①

The International ABS Regime

- Scope and definitions is a key issue for the fate of fair and equitable benefit-sharing -

Paris, ABSWG-7, April 2009, supported by: BD Berne Declaration Déclaration de Berne Erklärung von Bern, ECOROPA, eed, TWN Third World Network

One of the driving forces leading to the creation of the CBD was the notion that biodiversity serves as raw material for the development of medicines and other useful products. Biological diversity as a source for medicines has been used by humankind since time immemorial. Pharmaceutical companies develop modern drugs using single active ingredients derived from plants, microbes, and other organisms. They also produce phytopharmaceuticals using multi-substance extracts, in most cases based on traditional knowledge. Furthermore, numerous dietary supplements, functional foods and cosmetics based on the use of biological diversity including traditional knowledge are developed and marketed worldwide.

"The overwhelming number of bioprospecting cases that have emerged during the history of the CBD have been based on the use of biochemical components of genetic resources and only very few on the use of genes from genetic resources."

The point of departure in the CBD debate is that any ABS system has to cover and reward the use of biological diversity in all non-profit- and profit-making fields as medicine, cosmetics, food supplements, industrial processes, breeding, crop protection, and horticulture. As a general rule, two groups of industries use different components of genetic resources. While medicine, cosmetics and food supplements use biochemical compounds, many industrial processes and the breeding sector use the genetic information of the resource.

In principle, a future ABS regime must cover the use of all components of genetic resources. If an ABS regime would only cover the use of the genes and leave out the use of the biochemical components, such a regime will exclude the majority of uses from access and benefit sharing. The overwhelming number of bioprospecting cases that have emerged during the history of the CBD are based on the use of biochemical components of genetic resources and only very few on the use of genes from genetic resources. Both types of use have been promoted as best practice cases for ABS-agreements.[1]

"If an ABS regime would only cover the use of the genes and leave out the use of the biochemical components, such a regime will exclude the majority of uses from access and benefit sharing."

The citations on page 4 show that prominent actors in the field have always understood an ABS regime to include both the use of genes and biochemical compounds of genetic resources. Therefore, this understanding has to be kept in mind during the course of the negotiations, particularly when dealing with the definition of "genetic resource", "utilization", "products" and "derivatives".

The unclear situation concerning scope and related definitions stems from the CBD itself. While the Convention in almost all articles speaks of "biological resources", also when dealing with traditional knowledge, it refers to "genetic resources" in the ABS-relevant Art.15.

When the CBD was negotiated, a powerful PR campaign was ongoing to convince the delegations that gene technologies, especially GE crops will be essential to solve the environmental and agricultural problems of the world. It has been propagated that the major economic value of living beings lies in their genes. It can be assumed that as a result of this campaign the CBD speaks of genetic

[1] eg: UNEP. 1998. Synthesis of case-studies on benefit sharing. http://www.cbd.int/doc/meetings/cop/cop-04/information/cop-04-inf-07-en.pdf

resources in Art. 15. Now, 16 years after Rio, it is apparent that so far isolated genes from organisms covered by the CBD do not play an important role in the development of biotech medicines and GE seeds, to name the two most prominent examples where large (monetary) benefits were predicted.

To move the negotiations of the International Regime ahead, it seems to be advisable that experts and governments do not further try to explore what the creators of the CBD had in mind. They should rather start the discussion on how the given CBD definition can be interpreted and developed further to enable an effective ABS Regime, bearing in mind that it is still the biochemical substances that are of the greatest value for most of the research and industry actors using biological diversity to develop products.

Already in 2004, the Parties to the CBD had rectified another defect of the CBD in the ABS context: while the worldwide discussion on ABS is closely linked to the (mis)use and protection of traditional knowledge, the CBD separates the two issues in Art. 8j and Art. 15. To ensure that a future ABS-regime also deals with traditional knowledge, COP 7 decided that not only Art. 15 but also Art.8j has to be implemented by it.

Decision VII/19 The Conference of the Parties, 1. Decides to mandate the Ad Hoc Open-ended Working Group on Access and Benefit-sharing with the collaboration of the Ad Hoc Open ended Inter-Sessional Working Group on Article 8(j) and Related Provisions [...] to elaborate and negotiate an international regime on access to genetic resources and benefit-sharing with the aim of adopting an instrument\instruments to effectively implement the provisions in Article 15 and Article 8(j) of the Convention and the three objectives of the Convention;

It is our opinion that the negotiations on the ABS Regime have to take the definition of genetic resources as it is:
"Genetic resources" means genetic material of actual or potential value.
"Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity.
Starting with with "functional units of heredity" the most basic of the named biological objects, we would interpret it as follows.

