INITIATIVE for the PREVENTION of BIOPIRACY

Year IV No. 10 April 2009

The Development of an International Regime on Access to Genetic Resources and Fair and Equitable Benefit Sharing in a Context of New Technological Developments

*Santiago Pastor Soplín**

*Manuel Ruiz Muller***

Introduction

The explicit and implicit consensus between most actors participating in the Convention on Biological Diversity (CBD) process[1] is that in terms of national and international public policies and legislation on access to genetic resources and benefit sharing (ABS), progress is being made.

This paper suggests that this is not necessarily so, and that the direction taken by debates and proposals to implement Articles 1, 8(j), 15, 16 and 19 of the CBD on ABS[2] and, especially, to develop an International Regime on Access to Genetic Resources and Benefit Sharing,[3] may need review and considerable policy and legal adjustments.

To begin with, an important unsolved and often overlooked problem over the years, relates to *definitions* and to what is known as the "fallacy of equivocation". Basically, a valid argument is constructed (in formal terms), but results in a false conclusion because it is built on false premises. In the context of ABS, arguments being proposed at present, are based on an inaccurate and limited understanding of the subject matter "genetic resources", as well as on the forms of research undertaken over them. This situation has important implications, as the possibilities of adequate management of genetic resources are constrained, as is the generation of optimum public policies. Furthermore, the possibilities for the development and implementation of regulations related to ABS are also curtailed.

The conventional way of accessing genetic resources has been by physically obtaining and taking (or processing) a *tangible* component, including seeds, plants, bulbs, leafs, roots, natural extracts, resins, oils, chips, barks, etc. This differs substantially from the process of accessing, researching and developing the *intangible* component of what is generally known as "genetic resources". Although DNA, genes, genetic sequences, proteins, secondary metabolites and specific molecules, are originally obtained and decoded when accessing the *tangible* component, in many cases they

* Santiago Pastor, Biologist, Director of ProUsoDiversitas and Associate Professor of the Universidad Autónoma de Barcelona (santiago.pastor@uab.es)

** Manuel Ruiz Muller, Lawyer and Director of the Program of International Affairs and Biodiversity of the Peruvian Society for Environmental Law, based in Lima, Perú (mruiz@spda.org.pe)

[1] The CBD was adopted on May 22nd 1992 in Nairobi, Kenya. It was formally approved on June 5th 1992 in Rio de Janeiro, during the United Nations Conference on Environment and Development and entered into force on December 29th, 1993.

[2] These articles develop the principles of: State sovereignty, prior informed consent (PIC), mutually agreed terms (MAT), fair and equitable sharing of benefits, biotechnology transfer respecting intellectual property rights, adopting measures to comply with CBD objectives in countries providing and using resources at the same time, and protecting knowledge, innovation and practices of indigenous people. See: Glowka, Lyle, Burhenne Guilmin, , Françoise, Synge Hugh. *A Guide to the Convention of Biological Diversity*. IUCN Environmental Law Centre, IUCN Biodiversity Programme Environmental Law and Policy Paper No. 30. IUCN Gland, Switzerland and Cambridge, 1994.

[3] The idea of starting an ABS international regime negotiation process was originally proposed in February 2002, in the Cancun Declaration, which created the Group of Like-Minded Megadiverse Countries. A succession of different pronouncements by the group, contributed to the formal launching of the negotiation process of the International Regime on Access to Genetic Resources and Benefit Sharing, specifically through COP 7 and the mandate of Decision VII/19 of the CBD (2004).

are rapidly transformed into *intangible or informational* goods, equally important and useful for different applications.[4]

Within ABS debates, there are initial signs of a more explicit recognition to the fact that the problems of control and appropriation of seeds, bulbs, barks, leafs, etc. are very different to those related to the control and appropriation of genes, DNA sequences, etc. The common element to both these situations is the effects and implications of sovereignty property and intellectual property, according to the specific level of technological development and goals pursued in the research process.

Articles 1 and 15 of the CBD recognize the States *sovereignty* and regulatory powers over their genetic resources. But this is not as straightforward as seems. To illustrate with an example, the right over a crop and a landowner's right, may overlap with a breeder's right, if the seeds used are improved and protected under the framework of the UPOV system. Additionally, patent rights or *sui generis* database rights may also be invoked over certain genetic sequences, thus over *information,* related to the components of these seeds. Furthermore, the sovereign rights of States may also be of relevance if, as in Decision 391 of the Andean Community, the State has domain over genetic resources.[5] [6] Each of these rights and claims, with their own specificities and implications, requires special consideration in the context of ABS.

The hypothesis of this research is that ABS policy developments (at the national, state, provincial, regional and international level), are not taking appropriate consideration of key variables and differences in genetic resources as both a tangible and intangible element at the same time. Furthermore and more troubling, ABS laws and regulations seem inapplicable in practice when this lattter feature is taken into account.[7] Lastly, not accounting for the informational nature of genetic resources raises the real possibility of increasing gaps between public policies and technological developments, deeming ABS policies and laws inapplicable and eventually of little significance. Finally, there is also the risk that current approaches to ABS backfire and, inadvertedly, stimulate non-controlled access to and flows of genetic resources.

Throughout this research, three main reasons are proposed to explain the above:

- Debates and legal regimes do not consider the *informational* nature of genetic resources (even though it may be case that it is in the realm of intellectual property where this could be addressed more appropriately), [8]
- Technologies and emergent disciplines (bioinformatics, genomics, proteomics), in simple terms, allow to progressively do without (although not entirely) physical biodiversity components as a

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4 Virtual libraries and databases with genetic information which include DNA sequences, protein and biochemical structures, genetic make up of microorganisms and plasmids, etc. are more and more common. For example, by entering the National Center for Biotechnology Information (NBCI) web page (http://www.ncbi.nhi.gov) it is possible to verify the type and quality of genetic information available. In the specific case of the NBCI, established in 1988, its duty is to*"…act as a resource for molecular biology information by creating databases, conducting research in computational biology, developing software tools to analyze genome data and disseminating biomedical information…"* There are many similar public and private institutions which develop and maintain databases on genomics, biomedical imaging, protein chemistry, protein engineering, and discovery of drugs from small molecules and therapeutic antibodies.

5 In the case of Andean Community Decision 391 on a Common Regime on Access to Genetic Resources (1996), it is explicitly recognized that member states (Bolivia, Colombia, Ecuador and Peru) have domain and control over genetic components of all elements of biodiversity, and genetic resources and derived products in particular (molecules, genes, etc.).

6 Mariaca and Estrella also offer an interesting example, by distinguishing the tangible and intangible element in biological resources (including genetic resources), through a comparison exercise between a sheet of paper and a potato (which is a genetic and biological resource at the same time): "…*these may be used in different ways and therefore different legal regimes are applicable. In the case of the sheet of paper, one can access written information in order to develop a new piece of work or ignore the information and burn the paper in a chimney. When written information is used, a series of conditions exist under copyright laws to protect the written work. When the owner burns the paper, he has the right to do so, in as much as the paper belongs to him, though not the information contained in it. In the case of a potato, it can be used as food in which case the owner may sell, give away or simply eat it as a biological resource. This is governed by the laws of private property. However, if genetic information contained in the potato needs to be accessed in order to undertake research or breeding of a new variety or product based on such information, the applicable regime in the Andean Community countries is Decision 391 and an application must be presented to a national competent authority responsible for administrating genetic resources"*. Estrella, J.; Manosalvas, R.; Mariaca, J. y Ribadeneira, M. 2005. *Biodiversidad y Recursos Genéticos: Una guía para su uso y acceso en el Ecuador*. EcoCiencia, INIAP, MAE y Abya Yala. Quito, Ecuador. 116 p.

