



Report of the First Regional Workshop on Biopiracy and Related Issues

(Bogota, Colombia, September 01 - 02, 2005)











MAD III D	TO SOCIE	encies surgi	1.C. Sec.
Data	1	1	
Cod.	210		

Report of the First Regional Workshop on Biopiracy Prevention and Related Issues

Compiled by: Manuel Ruiz

Bogota, Colombia September 2005

Conference of the Parties to the Convention on Biological Diversity Eighth meeting Curitiba, Brazil

Organised by:

Secretariat of the Andean Community (CAN), Alexander von Humboldt Institute (Colombia), Instituto Socioambiental (Brazil), Peruvian Society for Environmental Law (SPDA – Peru), World Conservation Union – Regional Office for South America (IUCN), in the context of the Initiative for the Prevention of Biopiracy (with the support of the International Development Research Centre – IDRC Canada and the World Conservation Union - IUCN).

Backgound

Biopiracy can be defined as the phenomenon by which biological resources (and their derivates) and associated traditional knowledge of indigenous peoples (including indigenous, native, local and peasant communities, depending on each country's definition) are used illegally, irregularly, unequally or unfairly, without respecting basic principles proposed by the Convention on Biological Diversity (CBD) and specific legislation on access to genetic resources and protection of traditional knowledge. Biopiracy is also associated to the use of intellectual property (especially patents) to invoke rights over products derived from these resources and their traditional knowledge.

This phenomenon occurs regularly, affecting social, cultural, political and economical interests of South American biodiversity rich countries. Ayahuasca (Banisteriopsis caapi), yacón (Smallantus sonchifolius), maca (Lepidium meyenii), quinua (Chenopodium quinoa), cupuaçu (Theobroma grandifiorum), sangre de grado (Croton lechleri), colored cotton (Gossypium barbadense), bean (Phaseolus vulgaris L.) and camu camu (Myrciaria dubia) among others, are some of the resources which originate in the region and have been traditionally used by indigenous people, and which are being used wrongfully, illegally or have patent applications pending (and granted patents) mainly in USA, Europe and Japan.

At present, technological advances allow easy and simplified access and utilisation of different biological materials in commercial and industrial areas such as pharmaceuticals and cosmetics production, biotechnology development, agro-industrial processes, bioremedies production, etc. Genomics, bioinformatics and information technology contribute to the development and practical application of molecules, enzymes, proteins and genes in many of these areas. At the same time, traditional knowledge on biological diversity's nutritional and healing properties continue to be an important source of information and data for research and development processes of companies (and institutions), especially at their initial stages.

Within this context, why the need for a regional workshop on biopiracy?

- The concept of "biopiracy" and its practical implications with regards to its relationship with the intellectual property system needs to be addressed in a technical and detailed manner.
- There are various cases in the Andean and Amazon region (ayahuasca, cupuaçú, frijol, maca, etc.) that need to be analysed in order to understand the real implications of this phenomenon.



Conference of the Parties to the Convention on Biological Diversity Eighth meeting Curitiba, Brazil

- 3. There are important advances in regards to prevention of biopiracy (for example, in the context of the National Biopiracy Prevention Commission in Peru or the Andean
- Amazonian Initiative to Prevent Biopiracy, in a series of mandates of the Amazon Cooperation Treaty (OTCA) and CAN, and activities in Brazil, Colombia, Ecuador, Venezuela, among others) which require coordinated activities and positive synergies among themselves.
- 4. Various countries in the region have legislation which seeks to address this problem yet needs to be strengthened and consolidated in terms of its implementation and an assessment of the difficulties and challenges faced (for example, in the cases of defensive measures included in CAN Decision 486 and Provisional Measure 2 186-16 of Brazil).
- 5. To date, a specific workshop on biopiracy had not been organised.
- 6. A coordinated position needs to be agreed upon in relation to this subject, to support national positions for experts meeting related to access to genetic resources issues and article 8(j) of the CBD which will take place in Granada (Spain) in January 2006, and the Convention on Biological Diversity COP VIII to take place in Brazil in March, 2006.

