we identify the set of all the communities holding certain knowledge? Which communities should give consent in each case? Which ones should sign the contract of benefit sharing? To support the solution of this challenge, the elaboration of truly sui generis legal system has been proposed. This legal system should recognize the legal diversity of traditional societies and consider them as collective subjects of intellectual rights. Only in this way it is possible to prevent the establishment of rights from engendering competition and rivalry among communities.⁵

The Brazilian legislation did not yet establish the basis of a sui generis system. Rather, it applies the same logic to traditional knowledge as to genetic resources: the community providing traditional knowledge is the one that must agree and sign a contract of benefit sharing. This situation puts communities that hold the same knowledge but did not participate in the process of informed consent in a difficult situation. The cases in which there was no question by other communities resulted from a long consent process, covering a larger number of communities in the region.

One of the suggested solutions to this issue is the allocation of a percentage of benefits derived from exploitation of traditional knowledge to a fund that would support socio-environmental projects inside other communities. This fund should be managed with the participation of representatives of indigenous peoples and traditional communities. The requirement of a contract to be signed with the communities that participate actively in the project, represented according to their tradition, would remain. The other communities sharing this knowledge would benefit indirectly from the fund.

Another complex aspect is the definition of the scope of the term “access to associated traditional knowledge”. Thus, as in the case of “access to genetic resources”, it is necessary to identify what is considered “associated traditional knowledge”. Is not all knowledge traditional knowledge? For instance, should a biogeographical traditional knowledge on the distribution of animals in a given territory be considered “access to ATK”? Or should only knowledge that enables or facilitates access to genetic resources, such as a particular variety of plant, selected for generations, or the medicinal use of certain species be considered so? Although for many peoples and communities it is rather difficult to understand the logic of these issues, CGEN is considering only the last two examples as cases of access to ATK in Brazil.

The current Brazilian ATK legislation effectively established new rights and has contributed in promoting the issue and facilitating community involvement in the debate. It should be emphasized that the Provisional Act established important defensive protection, as it makes the granting of patents subject to access authorization. However, as in the case of genetic resources, this rule is not observed by the patent offices outside Brazil. In this sense, it is not effective to prevent misappropriation of traditional knowledge abroad. Hence, there is also the necessity of an international mechanism to establish measures in user countries.

Another important issue to be addressed is that of accesses occurring from secondary sources. Much knowledge, although produced in traditional contexts, is already available in scientific journals, inventories, and databases. Some of this knowledge has been widely published and disseminated, and this hinders the correct identification of the community where it originated. If a company develops a product from previously published knowledge, how can the rights of the communities be ensured? How will the prior informed consent be obtained? Who will be responsible for signing the contract of benefit sharing?

Some argue that this knowledge has to be considered as already being in public domain. However, this would be an unfair situation, since it would turn any new publication into an instrument of loss of communities’ rights. Moreover, “publicly available” does not necessarily mean that they are in public domain. The search for sui generis protection involves alternatives to the issue of rights prescription. One possible solution is to cut time - the date when the CBD came into force or the date of the legislation that established rights for communities, for example. It determines that it would not be possible to access knowledge of secondary source for economic uses without previous informed consent of the community and benefit sharing.

In the same way as the exportation of biological resources could be the beginning of the bioprospecting chain and of the genetic resources misappropriation (with no respect to the country of origin law) the publication of traditional knowledge, and its systematization in databases without restrictions of access, could become a means of free access. This is the reason ethnobiologists and communities have tried to establish mechanisms to avoid situations like this.

In 2004 the Associação PACARI, a non-governmental institution responsible for organizing the 1st Cerrado Folk Pharmacopoeia⁶, requested support to CGEN as it aimed at systematizing and disseminating the traditional knowledge held by traditional communities. The purpose of this institution was to recognize and preserve ATK, enabling even more people to benefit from their knowledge, and at the same time ensuring that this knowledge should not be unjustly appropriated by others. This attitude motivated the Ministry of Environment to develop a strategy for

5 Santilli, J. (2005). “Patrimônio Imaterial e Direitos Intelectuais Coletivos”. *Revista do Patrimônio Histórico e Artístico Nacional* 32: 62-79.