7 The case of the FAO International Treaty (2001) and its Multilateral System for Access and Benefit Sharing is exceptional, in that the use of Standard Material Transfer Agreements (SMTA) has proved to be efficient and has not interrupted the flow and movement of plant genetic resources (mainly as *tangibles*) which are important for food and agriculture, research, breeding, conservation and food security.

8 Although in the case of the International Regime on ABS preliminary drafts and some legal instruments such as Decision 391 of the Andean Community or Provisional Measure 2.186-16 of Brazil or Law 7788 of Costa Rica, make direct or indirect references to genetic information as such, their substantial content do not develop rules and principles which are applicable to the informational characteristics of genetic resources.

primary source of information, and complicate further the efforts or limit the possibility of identifying countries of origin, regulating and controlling the flow of these materials and components,[9] [10] and

- In terms of ABS norms and proposals, distinctions are not being made between access to genetic *information* to develop new, advanced, technological products and access to *materials* of biological origin (resins, oils, natural extracts, plant parts, seeds and fruits, etc.), which are processed, semi-processed and directly incorporated or used in commercial or industrial products (where the target and focus is not the genetic information *per se*).[11]

It is important to mention however, that the CBD principles and rules on ABS were conceived on the basis of a "classic" paradigm which is becoming in a way, outdated and illusory: this is well represented by the story of a researcher who enters a tropical forest and obtains ancestral knowledge from a traditional community regarding the use of a medicinal plant. Subsequently, the researcher identifies the plants active component and through biotechnology, develops a pharmaceutical product, applying for a patent that generates huge benefits for the researcher and promoters (usually foreigners) of the research and development process.[12] [13]

The scenario described has been gradually overcome by the reality of new technological developments (Box No. 1). The research and development process has become substantially more complex in terms of methodologies, actors involved (companies, universities, individuals), knowledge management, information technologies utilized and intellectual property applied, among others. This increase in complexity, has also multiplied the areas in which tangible genetic resources (biological material) and, especially, intangible genetic information and knowledge, can interrelate among each other and contribute to research and productive processes, which may not have even been envisioned when they started.

In short, the objective of this paper is to determine how ABS principles can be appropriately integrated into policies and norms that take into account the different challenges that these emergent issues raise, for international negotiations in particular. Thus, contribute to the generation of "sound" international policies and appropriate norms to regulate a complex reality, which has only very marginally been addressed in current debates in the ABS International Regime process.

9 It is true that purely basic research, without commercial application, which aims towards taxonomic identification or the analysis of species distribution and population dynamics, demands access to *physical* samples, even though molecular biology is increasingly assisting in specific taxonomic classification and provides precise scientific data and information regarding species distribution and evolution.

10 Regarding this issue, Oldham indicates that *"…trends in the genomics sector suggest a decreasing dependence on physical transfers of biological material and increasing trends towards electronic transfers because genetic material can be readily expressed as information in the form of A (adenine), G (guanine), C (cytosine) and T (thymine) bases in the case of DNA (deoxyribonucleic acid), and ACG and U (uracil) for RNA (ribonucleic acid). This also extends to amino acids, which form the basis of proteins. Thus, there are 20 common amino acids and these and other amino acids may also be expressed as information organized in sequences relative to DNA sequences i.e. G or Gly (Glycine), A or Ala (Alanine), V or Val (Valine etc. To date the implications of these trends have not been considered in debates surrounding access to genetic resources and benefit sharing"* Oldham, Paul. 2004. *Global Trends in Intellectual Property Claims: Genomics, Proteomics and Biotechnology.* Available as UNEP/CBD/WG-ABS/3/INF/4 document at http://www.biodiv.org.

11 Paradoxically, direct and continued access to genetic resources from the natural environment to sustain a productive process or maintain a market share, causes some of the most damaging effects on ecosystems and conservation efforts, especially when there is the need to collect wild components of biodiversity which cannot be reproduced or multiplied (with the exact desired characteristics) in farms or laboratories. Furthermore, these are activities that sustain businesses where benefits and returns on investments are obtained in the short term from the market and price system. More specifically this is the case of companies that develop and commercialize "natural products", nutraceuticals, vitamin supplements or functional foods based on harvest of wild species or "biocrops". See: Pastor, Santiago and Sigueñas, Manuel. 2008 *¿Bioprospección o Prospección Biológica en el Perú*? GPRI Project.SPDA. Available at: http://www.biopiracy.org.

12 The film "*The Medicine Man*" (Dir. John McTieman, 1992) reflects this paradigm in an interesting way, including descriptions regarding the loss of the tropical forests, indigenous peoples struggles, etc. In relation to this particular film, there is an equally interesting phenomenon which will not be covered in depth in this investigation, but is worth mentioning: "geopiracy". Although the location of the film is attributed to the Brazilian Amazon basin, it was originally filmed in Veracruz, Mexico, with the Orizaba Volcano in the background. On one hand, the film denounces "biopiracy" but, at the same time, it is an example of "geopiracy" due to a false geographic attribution for certain locations and scenes. See: Vogel, Joseph, Robles, Jenny, Comides, Camilo, Muñiz, Carlos. *Geopiracy as an Emerging Issue in Intellectual Property Rights: The Rationale for Leadership by Small States*. In: Kresalja, Baldo (editor) 2008. *Anuario Andino de Derechos Intelectuales*. Palestra Publicaciones No. 4. Lima, originally published in English as "*Geopiracy as an Emerging Issue in Intellectual Property Rights: The Rationale for Leadership by Small States"* con Janny Robles, Camilo Gomides and Carlos Muñiz, 21 Tulane Environemntal Law Journal (Spring 2008), 391-406.

13 Different norms on access approved since 1993, have widened their scope of application (see Box No. 4). Whether due to the actual definition of "access to genetic resources" or the scope itself, principles and obligations referring to access, the fair and equitable sharing of benefits, traditional knowledge and intellectual property, apply to a wide range of genetic resources, specimens, extracts, resins, oils and other "derived or synthesized products".

Box No. 1. The complex dimensions of ABS: are they totally understood?

Source of materials	Technologies and tools	Products
Genetic diversity In situ Ex situ Extreme environments Traditional knowledge	Morphological, genetic, chemical characterization Gene markers, genetic mapping Genetic engineering, genomics, proteomics Bioinformatics	Selected materials Extracts, molecules, bioactive compounds Improved materials Bioengineered products Synthetic products Gene libraries, data bases Modified organisms
Access and benefit sharing laws and regulations	**Intellectual property rights**	

Source: Adapted from Roca, Willy, 2007.

1. Brief reflections on *pure* genetic information

In the middle of the 20th Century, the physicist Erwin Schrodinger in his book *What is Life?*, did not refer to the concept of "genetic information" as such, although he was actually thinking in these terms when referring to "codes" as subjacent to everything biological. Likewise, Watson and Crick in their seminal paper of 1953, *Molecular Structure of Nucleic Acids: A Structure for Deoxyribose Nucleic Acid*, did not make reference to "genetic information", though they were referring to the concept when proposing a copying or photocopying mechanism. Towards 1958, Crick found the metaphor of information so powerfully convincing, that it defined the central dogma of modern molecular biology.

Although at present some philosophers question the real meaning of "information" as used in the concept of "genetic information", no one has really doubted its usefulness. The assertion of Dawkins in the sense that genes are *pure* information, can be even extended and used in social sciences and its principles applied to policy and law.

The concept of "information" has worked extremely well in biology as a metaphor, an analogy or an assertion of a concrete fact. However, its significance and implications have become diluted in the context of the Convention on Biological Diversity (CBD) debates, specifically in relation to access to genetic resources and its governing principles.