Workshop objectives

The workshop had the following objectives:

Analyse the economic, cultural, political and social impacts of biopiracy in Latin America and establish alternatives and strategies to face the phenomenon, Identify effective strategies and mechanisms to confront biopiracy from a policy and legal perspective, Disseminate information on biopiracy and generate awareness within the region at different levels, Prepare for a follow-up process through a parallel and complementary event to take place in Granada and/or Curitiba (COP VIII).

Summary of comments and presentations

As a preliminary comment of the workshop, it was stressed that biopiracy prevention actions are part of an integral sustainable use strategy (which should be based on equity, ethics and fairness) of biological diversity components, taking into account the interests of countries of origin and their indigenous people.

Session 1

Presentation: "Some conceptual aspects of biopiracy: manifestations and search methods in the intellectual property system" (Paul Oldham, Centre for the Social and Economic Impacts of Genomics) Panelists: Santiago Pastor (Consultant, Peru), José Carlos Fernandez (Instituto Nacional de Ecología, Mexico).

During the first presentation of this session, biopiracy and its implications were analysed, mainly in the light of new technological advances in genomics, proteomics, nanotechnology and bioinformatics (or biosystemics) in general. These areas although



Conference of the Parties to the Convention on Biological Diversity Eighth meeting Curitiba, Brazil

rarely addressed in the debate, are critically relevant and their importance will increase in the near future. In the context of the debate on biopiracy, it was stressed that access to biological samples and associated traditional knowledge is not the only problem to face, as long as development and advances in these new areas allow for the information linked to resources and knowledge to be of freely available and widely disseminated without applying access and benefit sharing (ABS) as provided for in the CBD.

Social, environmental, economical and ethical dimensions of this phenomenon were also mentioned and brought under the scope of the concept of "bioeconomy", to encapsulate these different dimensions and their different implications.

Focusing on the operations of the intellectual property system (as a means through which biopiracy is frequently materialised), the importance of the International Patent Classification System and International Classifiers was highlighted. These tend to disguise - behind scientific language - innovations, which are possibly not highly inventive. In this sense, it was pointed out how the patent system is at a stage were "biospeculation" is being encouraged through claims for non-productive innovations.

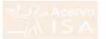
Comments and reflections from panellists during this first presentation established that through proper information and scientific databases, it is possible to identify potential cases of biopiracy – insofar as making reference to intellectual property rights granted. The importance of shared genetic resources between species and their alleles as a specific value was also mentioned. One of the points highlighted was how to approach molecular biology and make it understandable in its basic features for operators, mainly policy decision-makers at the national and international levels.

Some ideas were also proposed on how to detect biopiracy cases. Emphasis was made on biological, structural (tracking the biological material starting from the product) and legal origin. References were also made to nature inspiring chemical, artificial processes. The problem of incomplete data bases of ex situ collections (and their implications for countries of origin) and shared resources among various countries, was also mentioned. Finally, in relation to legal source, tracking and liability rules were identified as important elements in the value adding chain of products.

Presentation: "The Ayahuasca case: a new political and legal strategy" Joseph Vogel, (Universidad de Puerto Rico) Panelists: Antonio Jacanamijoy and Rodrigo de la Cruz (Indigenous representatives).

The Ayahuasca case was presented in order to justify the need to create a cartel or oligopoly of megadiverse countries. The "success" of the legal action taken by COICA and CIEL against the patent on Ayahuasca was put into discussion. On the other hand, it was argued that biodiversity and genetic resources are in essence information (made up of DNA). Therefore theoretical frameworks and legal mechanisms (such as intellectual property) which have already addressed the protection of information should be imported into the debate. Accordingly, the intellectual property system offers some tools to address biopiracy. Intellectual property does offer answers and alternatives in this particular context.

An important point raised during this presentation was the criticism to the concept of sovereignty (invoked and emphasised during CBD political debates). Sovereignty (as



recognised in the CBD) has contributed to consolidating a bilateral approach to the issue of access to genetic resources and, therefore, the objective of "encapsulating" or enclosing biodiversity (which in reality is information in DNA form) is not only destined to failure but promotes a price war between countries. The concept of "biofraud" is best applied to this situation, where bilateral contracts legitimise biopropecting activities (and use of traditional knowledge).