Gregor Mendel assumed that the observed phenotypical features in his studies must be caused by distinct physical hereditable "Elemente". In 1905, the Danish biologist Wilhelm Johannsen coined the word "gene" to describe Mendel's elements.[2] A review of the relevant literature reveals that the CBD term "units of heredity" is a frequently used explanatory translation for Mendel's German term "Element".[3] The understanding of the expression "unit of heredity" as "genes" prevails through the decades[4].

In the light of the scientific progress in the fields of genetics and molecular biology it is apparent that genes as originally defined by their linear structure within the DNA-strand are not the sole structures that constitute "units of heredity". Other molecules as RNA, the chemical alteration of the DNA and the three-dimensional status of the chromosomes contribute as well to that what the CBD calls "units of heredity".

The term "functional" has a broad meaning:
- *connected with, or being a function -or -*
- *performing or able to perform a regular function*[5]

---

2 Johannsen, W.. 1905. Arvelighedslaerens elementer. København: Gyldendalske Boghandel, Nordiske Forlag; Johannsen, W. 1911. The Genotype Conception of Heredity. American Naturalist 45 (531): 129-159.

3 eg. p.36 in: Hasan, H.. 2005. Mendel and the Laws of Genetics. The Rosen Publishing Group. http://tinyurl.com/44ua72

4 eg.: Anon. 1932. "Genes" - the units of heredity. Science Education 16(5): 368-379; or: Rhoades, M. M., B. McClintock. 1935. The cytogenetics of maize. The Botanical Review 1(8): 292-325.
or p.30 in: Kammermeyer, K., V. L. Clark. 1989. Genetic Engineering Fundamentals: An Introduction to Principles and Applications. CRC Press. http://tinyurl.com/52vmtw
or p.262 in: Miglani, G. S.. 2006. Mendelian Genetics. in: Dashek, W. V., M. Harrison. Plant Cell Biology. Science Publishers, p. 259-348. http://tinyurl.com/49afkv

5 http://www.merriam-webster.com/dictionary/functional

With that, a "functional unit of heredity" does not necessarily need to be active at the time when access to the respective genetic resource is sought for. It may be silent or potentially active, it might even only be functioning again when for example it is extracted from a dried herbarium specimen and engineered into another organism.

The CBD definition of genetic material describes its physical status: it must "contain" functional unit of heredity. Last but not least, the CBD defines those genetic materials as "genetic ressources" that have "actual or potential value" for the user. In the context of the ABS negotiations, it will be essential to keep in mind that "genetic material" is defined through physical status of a certain biological entity, while "genetic resource" is defined through the socio-economic value of this specific biological entity.

It is apparent that an ABS regime would be dysfunctional if the full set of provisions would apply to all possible forms of access and to all possible forms of using genetic resources. A solution comparable to the provisions of the Cartagena Protocol might be feasable, which covers all living modified organisms (LMOs) in its scope but creates different levels of minimal standards based on the respective LMO activities as eg. contained use, transit or use for food and feed. Certainly, the use of timber for furnitures or of fish for food is a very different case as the use of marine sponges for the development of a drug. Some national ABS regulations have already created such a multi-level system.

The first meeting of the Group of Legal and Technical Experts in December 2008[6] suggested following categories that describe typical uses of genetic resources in order to clarify the definition of "genetic resource" in the CBD - and consequently in the ABS Regime:

1) *Genetic modification*
2) *Biosynthesis*
3) *Breeding and selection*
4) *Propagation and cultivation of the genetic resource in the form received*
5) *Conservation*
6) *Characterization and evaluation*
7) *Production of compounds naturally occurring in genetic material*

With regard to the ABS discussion under the CBD, and specifically with regard to the many cases presented as exemplary ABS approaches, the use of genetic resources is not restricted on cases using the genetic information itself but also the vast diversity of biochemical compounds. The numerous case studies dealing with pharmaceutical and phytomedical R&D will certainly fall under the full provisions of an ABS regime, including PIC and MAT.[7] The same will be true for the use of biological resources for products with health or beauty claims based on traditional knowledge, as for example the well-known benefit sharing agreements in South Africa concerning the use of Hoodia or the cooperation between the U.S. company Aveda and Indigenous Peoples from the Amazonas region. The full set of ABS measure would also apply for the direct use of the genetic material in R&D of genetically engineered organisms for agriculture, pharmaceutical products or industrial production.[8] In the field of agriculture it has to be noted, that the access to a certain number of plant species when stored in the gene banks of the Multilateral System and used as genetic resources for food production is already been regulated through a specific ABS system of the International Treaty on Plant Genetic Resources for Food and Agriculture adopted in 2001.