Box No. 2 (below) presents a few important landmarks in the genesis and use of the concept of "genetic information" in its path towards the stage of embryonic discussions in the contexts of ABS policy and law.

The process of analyzing genetic resources from an informational perspective, raises important policy and normative challenges. These challenges are posed by the *replicability* feature of information (very low marginal costs for additional copies of a sequence), its *non rival* characteristics (the simultaneous use of exactly the same information does not affect individual users) and *widespread geographic* dissemination (genetic information is widespread among species and, at the genetic level, species are not that "different" between one another).

Ownership of information, through application of intellectual property rights or assertion of sovereignty, and its existence as a public (or private) good, furthermore complicates the policy and regulatory building process. It is precisely these issues which should be considered during debates regarding ABS and, thus, when designing an international policy framework for genetic resources.[14]

[14] Vogel has advanced even more in the formulation of his ideas. He suggests the need for a global awareness raising and capacity building effort directed towards society, to ensure a basic understanding of the implications of ABS issues and genetic information in the context of intellectual property. For this purpose, Vogel has proposed the creation of the *Museum of Bioprospecting, Intellectual Property and the Public Domain*, to effectively influence in decision making through the

Box No. 2. Genetic resources as pure information: analogy? metaphor? or assertion?: a brief historic sequence.

Author/Scientist	Book and year	Analogy, metaphor or assertion
Charles Darwin	*On the origin of Species* (1859)	Darwin was fully convinced that species are not immutable, but those belonging to the same genera are lineal descendants of some other and generally extinct species, in the same manner as the known varieties of any one species are the descendants of that species. Furthermore, Darwin was convinced that Natural Selection is the main but not exclusive means of modification. (**Assertion**)
Gregor Mendel	*Experiments on Plant Hybridization* (1865)	When categorizing the phenotype characteristics (in external appearance) of pea plants he named them "characters". He used the name "elements" to refer to separate generations. (**Assertion**)
Erwin Schrodinger	*What is life?* (1943)	Schrodinger suggested that each individual cell, even the most insignificant, must possess a double copy of a code-script. He used the analogy of Montgomery's troops being informed in detail about his strategies (up-down) to illustrate his point as an analogy – this actual fact is literally true. (**Metaphor**)
J.D. Watson and F.H.C. Crick	*Molecular Structure of Nucleic Acids: A Structure for Deoxyribose >Nucleic Acid* (manuscript, 1953)	Copying mechanism for genetic material (**Metaphor)**
Joseph Vogel	*Genes for Sale*: *Privatization as a Conservation Policy*	The reductionist approach might suggest conservation policies for habitats, starting with the reduction of the concept of genetic resources as "natural information" in contrast with "artificial information" of intellectual property rights. (**Assertion**)
Richard Dawkins	*River out of Eden* (1995)*Global Action for Biodiversity* (1997)	"Genes are pure information". **(Assertion)**
Timothy Swanson	Global Action for Biodiversity (1997)	**"**The value of biodiversity lies in its informational content". (**Assertion**)

dissemination of knowledge and ideas. See: Vogel, Joseph. A proposal based on "*The Tragedy of the Commons*": *A Museum of Bioprospecting, Intellectual Property and the Public Domain*. Social Science Magazine No. 16, 2007, 118-135. Vogel, Henry Joseph (ed.) 2007. The *Museum of Bioprospecting, Intellectual Property and the Public Domain: A Place, A Process, A Philosophy.* Anthology of the panel chosen as semi finalist for "The School for Advanced Research Prize of Nature, Science and Religion in Latin America" and presented at the 2007 Meeting of the Latin American Studies Association, Montreal, Canada, September 5 – 8, 2007. Available at: http://economia.uprrp.edu/PDF%20files/museum.pdf

2. When technological reality is far removed from public policies and regulatory frameworks

As a general rule, normative processes always follow the realities they seek to regulate. Simply: reality dictates what laws and regulations will eventually address. This rule is even more manifest in the case of issues that are complex and difficult to understand and distil. It happens in all fields of human development and social organization. Even though laws seek to respond (in timely manner) to reality, legislators often lack the ability and tools to anticipate future situations, especially when reality is defined by science and revolutionary technologies. Laws (most of the time) lag behind in terms of the human progress sequence. However, in some cases, laws are visionary and flexible enough to foresee future scenarios and adapt to changes. This is especially true when policy makers and legislators understand (even if the basics) or intuitively predict the direction or course of technological advances.

Over the past 20 years and even during the last decade, scientific and technological advances and innovations in the field of molecular biology and genetics have been astounding. But the policy and legal response to this new technological paradigm has been (and continues to be) nearly null in most countries. Except maybe in the field of intellectual property, which has built in flexibilities to cover and regulate, to an extent, this progress. In contrast, the International Regime on ABS process does not follow this exception and is almost totally removed from discussions regarding these new breakthroughs. Within the IR, attention is still centered on classical paradigms in biological material based research, which represents a decreasing component in scientific innovation and development (especially in certain areas - see Box 3).

In this context, it is not that biological resources (including seeds or plant extracts) are less important or useful. On the contrary, evidence shows that the commercial demand for new seed traits (especially in a scenario of widespread climate change) and processed or semi-processed natural products in certain industries, has substantially risen worldwide during the last few years. The demand and access to these resources is regulated mostly by the laws of supply and demand and to price as the key exchange variable,[15] plus phytosanitary measures, and in Europe for example, by Novel Food legislation.

What is stressed is the increasing possibility to advance in the knowledge of and research over biological and genetic materials, based on pre-existing collections (for example in *ex situ* facilities) and the use computational biology and bioinformatics, even before there is a need to obtain a specific biological sample from a foreign and maybe exotic *in situ* source.

Box No. 3. The differences that need to be understood: what will the International Regime on ABS and access norms cover?

<table>
<tr><td>ABS rules (PIC, MAT, Sharing of benefits)</td><td rowspan="3">▪ Bioinformatics
▪ Biotechnology
▪ Genomics
▪ Proteomics
▪ Synthetic biology
They can inform the development or be used in different fields.
▪ Nanotechnology
▪ Proboleomics
▪ Traditional knowledge
▪ Nanotechnology
▪ Traditional Knowledge
Everything translates into, transforms and is managed and valued as data and information.</td><td>PURCHASE/SALE RULES, COMMERCIAL PRACTICES, FAIR TRADE, ETC.</td></tr>
<tr><td>Bioprospecting – Access to Genetic Resources</td><td>Development (production)</td></tr>
<tr><td>Identification of and research in useful components (genes, DNA, proteins, metabolites, etc.)</td><td>Purchase of crude or semi-processed raw material (oils, flours, resins, specimens, roots and bark)</td></tr>
<tr><td>Contractual relations and ABS procedures</td><td>Patents, trade secrets, sui generis protection of data bases, biosafety, common use licenses</td><td>Patents, marks, breeders´ rights and taxes</td></tr>
</table>

Source: Manuel Ruiz, SPDA 2008

[15] For example, the market for natural/organic products for personal care has grown more than 20% in the year 2005, with total sales of US $5 billion according to the Natural Marketing Institute 2006 Health and Wellness Trend Report http: (http://www.happi.com). The demand for cosmetic products which derive from marine algae, natural oils, herbs,

The evolutionary nature of living organisms and the fact that all related species descend from common ancestors, also allows genes and metabolites to be shared. Therefore, the source of a single compound can simultaneously reside in many species and not only in the specie originally discovered. In practice, this is in fact the common rule. However, ABS regulatory frameworks have been constructed considering species as discreet and unique entities. As if a specific gene or active compound discovered in one specie could not be found in others. Rather, it is extremely common for most evolution related species, to share most genes, their variants, proteins and metabolites. This has become more evident and easier to demonstrate in the light of advances in bioinformatics and new technologies.