Suggestions were made to improve the use and distribution of resources: a) create an oligopoly on natural information, b) create a protocol to the CBD and modify intellectual property laws at the national level, c) emphasise on the origin and geographical distribution of species, d) establish a fund under the CBD framework to derive income generated from biodiversity products and, e) distribute benefits generated from products derived from this information based on the distribution of the corresponding species. Benefits will accrue to countries that have species within their territories.

In relation to the Ayahuasca case, speakers and commentators stressed the political element behind this case. This was more relevant than the actual technical solution finally reached in terms of the cancellation of the patent over Ayahuasca. They also mentioned how this debate has moved to different international and regional forums (for example, Free Trade Agreements -FTA-) and the problems for negotiators who are not familiar with the subject matter. This is related to an evident asymmetry of information which stakeholders have to face. The need to provide policy makers and indigenous peoples with relevant and timely technical information was highlighted as a critical element. Finally, there were also points made in regards to the problem of information products which are far and often "disconnected" from the original natural resource from which these were derived.

Session 2

Presentations: "The Cupuaçu case: answers and advances in Brazil" (Rogerio Magalhaes, Ministry of the Environment). "Patents on biodiversity in Brazil: a diagnostic of the application of Provisional Measure 2.186-16" (Henry Novion, ISA) Panelist: Manolo Morales (ECOLEX).

During this session, the Cupuaçu (a plant of Brazilian origin) case was analysed). A presentation was made on the Ministry of the Environment response and the existing legal and institutional framework on access to genetic resources and protection of indigenous knowledge in Brazil. It was pointed out how some registers on Cupuaçu had been cancelled in Europe and Japan due to the joint action of the Brazilian Government, Amazonlink and an NGO association. On the other hand it was indicated that this is not only a brand (trademark) problem: At present there are patent applications on "cupulate", a formula derived from Cupuaçu to prepare chocolate. Emphasis was placed on actions by the National Council on Genetic Patrimony – CGEN - (which depends of the Ministry of the Environment) and how this Council prefers not to utilise the concept of "biopiracy" but, rather, identify access cases were illegal use of resources has taken place. Sanction activities (under Decree 5494 of 2005) and control actions by different authorities at the Federal and State Governments level were also presented.

During this session a description of the work undertaken by ISA was made. This has included, identifying possible cases of biopiracy in Brazil, using certain methodologies and Acente A ISA

> WORLD CONSERVATION UNION Conference of the Parties to the Convention on Biological Diversity Eighth meeting Curltiba, Brazil

guidelines – including some proposed by Paul Oldham (Session 1). This work implies searching in databases, in coordination with the National Institute for Intellectual Property (INPI), patent applications that do not comply with obligations established under Medida Provisoria 2.186 -16. INPI does not require from patent applicants the origin of genetic material or associated traditional knowledge. Therefore, the Tribunal de Cuentas (Federal maximum tribunal) has ordered legal requirements of origin and certificates of origin established under Medida Provisoria 2.186-16 to be required. Finally, it was pointed out that declaring the origin and complying with disclosure of origin requirements is possible in practice, although they are complex processes requiring certain institutional strengthening.

During this session, panelists reflected on how biopiracy is being confronted in Ecuador and how some possible cases to be analysed have been identified. There were also comments on the difficulties of typifying offences and applying sanctions linked to biopiracy. A national working group has been formed in Ecuador to address biopiracy, and is evaluating cases of epipedobatidina, ayahuasca, microorganisms extracted from Galapagos and traditional knowledge (used as a source of information to identify medicinal plants) from Awa indigenous communities.

Finally, the problem of working with resources and shared knowledge among countries and indigenous groups was also emphasised.

Presentation: "The Maca case: strategy and advances in Peru" (Silvia Bazán, (INDECOPI) Panelists: María Elisa Febres (VITALIS), Brendan Tobin (IAS/UNU)

This presentation focused on the advances and progress in regards to the Maca biopiracy case in Peru. This specific case refers to the granting of bad patents in regards to inventions related to Maca. A summary and overview was made on the creation of a national working group on Maca in 2003 and the activities of a series of institutions – led by INDECOPI, the national IP authority – and their efforts to technically assess this specific case and recommend a course of action. Mention was also made to the positive synergies and levels of compromise by a wide range of institutions – from the public and private sector. International institutions such as CIP and Public Interest Intellectual Property Advisors (PIIPA) of USA, also proved to offer invaluable advise, counsel and support to the different activities undertaken by the working group.