6 1ª Farmacopéia Popular do Cerrado. It is a collection of information organized in accordance to the concept of pharmacopoeia which describes traditional medicinal uses of native plants of Cerrado, a Brazilian biome.

dissemination and discussion within the communities in order to include them in the debate through the creation of sensitization workshops. The methodology used was the forum-theater, designed by the playwright Augusto Boal, which allowed an understanding of the subject and the emergence of solutions for each situation experienced. This initiative was widely accepted and involved many indigenous peoples and traditional communities, generating a rich exchange of information.

Another initiative to meet this demand was an action by the Ministry of Culture to use the existing safeguards for the intangible cultural heritage (Federal Decree 3551/2000) for the case of ATK. In this context, the plea to register the folk pharmacopoeia of the Cerrado as a cultural inheritance of the local traditional communities is being evaluated. It is expected that this type of record, in addition to showcasing this cultural heritage, also works as a defensive protection, hindering the appropriation of the information contained therein as if they were in the public domain.

Conclusions

ABS implementation as a unique and novel topic is a tricky issue - because it is not only an environmental theme, but also combines various areas. Its main purpose is to include natural assets - the genetic resources, which are mostly shared by several countries - and intangible collective assets - ATK - into the international economic environment. Past experiences with multilateral environmental agreements (MEAs) have shown that, regardless their relevance, any environmental treaty that interferes with the existing economic order, however its merits, has a low implementation capacity, unless accompanied by an explicit political will of the parties involved. Unfortunately, this does not seem to be the case in the area of ABS.

Furthermore, the Brazilian experience demonstrates that some failures of national legislation combined with the absence of international instruments of law enforcement have undermined the successful implementation of ABS systems. There is a remarkable disparity between the benefit-sharing results achieved so far and the fact that Brazil is one of the richest countries in biodiversity.

On the other hand, these attempts to regulate the issue have allowed a better understanding of the problem and enabled the search for new solutions. The following are some topics and recommendations that can assist in building more effective national ABS laws.

1) Defining which uses of genetic resources should be included

Defining a use of genetic resources is not a trivial task. Moreover, the identification of which categories should be

regulated by ABS rules remains controversial. Under the CBD concepts of genetic material and genetic resources, a plant or an animal (as a whole or parts thereof) may be included, since they contain genes - the "functional units of heredity." Thus, all that is part of such living organisms could be considered a component of a genetic resource. The concepts of biological and genetic resources also remain ambiguous and allow more or less extensive interpretations.⁷

Several countries that have enacted their own laws on ABS have adopted some criteria to define more precisely the scope regarding genetic resources.⁸ Some, like Brazil, have adopted a "molecular clip" to assist in defining the scope of uses under ABS rules referring to the specific use of genes, biomolecules or metabolism substances as opposed to other hierarchical levels of biological organization, like fibers, tissues, pulps, etc. However, the experience has shown that this approach has not been sufficient to solve the "grey area problem".

The differences between the use of a biological resource and the use of a genetic resource are arbitrary and need to be explicitly defined. The reference to the use of a previously identified functionality of a specific gene or biochemical as the reason, or as a fundamental component, to create or prepare a commercial product seems to be useful. A practical solution is to analyze simultaneously what the component to be used is and what the proposed use is. A non-exhaustive list of examples of what shall be considered a genetic resource use, and competence granted to the ABS authorities to adopt technical decisions in cases of doubt, could help to solve the problem.

2) Shifting ABS regulated activities

The transfer of benefits exclusively to the landowners and the view that bioprospecting for commercial purposes always starts "inside the forest" has been a problem in designing ABS national laws. It has inappropriately extended ABS control to activities of collection and shipment of biological samples for scientific research purposes, resulting in burdensome obligations to the academic community. Along this way of thinking, the ABS system should control the whole chain of research and development, from the moment biological samples are collected from natural environments throughout all subsequent destinations, even when the purpose is not bioprospecting. One reason for this procedure is to deny access to bioprospectors interested in breaking ABS rules and to avoid the loss of information about the landowners, the in situ providers, along the custody chain.