The fact that the genetic make up of species overlap, more or less depending on their evolutionary distance, puts into perspective the actual value of genes and compounds of widely distributed species. But this also increases their value, in the case of rare or endemic species or attributes which are a reflection of the environment in which genes express themselves through phenotypic manifestations (for example, the toxicity of certain frogs depends on their *in situ* diet and environment). This type of argument should lead provider countries (especially the megadiverse countries) to reflect a little more on whether bilateral negotiations, strongly supported by the principle of *national sovereignty* over genetic resources, as proposed by most ABS norms, is the most convenient approach to safeguard their interests and ultimately ensure conservation and benefit sharing.[16] As a result of the above argument, during an ABS contractual negotiation, providers are really the *group* of countries where specific species are located *in situ* or where the taxon is distributed.[17] Unless of course there is a situation of endemism.

In order to better understand this situation, following are brief descriptions of a series of technologies, tools and disciplines derived from biological sciences which combine powerful informational capacities (hardware and software) with biology, chemistry, physics and mathematics.

Bioinformatics. Bioinformatics generates knowledge from the computational analysis of biological information. This may consist in the analysis of information stored in the genetic code, as well as of experimental results from different sources, patient statistics and scientific literature. Bioinformatics research includes methods to store, recover and analyze data and information. Bioinformatics is a fast growing biological study field, highly interdisciplinary, which uses informatic techniques and concepts, statistics, mathematics, chemistry, biochemistry, physics and linguistics. It has various applications for different areas in biology and medicine.[18]

Synthetic biology (systems biology). This refers to the design and construction of new biological components and systems that do not exist in the natural world and the re-design of existing natural biological systems for useful purposes.[19] The advances in nanotechnology (control of matter at the atomic scale) already allows for the production of new material used in cosmetics, sports goods (rackets, bats, golf clubs), paints, adhesives, computer monitors, among others.[20]

Genomics. This is a research strategy (and a discipline), that uses molecular characterization and genome cloning to understand the structure, function and evolution of genes and to respond to basic biological questions.[21] Genomics focuses on the study of genome anatomy; the number, size and structure of genes, as well as functional DNA regions and non-functional regions of the genome. The life of different organisms is specified by genomes. Every organism has a genome containing the biological information needed to generate, develop and maintain a sample of that organism.

Genomics allows:

- Determining the function of genes and elements which regulate genes in a genome,

fruits and seed, has multiplied five times around the world since 1990. A similar phenomenon can be verified in the field of nutraceuticals and food supplements.

[16] An interested actor would probably resort to a country with certain technological capacities in order to contribute to efficient research and development, and a value adding process. This may be the determining factor for a company or an institution and not necessarily the availability or accessibility of determined genetic resources, in as much these are widely distributed geographically.

[17] Vogel has been one of the most vocal promoters of this idea at the policy level and in the context of the CBD. However, the appealing conceptual foundations of these ideas and his arguments have been often sidelined and overlooked. His answer to the fact that gene make-ups of species overlap and have (in the majority of cases) a wide geographic distribution, mostly but not exclusively between countries rich in biodiversity, leads to the unavoidable conclusion of needing to think of a "Biodiversity Cartel", where economic benefits generated from the use and development of these resources are equally shared according to species geographic distribution. For more details on this proposal, see: Vogel, Joseph (Ed.) *The Biodiversity Cartel. Transforming Traditional Knowledge into Trade Secrets*. Project SAN REM, ECOCIENCIA, USAID, CARE. Quito, Ecuador, 2000. Available at: http://www.elcarteldebiodiversidad.com

[18] http://www.nlm.nih.gov/research/umls

[19] ETC Group. *Extreme Genetic Engineering. An Introduction to Synthetic Biology*. January, 2007. Review: Endy, Drew. Foundations for Engineering Biology. In: *Nature*. Reviews, Vol. 438/24 November 2005.

[20] The great nanotech gamble. In: *New Scientist*. July 14-20, 2007, p. 38-14.

[21] http://www.fao.org/DOCREP/004/Y2775E/y2775e08.htm. bm08 Also recommended: *Junking the Genome*. In: *New Scientist*. July 14-20, 2007, p.42-45.

- Finding DNA sequence variations to determine their importance – mainly in humans (for the purpose of identifying the risk of diseases and predict responses to drugs),
- Finding tri-dimensional structures of proteins and determine their functions,
- Exploring the interaction between genes and proteins,
- Designing strategies to detect, diagnose and treat diseases,
- Sequencing genomes of different organisms to compare similar genes between species,
- Designing new technologies to study genes and DNA on a large scale and store genetic information efficiently.

Genomics has advanced at a dazzling pace and databases are permanently updated with entries of recently described new sequences and complete genomes. Information is also updated daily. When these lines were written (April 17th 2008), 4369 species had already been registered with their genomes totally described and registered in the Entrez Genome and Gen Bank of the National Centre for Biotechnology Information (NCBI), which is a branch of the United States National Institutes of Health.[22]

Synthetic genomics. This discipline focuses, quite simply, on programming and synthesis of DNA. It involves the design of genes and complete chromosomes from chemical components of DNA. In terms of an analogy, the genome of a cell is the *software* (operating system) and the cytoplasm the *hardware*. The goal of synthetic genomics is to modify the cells operating system, design new genomes, codify for new types of cells with desired properties for the production of bio-energy or substitutes for petrochemicals. In 2008, two researchers of the J. Craig Venture Institute, reported having synthesized the complete genome of a small (*Mycoplasma genitalium*),[23] *which is an example of the relative dependence on biological materials, as control and use of information and new biosynthesis technologies become more common place. With synthetic genomics, artificial information -the value added by researchers- has managed to simulate natural information.*

Proteomics (functional genomics). Genes codify proteins which, in turn, form the mechanism which recognizes specific DNA regions which contain other genes promoting their expression, resulting in other structural and functional proteins in the cells of the organism. Proteomics is the field of technology that uses protein sequences, expressions and structures to determine their function, interaction and response in a single organism. This includes the characterization of proteins, cataloguing, building protein libraries, and comparing between proteins and their functional roles. These activities are highly "automated" and require the use of bioinformatics to decipher their content.[24] It is also defined as a part of technology that applies molecular biology, biochemistry and genetics to analyzing the structure, functions and interaction of proteins produced by genes in a single cell.

Figure 1. Total of species whose genome has been totally described according to major taxonomic groups: virus, eukaryots, bacteria, archaebacteria, viroids and plasmoids.

Total species (4369)

Viruses	Eukaryota	Bacteria	Archaea	Viroids	Plasmids
1890	1491	65	65	38	38

The common and cross-cutting element to all these disciplines and technologies, is that their subject matter are genetic resources, understood in terms of *information*. Such information can be found widely distributed among many countries and institutions in *in situ* and *ex situ* conditions. A second cross-cutting element refers to intellectual property as a tool to promote and support research and innovations. Paradoxically, intellectual property can also become a potential obstacle of this research and developments (see comments in point 4 below).

3. The situation of access regimes around the world.

If success is measured only by the number of processes, legal proposals and laws in place, there is no doubt that the CBD and its "process-launching" function in ABS can probably be measured as a success (see Box 4).