As a result of the efforts of the Maca working group, Law 28216 created a National Commission for the Prevention of Biopiracy in 2005 (providing with an institutional framework under which to undertake a series of activities related to biopiracy). Institutional efforts and commitment by members of the Commission have made it possible for the Commission to rapidly take action in a series of fields. The commission has undertaken a strategic planning process; it has also – preliminarily - identified possible new cases of biopiracy regarding resources of Peruvian origin; and it is under permanent coordination and meets regularly. Some of the activities of this Commission have been supported by institutions such as IDRC - Canada through the Initiative for the Prevention of Biopiracy, which is coordinated by SPDA.

This session also addressed the situation in Venezuela and some advances in identifying biopiracy cases through activities of a national working group led by VITALIS. It was suggested that cases must be very convincing in order to really catch the attention of

5



policy makers and officials and substantially influence the international process. Preliminary cases have already been identified linked to chloromycetin, taxol and curare.

Additional comments during this session referred to bioprospecting activities in the Antarctic and deep-sea beds, which imply situations, which should be seen from another perspective and in the light of specific international rules and treaties. The urgent need to associate the debate on biopiracy with discussions oriented towards an international regime to access and benefit sharing was also mentioned. In this sense, discussions and proposals on certification of origin may contribute to offering alternatives and answers. Biopiracy prevention is not an end in itself but a means to contribute to generate equitable access systems and promote to the efficient use of resources and knowledge. In any case, it is a public policy objective to be pursued. Questions linked to this issue include: who defines what is biopiracy? Is it possible to create an international "biotax" of some sort?

Session 3

Presentations: "An Andean Amazon Initiative for the Prevention of Biopiracy" (Manuel Ruiz, SPDA), "Advances of a biopiracy study in Colombia under the framework of the Initiative" (Juanita Chaves, Humboldt Institute) Panelists: Luisa Elena Guinand (CAN), Fernando Mathias (ISA)

The first presentation explained the scope and features of the Andean Amazon Initiative for the Prevention of Biopiracy, coordinated by SPDA and sponsored by IDRC Canada. This is an initial effort to coordinate and promote activities to prevent biopiracy at the national, regional and international levels. It was highlighted that biopiracy is a complex problem requiring integral and multidisciplinary and combined efforts of States, indigenous organisations, NGOs, research centres, among others. This Initiative is the starting point of an effort to strengthen the National Commission for the Prevention Biopiracy in Peru; create national groups or commissions in Venezuela, Columbia and Ecuador to undertake research (including Brazil); establishing strategic alliances with CAN and OTCA; promoting debate and discussion spaces, among others. The web page for this Initiative is www.biopirateria.org. It has been translated into English and French.

The second presentation was centred on advances achieved on biopiracy prevention in Colombia, mainly with the creation of a national working group. Work undertaken by the Humboldt Institute was also presented. Activities in Colombia are also combining scientific and technical input as the basis for a more informed decision. In this sense, biopiracy will also be addressed in its aspects associated to intellectual property (including issues on trademarks, design, and new plant varieties) and illegal and wrongful access to resources and traditional knowledge. Also, advances regarding training efforts, generation of awareness, teaching materials for indigenous communities, among others was presented. Some comments by panelists highlighted the concrete activities the Initiative seeks to focus on.

It was also mentioned how political discussions are critically important and how the Initiative may contribute and offer input and basic information to the policy process. The limitations indigenous people have in terms of effective participation in decision-making processes – at the national and international levels – was also highlighted. In some countries civil society finds it difficult to approach the Government and public institutions that ultimately make decisions. It was recognised that INDECOPI (Peru) and Humboldt



Institute (Colombia) were exceptional cases were interrelation between the public sector and civil society was very fluid.

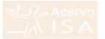
An important point emphasised was the need to take the debate to USA, Europe and Japan; these are the actual countries and region were biopiracy are most frequent – at least in their relation to intellectual property.