It is known that samples collected for scientific purposes are mainly used for the purpose of categorizing and describing the chemical and biological structures that are then either stored as a record of evidence or destroyed and discarded at the end of the investigation. The way

⁷ In 2008 the Conference of the Parties to the Convention on Biological Diversity established a group of technical and legal experts to examine the issue of concepts, terms, working definitions and sectoral approaches to assist the Working Group on Access and Benefit Sharing (CBD 2008). *Convention on Biological Diversity - CBD (2008). Report of the Meeting of the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches. Doc. UNEP/CBD/ABS/7/2*

⁸ Cabrera Medaglia, J. & López-Silva, C. (2007). *Addressing the Problems of Access: Protecting Sources, While Giving Users Certainty*. IUCN, Gland, Switzerland. 77p.

that much of this biological material is prepared and stored in zoological and botanical collections decreases its availability as a source of biologically active compounds for bioprospecting. Moreover, the argument that it is possible to extract genes of scientific collections, and it really is, faces with the fact that most of bioprospecting does not use genes.

Moreover, control measures should focus on the end of the value-added chain, when the intention to exploit economically the genetic resource is the clearest. Commercial research and the commercial use of genetic resources represent those purposes where the effective conditions to negotiate benefit sharing emerge. Besides access authorizations limited to these activities, the disclosure of legal provenance in patent applications and in product registration is another important option to enforce ABS legislation.

Non-commercial research could be excluded from ABS regulations. Whenever the genetic resources are within national jurisdiction, new commercial uses will have to comply with ABS rules, making this kind of control unnecessary.

Along this line, ABS controls also should be directed at identifying connections between genetic resources (genes and biochemicals) present in species that occur in each country and their use in patents or new commercial products to verify if they have met ABS obligations.

3) Accessing genetic resources from ex situ condition

It is important to recognize that institutions interested in new products from biodiversity do not always start their activities by making expeditions to collect plants and animals, or even their molecules and genes, in the wild. Furthermore, they can be obtained in local markets and scientific collections. With economic globalization, the ease of goods transport among continents, and an increase in biological resources trade, there are no borders to genetic resources. Samples for screening for active ingredients can be obtained in raw materials exported commercially (leaves, bark, roots, seeds etc); in products for fresh consumption (like tropical fruits); or with ornamental (trees, bushes, herbs, flowers, tropical fish, etc.); agricultural (crops); or forestall (trees for timber or oil production) purposes.

In summary, in many cases, it is no longer necessary to go to in situ sites or even to the country of origin to have access to their genetic resources. This helps to explain why countries that already have ABS national legislation, like Brazil, have not been sought to negotiate benefit-sharing agreements with foreign institutions.

New ABS laws have to recognize that access from ex situ conditions is not an exception, and they have to provide for specific mechanisms allowing an effective benefit sharing among national and foreign users. A practical solution is to entitle a national authority to negotiate the benefits once it is probably no longer feasible to identify the in situ providers. Furthermore, to allow simplified conditions to negotiate with foreign users could stimulate ABS agreements in such specific access circumstances.

It is important to clarify that the right of ownership over the biological resource - which starts whenever a European user purchases a tropical fruit, as an example - does not negate the need for compliance with ABS legislation of the country of origin. Now imagine that, instead of consuming the imported fruit, this user wants to bioprospect it to identify an active compound, ask for a patent, and develop a new commercial product. Without this recognition, ABS systems are doomed to fail.

However, it is also increasingly easy to access information on biochemical structures in articles and in other publications that are available on the Internet or in genetic and chemical databases. A quick search for açai - a tropical palm tree (*Euterpe oleracea*) native to the Amazon rainforest, - on Medline⁹ reveals more than 60 scientific articles that describe or characterize its main bioactive compounds and some of its functional properties, for instance. The commercial use of this information also demands compliance with the ABS legislation of the country of origin of the corresponding genetic resource.

4) Developing ABS guidelines to patent analysts

One of the difficulties in implementing the disclosure of legal provenance in patent applications is the ability to detect the use of a national genetic resource in certain kinds of inventions. Often patent applications involve a gene sequence or a chemical structure of a biomolecule of species that are not even mentioned in the application. Without this information it is difficult to identify whether the genetic resource was obtained in the country, unless some information enabling the patent analyst to do this type of binding is available. In this sense, it seems to be important that countries make existing information available in databases by listing local species and genes, biomolecules, and substances of metabolism associated with each species already known. The systematization of this information would be of great practical importance for supporting the management of access and patents.