However, a preliminary analysis on the state of implementation of ABS laws indicates that their effectiveness has been very modest and that realization of benefits (a key objective in all ABS policies and laws) is still to be materialized. At present, there are valid concerns regarding how to guarantee a minimum of effectiveness and results from ABS regulatory frameworks worldwide.[25] [26]

[22] http://www.ncbi.nlm.nih.gov/sites/entrez

[23] This bacteria is made up of only 580 genes against 26,000 genes in human beings.

[24] http://www.ncbi.nlm.nih.gov/Tools/index.html

[25] The FAO International Treaty on Plant Genetic Resources for Food and Agriculture is an exception to this. In this case, although it has been in force since 2004, it implementation has been effective, in terms of the *number* of Standard Material Transfer Agreements (SMTA) which have been used to transfer plant genetic resource samples for food and agriculture (and the subsequent exchange of these resources).The number of genetic material transactions using SMTA is over 1000, specifically in the case of access to materials held in *ex situ* conservation collections and International Centers in particular.

[26] For further details regarding the degree of implementation of ABS laws and regulations around the world, see: Carrizosa,

At the same time, many of these policies and laws *have* been very useful in terms of triggering national and international debates regarding the role of IP, the possibilities of protecting traditional knowledge, the need for developing PIC standards, the relation of genetic resources with agrobiodiversity, etc. and furthermore, international forums including CBD, WIPO, FAO and many others are addressing and reviewing some of these issues. This is certainly a positive sign. Their awareness raising effect has been considerable among wider sectors of society.

Although definite studies have not been undertaken as yet, it can be argued that these difficulties arise from limited and weak national institutional capacities to manage and transform genetic resources into useful products and goods, and from some of the substantial content of these norms. For example, their often undefined scope and coverage, their overall "clarity", the burdens of administrative procedures imposed on applicants, overlapping rights over the same subject matter (genetic resources) from State, individuals, communities, among others, contribute to these difficulties. In any case, it is not a mere academic exercise to ponder on the actual core reasons why ABS regimes haven't been as effective in practice as desired, notwithstanding the previously mentioned positive advances (see Box 4).

On the other hand, it is also surprising to verify that except for ABS legislation in Costa Rica and Brazil and the FAO International Treaty, none of the legal frameworks addressing access to genetic resources make references to genetic resources as *information*, with the implications that have been suggested.[27]

In practice since the acknowledgement of the Schrodinger metaphor and Crick assertion, the structure and function of genes as a software code have been better understood by a wider public. People can relate well to the concept of a "software code", even if they do not fully understand it.

In simple terms, the genetic code is written with four "characters" or nitrogenated bases, arranged in very long and different sequences, which are specific to species, races, including individuals and, in general, taxonomic groups. But a part of the code will be similar in all mammals. Another part of the code will be common in primates and, the most important part, will be common in all humans. Finally, part of the code will be unique in each individual, which will confer its individual "singularity". This code contains the functions for each cell, which are the essential matter of which all the organisms are made.

The Action Group on Erosion, Technology and Concentration (ETC Group – previously the Rural Advancement Foundation International – RAFI), explains this in the following way: computers store and process information in a binary code which uses the numbers 1 and 0. DNA is coded with a sequence of four nucleotide bases: A, C, T and G. These bases are separated every 0.35 nm in the DNA molecule, giving it a density which makes it possible to store about half a million gigas of data per square centimeter, more than the typical density in a hard disk. To put this in perspective, a trillion CDs would be needed to store the amount of information DNA contains in a cubic centimeter. In many cases, different parts of DNA may simultaneously solve different problems.[28]

These days, genomics (which allows reading gene sequences), synthetic biology (which allows a genetic code to be "created" – see above on Synthetic Genomics) and bioinformatics (which allows "storing and interconnecting" the code digitally), makes it essential to rethink and reconsider the traditional way in which genetic resources have been addressed in terms of policies and laws.

As a result of these technical advances and convergence of technologies (for example, informatics and biotechnology), it can be assumed safely that users of biological resources for research will be less dependent on access to physical specimens, as long as genetic resources, as *information*, are available electronically and digitally.[29] In some cases it is already

Santiago; Brush, Stephen; Wright, Brian; McGuire, Patrick (Editors) *Accessing Biodiversity and Sharing Benefits: Lessons from Implementing the Convention on Biological Diversity*. IUCN Environmental Law and Policy Paper No. 54. Gland, Switzerland and Cambridge, United Kingdom, 2004.

[27] It is quite striking that as part of ongoing debates regarding the relation between ABS and intellectual property and its conceptual foundations (especially in the case of patents as applied to information related innovation such as biotechnology products and software), little attention has been paid to the fact that the economic justification for patents in these fields is based on the *informational* nature of innovations. Exactly what genetic resources are and where their value resides. According to information economics and classic IP, the fixed costs of research and development are high, while the marginal costs to reproduce a copy of the same innovation is very low (especially when using available technologies). To correct this market failure, privileges are granted in the form of IP and exclusive monopoly rights. These are supposed to act as incentives for continued innovation. In the case of genetic information, the analogy with protecting research and development is the cost of opportunity of maintaining (through investment in conservation or other means) a minimum critical habitat (for example, the tropical jungle) and therefore genetic information contained therein. For more detail on this discussion review: Vogel, Joseph. *Genes for Sale*. Oxford University Press, New York, 1994. Also see: Swanson, Timothy. *Global Action for Biodiversity*. IUCN, WWF, Earthscan Publications Ltd., United Kingdom, 1997.

[28] ETC Group (2007), Ibid.

[29] Oldham makes interesting points in relation to this issue. When considering the implications in the development of public policies (for example the International Regime on ABS), it is important to ask questions such as: what type of norms regulate the electronic transfer of genetic information – if any? should these transfers be regulated? what would the costs and benefits to regulate these transfers be ? what type of transfer is feasible? These questions are critical in the context of DNA sequence data, (for example from a medicinal

Box No. 4. Examples of laws and legal proposals regarding access to genetic resources and the fair and equitable distribution of benefits

Country/region/forum	Laws and their *status*	Scope	Issues covered
Brazil	Provisional Measure 2.186-16 on access to the genetic patrimony (2001)	Access to genetic patrimony (genetic information in the form of molecules, extracts, etc.)	Access, distribution of the benefits, protection of traditional knowledge
Andean Community	Decision 391 (1996)	Access to genetic, biological resources and derived products (molecules, extracts, etc.)	Access, distribution of the benefits, protection of traditional knowledge
Costa Rica	Law 7788, Biodiversity Law (1998)	Biodiversity elements	Conservation, sustainable use, access to biodiversity components, traditional knowledge
Bonn Guidelines on Access to Genetic Resources	Bonn Guidelines on Access to Genetic resources (2002)	Genetic resources	Genetic resources, distribution of the benefits, measures in user countries, training, capacity building
Philippines	Executive Order 147 (1996)	Genetic and biological resources	Access, traditional knowledge
Indian	Biodiversity Act (2002	Biodiversity conservation	Access, intellectual property, institutional framework
African Union	The African Models Law for the Protection of the Rights of Local Communities, Farmes and Breeders and for the Regulation of Access to Biological Resources (1998)	Traditional varieties of crops, biological resources and traditional knowledge	Community rights, access and distribution of the benefits from access to and use of biological resources and traditional knowledge
Nepal	Law 2058 on Genetic Resources (2001)	Genetic and biological resources	Conservation and access to genetic and biological resources
Panamá	Decree 257 on access to genetic resources (2007)	Genetic resources	Access, distribution of the benefits, institutional framework
Panamá	Law 20 on the protection of indigenous knowledge (2001)	Indigenous knowledge related to art, designs, folklore, etc	Protection and registration of indigenous knowledge
Perú	Law 27811 on the protection of collective knowledge of indigenous peoples	Collective knowledge associated to biodiversity	Access, use, distribution of the benefits, registers
African Regional Intellectual Property Organization (ARIPO)	Legal Instrument for the Protection of Traditional Knowledge and Folklore Expressions (2006)	Traditional knowledge of local communities	Access, use of traditional knowledge and folklores expressions
FAO International Treaty on Plant Genetic Resources	FAO International Treaty on Plant Genetic Resources (2001)	Plant genetic resources for food and agriculture	Multilateral system, access, distribution of the benefits

Source: Ruiz, 2008

feasible to minimize the need of accessing tangible genetic resources and advance in their use based on their informational nature and through synthetic or semi-synthetic regeneration.