Some comments were also made in regards to need for the Initiative to take a position in relation to intellectual property. It was pointed out that the Initiative is not designed to destroy the IP system but emerges precisely from recognising that the intellectual property system operates in an unjust and unbalanced manner and therefore the need to take action. Biopiracy reflects this unbalance. It was pointed out that Surinam, Guyana and French Guyana are part of the Amazon region and should integrate this effort and future projects. It was informed that in the context of OTCA, the Manaos Declaration (2004) recognises the importance of traditional knowledge and need to promote mechanisms to ensure a fair and equitable participation of resulting economic benefits. Also mentioned was the importance of identifying and coordinating with existent networks; developing a critical route of actors involved in the biopiracy phenomenon and establish -specifically in the case of this Initiative- criteria and assessment indicators. Finally, the issue of levels of awareness of the biopiracy problem, mainly in relation to the academic and scientific community, was also raised. In many cases, the scientific community is responsible for the flow and movement of genetic resources among countries and in some occasions these flows do not adjust to existing legal frameworks and mandates.

Presentation: "The case of beans and the response from CIAT as part of the CGIAR System" (Daniel Debouck, CIAT) Panelist: María Claudia Fandiño (Humboldt Institute)

During this session, a biopiracy case associated to intellectual property (patents) granted in relation to an "invention" derived from a bean sample from the CIAT collection accessed by a third party with the protection of a Material Transfer Agreement - was presented. This becomes an additional problem as these materials are subject to a special status within the CGIAR system and agreements between CGIAR and FAO. It was recognised that the intellectual property system can generate problems and be misused: in this case, the protected bean did not have the required level of inventiveness. CIAT undertook an analysis of the patent to invalidate the arguments of novelty and inventiveness, which were being claimed. This case demonstrates, there is the urgent need to correct the operability and application of the intellectual property system. One of the additional problems in relation to this particular patent, was the determination of the technique utilised and difficulties to access relevant information. In this context, one way to address biopiracy is to include clauses in research agreements, which establish conditions and restrictions on possible uses of materials, including limitations on future transfers. Finally, it was established that all biopiracy prevention activities should complement and be linked to national regimes on access to genetic resources.

Comments from the presentation complemented this particular case, emphasising the process driven by USA which intends to globalise the intellectual property system, violating the CIAT Agreement (CGIAR)-FAO by which material delivered is of "public domain" and therefore, not susceptible to any claims for intellectual property. It was argued that the idea of "facilitated access" under the framework of the FAO International Treaty helps to



establish access and utilisation parameters, conditions and standards. This overall policy challenge implies allowing the legal control on basic foods and medicinal plants, which represent the cultural heritage of many indigenous peoples.

Session 4

Presentations: "The BIOZULUA database: biopiracy or confusion?" (Ramiro Royero, PDVSA), "New information technologies to promote traditional knowledge and prevention of biopiracy (Enrique Sánchez y Ximena Franco, Humboldt Institute) y "Databases on indigenous knowledge: an effort of INDECOPI" (Silvia Bazán, INDECOPI)

This session focused on databases in relation to biopiracy. In the case of the BIOZULUA database of Venezuela, the role of Fundación para el Desarrollo de la Ciencia y Tecnologia (FUDECI) and its activities was explained. It was established that the database was created to improve scientific knowledge on Venezuelan biodiversity. This database includes scientific and ethnobotanic information, taxonomy identification, geographic location and most important, traditional knowledge of Venezuelan indigenous peoples in relation to the use of biodiversity. This database was presented as merely a scientific instrument.

In the case of Colombia, progress made by the Humboldt Institute in the creation of an Information System on Biodiversity in Colombia, facilitating the management of data and information (normally found physically disperse and conceptually heterogeneous) in a way to efficiently support research, education and decision-making processes, was also presented. This system involves and intends to conciliate interests of indigenous, scientific and academic communities and civil society, through networks. The final objective of this system is for "providers" to administrate their own information and create access and utilisation conditions establishing the "rules of the game" (standards, policies and norms).

Finally, in the case of Peru, a presentation was made regarding advances of the web site on indigenous traditional knowledge being developed by INDECOPI with the collaboration and advice of various institutions, including indigenous organisations. This web site offers a platform of general information on traditional knowledge, but at the same time will serve as access to the Public Register of Traditional Knowledge (provided by Law 27811). Access to this register will be subject to the acceptance of a series of protocols and conditions by third parties.