6 CBD. 2008. Report of the Meeting of the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches. http://www.cbd.int/doc/meetings/abs/absgtle-01/official/absgtle-01-abswg-07-02-en.pdf

7 eg.: CBD case studies 1, 2, 5, 7, 8, 11, 13, 15, 19, 20, 21 at http://www.cbd.int/abs/cs.shtml
or: International Chamber of Commerce. 2008. Good Business Practices and Case-Studies on Biodiversity. Report submitted for the Windhoek meeting at http://www.cbd.int/doc/meetings/abs/absgtle-01/information/absgtle-01-inf-01-en.pdf

8 eg.: CBD case studies 17 & 24 at http://www.cbd.int/abs/cs.shtml

Novo Nordisk uses a broad variety of natural resources in its research and development programmes for new pharmaceuticals and industrial enzymes. [...] No microbial strain or natural material obtained without proper prior informed consent from the country of origin will be included in screening; All materials screened should be covered by contracts and/or material transfer agreements; [...]

Novo Nordisk: Environment & Bioethics Report, 1998

Many believe the potential of bio-resources has barely been tapped, and that traditional knowledge about the medicinal properties of plants, for instance, still has valuable secrets to offer. Apart from drugs from plants known locally through traditional knowledge, disease-resistant or hardy crops are examples of the kind of resources that might become available through biotech inventions. The biodiversity of the rainforest is a resource as real as any precious metal.

EU Trade Commissioner Pascal Lamy: As precious as gold, 6 Feb 2002

Mr Toepfer said the wealth of animal and plant life nurtured by indigenous, tribal and local peoples "for generations, for ages" amounted to a treasure trove of potentially promising new drugs, crops and industrial products for the 21st century.

UNEP Executive Director Klaus Töpfer: Big development projects need cultural impact assessments, 18 Nov 2002

Genetic resources are materials of plant, animal or microbial origin. [...] They are of fundamental importance to many areas of scientific research, like plant breeding for agriculture and horticulture, and for a wide range of industrial sectors, including biotechnology, pharma-ceuticals, medicine, and cosmetics. For example, various plants have cosmetic applications: cinnamon has essen-tial oils with antiseptic properties, green tea has a free radical scavenging property and horse chestnut is an astringent.

European Commission: Commission encourages international solidarity when utilizing exotic plants, 7 Jan 2004, Press Release IP/04/21

Biodiversity, the result of over three billion years of evolution, is a natural heritage and a vital resource for mankind. We draw from it directly our food, shelter, medicine, raw materials, recreation and culture.

CBD Executive Secretary Ahmed Djoghlaf: Winning the battle for life on earth: Fulfilling the 2010 biodiversity promise of the Heads of State, 2006, Gincana Magazine

Many top selling drugs, such as penicillin, cyclosporine and the anticancer drug Taxol, have been derived from nature; and traditional medical knowledge can point the way to new drug development. Future drugs, industrial products and genes for improved crops are being sought from plants and animals, particularly in the genetically rich developing world. [...] Establishing effective and fair rules, in which companies and local communities share in these profits and other non-monetary benefits that arise from the use of the biological resources, will not only help fight poverty in developing countries but will also create sustainable development on a broader base. It should also generate incentives for local people to conserve their biodiversity and reduce the threat of overexploitation.

UNEP: Study takes critical look at benefit sharing of genetic resources and traditional knowledge, 10 Feb 2004

Forests play a vital role in fighting poverty and in promoting medicine and food security UN Secretary-General Kofi Annan told Central African leaders this week. [...] Their capacity to retain water offers safeguards against flooding and erosion, and the genetic resources found in them are the basis for many advances in medicine and food security, he added.

UN Secretary General Kofi Annan: Annan calls for cooperation to save Central Africa's forests, 11 Feb 2005

Biodiversity is a prerequisite for the traditional medicine that much of the world relies on as well as many pharmaceutical products. Natural resources represent an important source of potential new drugs for patients, hence the preservation of biodiversity is essential in our efforts to cure diseases and save lives. Bioprospecting, or tapping into the vast molecular diversity occurring in nature to help create innovative new medicines, provides a complementary alternative to synthetic approaches to new drug development.

NOVARTIS: Position Paper Biodiversity/Bioprospecting, Nov 2005

As the CBD definition also includes the potential value of such resources, almost all genetic material falls under the provisions of the ABS system. Furthermore, the valuable information need not be exclusively genetic, for example, it may also be associated, with the biochemical information contained in the material.

Swiss Academy of Sciences: ABS - Good practice for academic research, 2006