From the point of view of a user, it is practical to add value to the genetic code and all products derived thereof in the form of information, as the importance of access to physical specimens decreases or at least becomes less critical. This can be easily compared with the system of copyright and patents, where the value rests in the computer program and its codes, rather than on the material support of these (the *physical* computer or hardware for which other valuing mechanisms, including IP may be relevant). ABS international policies and legislation should respond or, at the very least, take into account these considerations. It has already been demonstrated that genetic resources are information, and the concept, as an analogy, metaphor or simple assertion, is not that complicated to understand even if in its basic elements. This is mainly to ensure that genetic information available in databases does not benefit only countries with technological capacities to construct and develop knowledge and products based on this data and information. In this regard, when negotiating the ABS International Regime, policy makers and those involved should urgently take these advances into account in order to secure that the principles of equity and fairness of the CBD do not become redundant, at least in the realm of this very specific and important, scientific and technological context.

To the extent that genetic resources are valued mainly as information, this will have implications with regard to the interests of different stakeholders such as indigenous peoples, for whom this type of reductionism collides directly with their holistic conceptions related to biodiversity and its components. However, indigenous groups, by claiming collective ownership, in the same way as States claim and invoke sovereignty over the tangible element of biodiversity (and rely on contracts), may be unconsciously promoting a position which is contrary to their own interests.

Fortunately there may be a way out to this problem. Opposition to reductionism is not confined to religious and moral positions. Professor E.O. Wilson, the most prominent naturalist of the 20th Century, has enabled an alliance between science and religion under the title *The Creation: An Appeal to Save Life on Earth* (2006). Some of his followers, Vogel among them, suggest that the notion of "sovereignty" should be understood as a national right to participate in an *international* regime (a "cartel") and not a right to negotiate bilateral ABS contracts.

A shift in the debate (or at least seeking a more provocative debate), is necessary to stimulate an in depth analysis of resources as information, in the light of technological advances. This shift will raise important ethical, religious, economic and legal questions and challenges during the development of an ABS International Regime (and national norms), but at the same time will ensure the right incentives are in place to support innovation systems and knowledge generation as well as the rights of different actors. This will also enable a new approach to the issue of ownership and the appropriation of genetic resources (information).

4. The changing role of intellectual property and its effects

During the last few years, debates regarding genetic resources and intellectual property, have focused on how judicial decisions and certain laws have enabled the patenting life forms or, in other words, served to "add value" to these resources through a series of technologies.[30] With a strong resistance from civil society and indigenous organizations,[31] the trend to legally protect inventions over or derived from biological material, has expanded worldwide. As a result, many countries and organizations have called the attention to the problems of direct and indirect appropriation of genetic resources and traditional knowledge of indigenous peoples through the granting of these patent rights in particular. In general, the

plant) which can be uploaded to a web page or sent electronically through an e-mail. The extraction of genetic information has traditionally been based on the collection, identification and storage of field samples, for example, in a herbarium. However, it is feasible to imagine a situation in which the same information is transferred without requiring a collection, nor immediate taxonomic identification nor storage of physical samples. See: Oldham, Paul (2004) Ibid. at 10

30 In 1980, the door finally opened for patents over life forms. The United States Supreme Court determined in a close 5 to 4 divided decision, that a genetically modified bacteria could be legally protected through a patent (Diamond v. Chakrabarty, United States Patents Quarterly, 1980). This not only changed North American jurisprudence, but also catalyzed a series of other policy and normative processes around the world. This decision also paved the way for industry in the US to lobby for stronger international IP standards and, as a result, the US government to incorporate IP into the Uruguay Round of the General Agreement on Tariffs and Trade (GATT), as a negotiating issue first and secondly, the adoption of an agreement (TRIPS) which obliged all countries to grant patent protection for biotechnological inventions.

31 Since the 1990s, indigenous organizations have expressed their opposition to patents over life forms, due to religious, cultural and moral reasons. Some of the indigenous statements expressing this opposition include: The Kari-Oca Declaration on Indigenous Peoples (1992), the Global Indigenous Forum (1992), the Mataatua Declaration on Cultural and Intellectual Property Rights (1993), the Call of the Earth (2003), among many others. They have also reaffirmed their opposing views during sessions of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) and at Conferences of Parties to the CBD.

concept of “biopiracy” has been useful to highlight and describe this phenomenon.[32]

Two clear trends can be at present identified in regards to intellectual property in general. On one hand, there is a policy and regulatory preference towards *strengthening* intellectual property rights, in favor of right holders and weakening the exceptions which the IP system has in order to satisfying public interest and promote continued innovation by building on existing innovations.

On the other hand, during the past few years, important scholarly, social and policy movements have also sought to promote changes in certain intellectual property instruments, especially in terms of ensuring that rights granted are balanced against social needs and interests and ultimately, that flexibilities are left for countries to make use of these exceptions as their own realities dictate.[33] In the context of this research, availability and accessibility to genetic information tends to be affected by patents, trade secrets, plant breeders’ rights and, increasingly, by *sui generis* systems for the protection of databases and by technological restrictions.[34]

Very intensive debates have taken place, especially between advocates of an “enclosure movement”[35] and strengthening of intellectual property (in contrast to open access) and supporters of a new paradigm regarding access to and availability of information. This latter group suggests that original incentives for the granting of monopoly rights -the promotion of innovation for the public good- should be revisited.[36]

The debate between these groups has become especially controversial in the context of scientific data and information generated as part of technological projects which use public funds (often matched by private funds).[37] As raised by Ulhir, what was considered until a few years ago public knowledge (data generated as a result of research), is becoming enclosed as legal barriers are built through the application and use of certain rights which affect access to and availability of this data and often research results thereof.

5. Rethinking an international regime on access to genetic resources: an international regime on technology transfer and cooperation?

A concern which immediately arises among some analysts is whether the current principles and norms on access and benefit sharing are applicable or even relevant (and to what extent) in the light of the issues raised and reflections presented in this research paper. An initial answer would probably be that current public policies and norms on ABS matters say little or nothing on the issues raised previously, although they are extremely relevant in the context of countries who wish to participate in the benefits generated from innovation and technological development.

The informational nature of genetic resources implies the need to rethink about the type of international rules, which will ensure the realization of the CBD justice

[32] Institutions such as RAFI (ETC Group) and GRAIN, were pioneers in reporting “biopiracy” cases around the world. Their web pages: http://www.etcgroup.org and http://www.grain.org incorporate considerable information and details on specific “biopiracy” cases. A recent document on potential cases of biopiracy is: National Commission on Biopiracy. *Analysis of potential cases of biopiracy in Peru*. Research Documents. Initiative for the Prevention of Biopiracy. Year I, No. 3, September, 2005. Available at http://www.biopiracy.org. Vogel refers to “biofraud” when distinguishing access and inequitable use of genetic resources and TK, through bilateral contracts (with extremely low monetary benefits). Vogel (2005), Ibid. at 17

[33] This is especially but not exclusively the case in copyright, in the context of major changes mainly due to the impacts of information technology and the Internet. See: Hall, Brownyn. *On Copyright and Patent Protection for Software and Databases. A Tale of Two Worlds*. Paper for Grandstand Volume, June 2002. Also see: Litman, Jessica. *Sharing and Stealing*. In: Berman, P.S. (Ed) *Law and Society Approaches to Cyberspace*, 421, International Library of Essays on Law and Society, London, Ashgate, 2007.