Comments to these presentations were mainly focused on the role of registers and databases that include traditional knowledge. There was concern for the way in which the process to construct the BIOZULUA database was developed and for not having obtained the corresponding PIC from communities. The indigenous organisation ORPIA (of the State of Amazonas, Venezuela) strongly criticised this specific project. On the other hand, possibilities and risks when working these databases which incorporate traditional knowledge in public domain was highlighted and the fact that being of public domain does not necessarily imply the loss of rights (at least compensatory) due to the use of such knowledge.

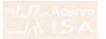
北元 Adenia 小 ISA

> WORLD CONSERVATION UNION Conference of the Parties to the Convention on Biological Diversity Eighth meeting Curitiba, Brazil

Critical points identified

Following is summary of critical points identified throughout the workshop. By "critical points", reference is made to issues and aspects, which have emerged from the debate and were particularly highlighted and discussed during presentations and overall exchanges.

- a) The operation of the patent system is extremely complex, mainly in relation to new disciplines such as genomics, proteomics, nanotechnology and bioinformatics in general. Therefore, the interpretation of biopiracy in this context also becomes difficult and complex.
- b) Any discussion on biopiracy must take into account its economical, ethical, social, cultural, environmental dimensions, particularly legal and political.
- c) There are serious problems in relation to non-productive patents (patents that are claimed for speculative purposes and to generate incomes): Biospeculation and problematic claims, based on well known, basic science are also a challenge to face within the biopiracy discussions.
- d) Information and leads on biopiracy can be found in databases on intellectual property and by using scientific databases. In this context, the International Patent Classification System plays an important role.
- e) Biopiracy can be detected through efforts based on legal, structural and biological origin. Tracking and a responsible regulatory system are mechanisms to help identify and prevent biopiracy cases.
- f) There is a problem with informational products by which artificial structures are modelled and a "distance" to natural resources or biodiversity is determined.
- g) The idea of a biodiversity "cartel" was pointed out oligopoly on artificial information (biodiversity understood as DNA). Some components of this approach include: emphasis on the origin of species; when sharing resources, the idea of a fair distribution of benefits in relation to resources and traditional knowledge; recognising that information should not be confined; concept of "biofraud"; and the idea that sovereignty in this case would imply a war on prices.
- h) How to streamline technical information into political debate was highlighted (to support a technical basis for the decision-making process). It is imperative to link what is considered technical to political debate, including discussions on the international regime to access genetic resources and sui generis regime to protect traditional knowledge.
- i) Awareness efforts at all levels (particularly in the academic scope) would be basic.
- j) Biopiracy prevention is not necessarily the end of the path but part of a strategy to seek equity, justice and recognition at the national, regional and international levels.



Conference of the Parties to the Convention on Biological Diversity Eighth meeting Cuntiba, Brazil

- Biopiracy is expressed at the level of patents, trademarks, and breeders' rights and illegal physical access (to information products).
- The slow globalisation of the patent system -compared to the system in USA and Europe- generates unsustainable burdens for developing countries.

Some specific recommendations

- 1. The Andean Amazonian Initiative to Prevent Biopiracy should at this stage or in a following phase establish some indicators of results.
- The workshop report should be distributed to intellectual property authorities and other actors.
- Efforts on "biopiracy" awareness should be particularly focused to impact the academic sector.
- The debate on biopiracy should be targeted towards Europe, USA and Japan at the level of competent national authorities of intellectual property matters.
- The Initiative is presented as an adequate mechanism to coordinate and carry out institutional efforts.
- The CBD, IGC of WIPO, WTO and regional events are ideal to organise efforts to disseminate debate and discuss biopiracy matters, following the regional workshop.
- The Initiatives web page can be used to disseminate reports, presentations, documents, and results of debates, among others.
- 8. The Initiative should cooperate and be linked to existing networks.
- As part of the Initiatives Research Documents, study cases carried out in Columbia, Ecuador, Venezuela and Brazil should be published.
- Pilot projects should be carried out to help operationalize the certificate of origin proposals.
- 11. It is important to analyse economic and legal implications of new disciplines such as bioinformatics proteomics, genomics, among others in relation to the ABS international regime being negotiated at present.