Furthermore it is important to establish some technical guidance for patent analysts regarding the use of these databases and on what type of information, component, and sort of invention is relevant to identifying the use of genetic resources.

5) Ensuring participation of indigenous peoples and traditional communities

In many cases the access to genetic resources is accompanied by access to traditional knowledge, as they facilitate and enable access to genetic resources, indicating possible uses. Bridging ATK and ABS systems increases the complexity. Yet, intangible knowledge collectively produced and orally disseminated by different peoples and communities needs to be managed in some way.

In recognizing the importance of traditional knowledge to the conservation and sustainable use of biodiversity, the CBD has a cultural dimension. Although it does not deal with the subject in such detail, it calls for respect, preservation, and maintenance of ATK in accordance

⁹ MEDLINE is the largest database of journal articles in medicine and health sciences

with national legislation.¹⁰ The CBD also encourages its implementation with the approval and involvement of ATK holders and the equitable benefit sharing arising from their use. This has motivated some ABS legislation to include ATK with a similar approach.

The process of defining mechanisms for implementing ATK legislation is somewhat limited due the limited participation of indigenous peoples and traditional communities in national and international negotiations. The CBD is a convention signed by many countries with different levels of freedom of expression and participation of indigenous and local communities. In order to ensure their participation in these negotiations they need to be supported in such a way that governments be able to incorporate some of their demands in official positions and also to attend several international fora (CBD, WIPO etc.).

In order to make progress on this issue, ensure legitimacy for decisions on sensitive themes, and avoid conflicts with holders of traditional knowledge in defining and implementing national laws and international agreements, it is essential to ensure effective and permanent conditions of participation. The International Indigenous Forum on Biodiversity is an important body that brings together different views of indigenous people. It has sought to raise awareness of some countries on their rights and mark positions at CBD meetings. However, many traditional communities do not feel represented by this institution and seek to organize an alternative forum.

6) The need for an international regime on benefit sharing

Even though many of the already mentioned issues are adequately addressed in ABS national laws, they will not be sufficient to ensure that the system will work effectively. Complementary domestic and international actions are essential. The ABS system has been negotiated to overcome the mismatch between the user countries - holders

of technology - and countries of origin - i.e. of genetic resources in the form of biodiversity. One could assume that it would be enough if countries of origin enacted laws regulating the use of their genetic resources, which in effect has occurred. Under that scenario, whenever a user country wishes to undertake a bioprospection project to develop a new commercial product based on the genetic resources, it would be sufficient to seek authorization from the ABS authority in the country of origin by fulfilling the necessary requirements to access genetic resources and ensure benefit sharing, under mutually agreed terms.

Yet, this has proven to be insufficient as the practical consequences of national laws and their sanction mechanisms extend to the national jurisdiction only. Thus, ABS national legislation has generated obligations mainly for those users of genetic resources that are established within countries of origin. Even though globalization has transformed many of these "national" users into publicly traded companies, with foreign shareholders, it is important to ensure that all genetic resource users share benefits, regardless of the origin of their capital.

The CBD is an international environmental treaty, whose dispositions need to be internalized at the domestic level to achieve their goals. The isolated action of the ABS national laws has not solved the main problem, i.e. the asymmetry between provider and user countries. Instead, this might create problems of competitiveness. The user countries remain using the genetic resources of countries of origin without sharing benefits, while companies based in countries of origin and exploring the same genetic resource, have an additional obligation to obtain access permits and share the respective benefits. This could increase their production costs and undermine goods exports. Therefore, the implementation of an international regime on ABS that applies to all users irrespective of their origin and thus prevents users to leave the countries of origin is more important than ever.

¹⁰ CBD, Art. 8j

About the author

Eduardo Vélez is a biologist and an independent consultant who has been working on Access and Benefit Sharing since 2003. He was Executive Secretary of the Genetic Heritage Management Council at the Ministry of Environment, Brazil (2003-2007). Currently is carrying out his PhD studies in Ecology at Federal University of Rio Grande do Sul (UFRGS).

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ICTSD welcomes feedback and comments on this document. These can be sent to Marie Wilke at mwilke@ictsd.ch.

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