[34] Recently (2007) in the case of *KSR International Co. v. Teleflex Inc.*, the United States Supreme Court determined the threshold for inventiveness required to comply with patent requirements. In this particular case, the Court (correcting a decision by the Federal Circuit Court) ruled that a certain way of positioning a sensor on an electronic pedal would be obvious for the effects of “state of the art” analysis. This has raised the bar for inventions to effectively have and demonstrate an inventive step and not be minor or “cosmetic” adjustment to precedent innovations.

[35] On the enclosure of the commons see: Boyle, James. The *Second Enclosure Movement and the Construction of the Public Domain*. Available at: http://www.creativecommons.org/licenses/by-sa/1.0

[36] LINUX, Wikipedia, Open Source, Copyleft, Creative Commons, Kazaa, etc. are mechanisms, which aim at guaranteeing the dissemination and flow of information, for the overall benefit of society. These are reactions to the enclosure movement supported by current intellectual property trends.

[37] Of particular interest in the debates regarding genetic information, are the different initiatives to protect *non-original* databases. In the case of the European Union, the EU Directive on the Legal Protection of Databases (1996) includes a *sui generis* legal protection for non-original databases, in which investment in time and money can be verified. In essence, it is possible to protect pure data with the negative effects this may have on scientific investigation and development processes. Although the United States Supreme Court decided in *Feist Publications Inc. v Rural Telephone Services Co*. to refuse the possibility of protecting the mere compilation of data through copyright, there is considerable political pressure to regulate this issue and apply the principles of unfair competition to protect non-original databases. These examples are a reflection of a trend to privatize information, even in its most basic form and level: data. For more information on these issues see: National Research Council (1997). *Bits of Power, Issues in Global Access to Scientific Data.*Produced by the Committee on Issues in the Transborder Flow of Scientific Data. US National Committee for CODATA. National Academy Press.

and equity principles, as well as support implementation and compliance efforts. This new approach needs to take into account that research on and development of genetic resources stopped being a flow and exchange of tangible or physical (only) materials between countries, quite a long time ago.

In the light of this new situation, it should be stressed that there is still an interest in finding new molecules and active compounds from biodiversity. However, this interest is shifting to microorganisms as a source, an aspect which presents yet additional complexities for countries in terms of the exercise of their sovereign rights. As a result, there is the need to consider and explore new regulatory alternatives in order to ensure implementation of the CBD principles in these emerging fields of interest.

Paradoxically, in the early 1980´s, the idea of implementing an international fund (in the form of an International Fund for Plant Genetic Resources) to channel the economic benefits from the commercial use of plant genetic resources in the field of food and agriculture was rejected by the international community and the private sector as being far to complicated. The CBD is in part an explanation to this, and the prevalence of bilateral, contractual approaches to regulating access to genetic resources a result thereof. Enter 2001, and the idea of an international fund has been recaptured in some way, in the case of the FAO International Treaty and the financial mechanism being constructed and which will capture the monetary benefits generated from commercialization of plant genetic resources covered by its Multilateral System.

Based on some of the reflections presented throughout this research, it may be a good opportunity for policy makers to consider assessing how the International Regime on ABS can guarantee effective benefit sharing from the use of genetic resources, through the creation and development on a global fund. The idea of this fund would be to distribute monetary benefits according to the spatial distribution (conservation) of specific species, from which natural information expressed by a gene, metabolite, enzyme or protein, was obtained. Indeed, value may have been added to these expressions of information through technology, knowledge, and maybe a patented invention. The bilateral approach, contractual which almost naturally derives from the invocation of state sovereignty in the CBD, makes equity and efficiency nearly impossible to attain, except in cases when a gene or very specific compound is obtained from a very unique ecosystem (mainly cases of endemism) and does no share its informational codes and features with higher taxon species.[38] [39]

Secondly, due to the critical role technology plays these days in genetic resources development processes, the ABS International Regime negotiation should also consider discussing provisions which facilitate exchange and transfer of such technology. Not in general terms as the CBD already does, but in more specific ways and guaranteeing developing countries participate in and also benefit from these advances – even in a context of the strengthening of intellectual property.

Thirdly, it is in essential for the International Regime to explicitly distinguish between activities aimed to specifically access and use biodiversity components in a small scale (small samples which do not erode genetic populations nor ecosystems) for research and development, for commercial and non-commercial purposes, from activities which do require a permanent and larger supply of raw materials - plants, oils, resins, determined specimens, plant parts, pelts, animal parts, etc. These activities are much more damaging to biodiversity, mainly especially when obtained and collected in natural ecosystems or from the wild. Although some countries are placing the latter activities and components under the scope of collecting "derivates", the problem may be that ABS rules are not necessarily the appropriate tools for these situations where an almost *direct*, semi industrial and commercial use of biodiversity take place.

In this context, countries are free to apply and expand the principles of ABS to a wider set of activities and subject matter. However, the norms and procedures required to regulate them would probably need to differ from those used to identify useful specific components to which technologies are intensively applied and which are subsequently transformed into new products and innovations. For the latter type of activity, the research involved is probably different in terms of the technologies used; the objectives when using natural products or "derivatives" are often 100% commercial; the productive and transformation processes are clearly identifiable; the possibilities for authorities to control and monitor activities are relatively simpler; and the existence of a local, national and often international market clearly established according supply and demand principles and exchange terms (price), among other features. It could be argued that at least in some countries with ABS laws and regulations, some of the problems in their implementation stem from seeking to apply a set of rules which are intrinsically not suited for these activities.

[38] A useful exercise is to think about the not so uncommon case where species and resources are shared between countries. Does one country have more rights than the other to benefit from their exploitation? Will a bilateral contract ensure the best negotiating position? Is it realistic to consider that one country will take into account the interests of other countries which share species and resources and thus actively commit to its equitable participation in the benefits generated? The answer seem most likely to be "no" in all cases.

[39] This is the conceptual foundation for a group of megadiverse countries (in the form of a biodiversity cartel). Vogel, Joseph. "Reflecting Financial and Other Incentives for the TMOIFGR: the Biodiversity Cartel". Pages 49-76 In: Ruiz, Manuel and Lapeña, Isabel (Editors) *A Moving Target: Genetic Resources and Options for Tracking and Monitoring International Flows of Genetic Resources*. IUCN, Gland, Switzerland. Avaialable at: http://www.data.iucnorg/dbtw-wpd/edocs/EPLP-067-3.pdf

Finally, it is important to highlight that the coherence of the ABS International Regime, also depends on the coherence and clarity of national regimes on ABS. The International Regime negotiation may need to prioritize and reflect upon some of the issues presented in this investigation and regulate aspects of ABS which may require multilateral consensus. In this regard, the areas which may need an international consensus may be limited to support for compliance and enforcement of *national* ABS norms in foreign jurisdictions and therefore, the adoption of measures and commitments by countries using and developing genetic resources in order to guarantee that the CBD benefit sharing objectives are realized. The certificate of legal/origin may be one tool to consider to support compliance. In the case of an international cartel for biodiversity, the certificate would simply reveal the specie whose gene or active component was being industrially used (or had the potential to be used), for example when a patent application is submitted.[40]

Conclusions

1. Genetic resources are in essence, information. Information whose legal protection should be governed by basic principles of economy (non rivalry, low marginal costs of reproduction and existence of market failures to stimulate innovation).
2. To think of genetic resources as *information* implies a number of unappreciated consequences regarding the availability of these resources and the possibility to regulate their access and utilization. Accessibility and the protection of information (including genetic information), relates to the fields of database protection, copyright, trade secrets and patents. ABS laws and regulations (at present), do not necessarily offer appropriate options to address these feature of genetic resources. This could have important practical implications.
3. Genetic resources are not discreet, unique entities as living beings share most of the genetic information between them (depending on their evolutionary proximity and ramification in the evolution tree). This implies that the availability of these entities does not respond to the particularity or specificity of a determined species. At the same time, this has consequences regarding the notion of “country of origin” and may affect the way of understanding the relation between countries and ABS principles.
4. Current national and regional ABS norms and the ABS International Regime negotiation, are not taking into due account genetic resources *informational* characteristics. In this regard, there is an increasing separation between the scientific and technological reality of genetic resources and the policy and normative approaches being consider for their regulations.
5. It is important to solve the tension among countries proposing to include “derived products” or “derivatives” under the scope of the ABS International Regime (natural products extracted directly from biodiversity and processed or semi-processed industrially or commercialized directly), and those countries who propose that these activities respond to other principles (supply, demand, prices, fair trade and certification). A focus on *information* may solve the problem given that in most cases of adding value to a biological product (for example, grinding herbs or extracting a resin or oil), this will not involve a new or non-evident process. ABS principles should be applied when value is effectively added (generating something new involving an inventive susceptible to patentability). Another option may be for the IR to simply mention derivatives, but leave their definition to scope coverage in national legislation. Solving these differences in perceptions may contribute to focalize the debate and address some of the issues raised in this investigation in more detail.

Recommendations

a) Countries that are rich in biodiversity and have traditionally acted as providers of genetic resources, should ensure that national legislation on ABS (and the International Regime negotiation process), include principles applicable to the informational nature of genetic resources and even associated traditional knowledge.

b) These countries could consider applying existing legal mechanisms such as copyright, *sui generis* protection of databases or the patent system respectively, in order to protect their interests over genetic resources.

c) The debates on ABS should rapidly take into account that biodiversity is a short term promise, as the coding in units of information is growingly done at a greater speed, making it difficult for provider countries to regulate access to these resources (especially in the case of megadiverse countries). The threats of mass extinctions continue to accelerate and, therefore, this may offer a considerable incentive for States to conserve habitats and ease the threats of land use change.

d) Clearly, any country intending to generate economic benefits from its biodiversity should build and strengthen capacities in new technologies, with an emphasis on bioinformatics.

[40] Ruiz, Manuel. *Accounting for the Scientific Present. Technological Advances and Genetic Information in the Negotiations of the ABS International Regime.* Policy and Environmental Law Series. SPDA No. 19, October 2007. Lima, Peru

In this context, training national researchers and investing public funds in research and technological development is a strategy that would capture benefits besides the compensation for raw material. Comparative advantages should be exploited by countries.

e)When working in the development of ABS national norms and during International Regime negotiations, the following elements should be taken into account:

- State sovereignty *per se* and individual national actions (laws and regulations) do not allow for economically efficient controls over the flows of genetic resources.
- Technology allows research and development processes on genetic resources whose structures have already been decoded, *without the need to access physical samples*.
- Genetic resources are not discreet units and *can be found widely distributed in terms of the genetic information they contain*.
- Ex situ conservation centers, extreme environments (for example, deep sea hydrothermal vents and Arctic and Antarctic ecosystems) and the world of microorganisms *offer an almost inextinguishable source of molecules, genes, DNA, etc*. which allow innovation and development processes to begin and continue.
- Intellectual property from an economic point of view, is not very appreciated nor fully understood in the context of the ABS debate, *but has considerable implications in the innovation and development processes of genetic resources*.
- With regard to the direct and permanent use of resins, oils, flour, bark and crude, semi-processed or processed natural products in general, *there is a commercial world with important implications related to biodiversity conservation, therefore, it is important for CBD principles to be taken into account. This does not mean it is necessarily adequate to apply present ABS models or proposals to these specific type of activities*.

f) The knowledge, innovations and practices of indigenous peoples and communities in general, should be subject of protection under a *different* policy and legal process than that of the International Regime. Although reference to the knowledge should be made, effective and practical protection mechanisms must be developed in view of other legal instruments, not necessarily under the CBD but, for example, making use of the spaces and new agendas of the World Intellectual Property Organization, mainly the Development Agenda, and activities of its Intergovernmental Committee.

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Editorial Note

This investigation is part of the Series “Research Documents” of the Andean Amazon Initiative for the Prevention of Biopiracy, a project led by the Peruvian Society for Environmental Law (SPDA), with the support of the International Development Research Center (IDRC) of Canada.

The second phase (2008 – 2010) of this Initiative seeks to consolidate research activities oriented towards finding and facing solutions to social, economic, legal and policy challenges which raise a series of issues linked to the complex relations between access to genetic resources, intellectual property, technology transfer, legal protection of traditional knowledge of indigenous peoples and ultimately, biopiracy.

The different investigations that will be undertaken place will contribute with practical and effective options and answers to different problems associated to the issues mentioned previously. Hopefully, the results will positively impact national and international debates and discussions, in order to reach the objectives of justice and equity proposed by the Convention on Biological Diversity, mainly in relation to access to genetic resources and similar topics.

The expressions and opinions expressed in each of these investigations only compromise the authors and do not necessarily reflect the institutional point of view of SPDA, IDRC and other participating organizations and collaborators.

Acknowledgements

We wish to thank Joseph Vogel and Emily Taylor for their valuable comments and suggestions to this paper. We also thank the International Development Research Centre (IDRC) of Canada for supporting this investigation and project in general.

The Peruvian Society for Environmental Law (SPDA) is a non-profit organization founded in 1986, working in the areas of Environmental Law and Policy. The SPDA is organized in five programs: International Affairs and Biodiversity; Environmental Policy and Management; Forestry; Conservation, and Public Interest Defense. It provides technical/legal assistance and consultancy services, carries out specific projects, promotes and disseminates Environmental Law through the information centre and training activities.

The *Andean-Amazon Initiative for the Prevention of Biopiracy of the Peruvian Society for Environmental Law* is a two year project in its second phase, supported by the *International Development Research Centre* (IDRC) of Canada. The website of the Initiative is: http://www.biopirateria.org

This projects objective is to prevent biopiracy with regard to biological resources and traditional knowledge in the region. A series of national and international activities have been already undertaken. These include: strengthening the *National Commission for the Prevention of Biopiracy in Peru*; undertaking research (Research Documents); organizing regional meetings with different actors, including intellectual property offices in order to evaluate measures to face biopiracy; coordinate actions and strategies between member institutions in the countries; coordinate actions with the Amazon Cooperation Treaty Organization, among others.

The Peruvian Society for Environmental Law wishes to thank the International Development Research Centre (IDRC) for supporting this Initiative.

Sociedad Peruana de Derecho Ambiental

President: Jorge Caillaux   Executive Director: Manuel Pulgar Vidal

Initiative Coordinators:

Manuel Ruiz Muller, Co Director of the Program for International Affairs and Biodiversity of SPDA, mruiz@spda.org.pe;

Isabel Lapeña, Co Director of the Program for International Affairs and Biodiversity of SPDA, ilapena@spda.org.pe

Prolongación Arenales 437, San Isidro, Lima 27   http://www.spda.org.pe

Phones: (511) 422 2720 / 441 9171 Fax: (511) 442 4365

SPDA

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