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AN ASSESSMENT OF THE ADVANTAGES AND DISADVANTAGES OF AN INTERNATIONAL REGIME FOR ACCESS TO GENETIC RESOURCES AND BENEFIT SHARING

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Introduction

Do we need an international regime on access to genetic resources and benefit sharing (ABS)? The Seventh Conference of the Parties (COP) of the *Convention on Biological Diversity* (CBD, 2003) to be held in February 2004 will probably give a political answer to this question. However, we would hope there is time for further legal, technical and economic analysis of this proposal before a definite decision is taken, especially as to the *nature* of this regime.¹

The drive for the development of an international regime on ABS is rapidly gaining momentum and enthusiasm among many countries is high. Given the practical limitations of national legislation in securing the realisation of the CBD benefit sharing objective and ensuring an effective implementation of ABS principles, an international regime seems an immediate and obvious response.²

The political commitment by a number of countries led by the initiative of the *Group of Like Minded Megadiverse Countries* and reflected in a series of international instruments (including COP Decisions, WSSD Plan of Action, declarations by the Like Minded Group, etc.), is firmly on track.³

However, not all Parties (and non Parties) to the CBD necessarily favour an international regime and, furthermore, there are still considerable questions which require analysis including issues of scope, objective, cost / benefit of the regime, etc. in order to embark in a negotiation process and design (and implement) a sound and operational regime.

This paper offers a brief analysis of the foundations, advantages and potential disadvantages of entering into an international ABS regime negotiation process. It also addresses some key substantial issues which may arise regarding the design of this regime.

1. The current situation regarding national efforts to implement the CBD ABS principles.

Over the past few years, considerable progress has been made in the process of developing national legislation to specify and define the CBD's ABS principles. National and regional policies and regulations on ABS have multiplied throughout the world⁴, addressing, in their own particular way, prior informed consent (PIC), mutually agreed terms, benefit sharing, etc.

Nevertheless, the practical impacts of these efforts regarding whether or not they've achieved the objectives of securing benefit sharing and, ultimately, supporting conservation, seems to be –from available preliminary evidence– very limited. Some experts argue these laws have been in place only for a short period of time and, thus, an assessment of their impacts is rather premature and unfair. Others, believe time is not the only factor to take into account and their effects can already be determined and even if proposals are in draft form, effects can be inferred.

At least –but not only– within the scientific community there has been concerns that ABS laws and

regulation (as they are currently being modelled, drafted and enacted) could seriously undermine biodiversity research possibilities, especially in the field of taxonomy and basic research⁵. They cite numerous examples where research institutions have decided not to undertake research activities on biodiversity components in certain countries due to excessive formal and substantive requirements in ABS legislation and overall transaction costs and restrictions they entail. This has probably been most noticeable in the case of Executive Order 247 (and its regulation) in the Philippines (1996) and Decision 391 of Andean Community (1996).

These laws are explained, not only as an effort to implement the CBD in a particularly sensitive political area but as an immediate (and probably understandable) defensive reaction by countries of origin to the “biopiracy” phenomenon and their commitment to derive concrete benefits from the commercial and industrial use of their own genetic resources.

Furthermore, effectively exercising sovereign rights in opposition to the previous common heritage of humankind principle which governed flows of resources (as enshrined in the FAO International Undertaking of 1983), is at the heart of this new paradigm for countries rich in biodiversity and traditionally exporters and suppliers of samples, specimens and raw biological materials in general.

2. Is an international ABS regime necessary?

Conservation and sustainable use of biodiversity requires collaboration among countries on all fronts. Common but differentiated compromises reflected in the CBD, clearly demonstrate that countries, individually, will not be able –or will find it ever more difficult– to overcome the challenge of ensuring conservation, sustainable use and, especially, an equitable sharing of benefits derived from access to and use of genetic resources.

Given the physical nature of genetic resources, their distribution, their continued flows across borders, their maintenance in *ex situ* centres, the advances in genomics and bioinformatics, among other factors, national legislation on ABS, targeted at controlling flows “from” countries of origin,

will only partially ensure the realisation of CBD objectives and national policy goals. It is not a coincidence, that action and legislative measures have mostly been undertaken and developed by countries of origin (or rather biodiversity rich, developing countries).⁶

Thus, it seems logical that actions are also required on the part of countries which have traditionally collected, maintained, researched, developed and, in many cases, industrialised biological and genetic resources. These are generally countries “to which” resources have regularly flowed (industrialised and technologically advanced countries).⁷

The CBD has made it clear throughout its text that different types of measures may be needed depending on the country (and institutions) concerned and its regular role (as a provider or user). For example, article 15(7) of the CBD determines that each Contracting Party “... *shall take legislative, administrative or policy measures, as appropriate, and in accordance with articles 16 and 19 [transfer of technology and handling of biotechnology] with the aim of sharing in a fair and equitable way the results of research and development and benefits arising from the commercial and other utilisation of genetic resources with the Party providing such resources ...*”. Similarly, article 19 (1) determines that each Contracting Party “... *shall take legislative, administrative or policy measures, as appropriate, to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources*”.

Many other articles (loaded with qualifiers) reflect the need for differentiated measures among Contracting Parties. COP Decision IV/24, which approved the Bonn Guidelines also reflects this by recognising different roles and responsibilities in ABS pursuant to article 15 and referring to providers and users of genetic resources. The Bonn Guidelines for the first time expressly and formally incorporated the “user side” of the equation as a factor which needs to be further explored and its potential fully realised.

In this context, an almost natural question is ***whether an international ABS regime is required, whether an international regime per se in prac-***

tice already exists and what would its distinct features be (see Section 4).

3. The advantages and disadvantages of an international ABS regime.

One key issue –to be discussed later (see Section 4)–, is what exactly do we mean by an “international ABS regime”. Whatever the answer may be, it may also be useful to briefly assess some of the pros and cons regarding undertaking the development of this regime.

In terms of its advantages, an international ABS regime may :

- a) Determine specific commitments by countries traditionally considered users of genetic resources in terms of adopting effective measures to ensure CDB ABS objectives are realised (implementing the common but differentiated responsibilities approach) (see Box 1).
- b) Promote a more practical, cost / effective policy and regulatory approach to achieve CBD ABS objectives and goals by supporting countries’ of origin national efforts (legal measures).
- c) Generate an incentive for countries of origin to consider more flexible and less restrictive ABS policies, laws and models, if user countries support realisation of the CBD objectives through their own specific measures (this may have a bearing on reducing implementation costs in all Parties).
- d) Consolidate the policy interests and positions of countries traditionally considered providers of genetic resources (i.e. Like Minded Group and other biodiversity rich nations).
- e) Promote a more effective mechanism to ensure monetary and non monetary benefit sharing among providers and user of genetic resources.
- f) Promote more collaborative (North – South, South – South) research and development activities in biodiversity.
- g) Facilitate consensus and agreement on the need to develop an international regime for the protection of traditional knowledge (within the CBD forum or as part of WIPO’s ongoing activities) as a closely related matter to ABS.
- h) Specify and clarify some of the CBD ABS principles (including PIC, mutually agreed terms, etc.)⁸

Box No. 1 An example of how international efforts may assist in the implementation of ABS principles : the TK and IPR discussion.

The idea of implementing the ABS provisions of the CBD through the use of common but differentiated responsibilities, in countries of origin and user countries alike, first became apparent in discussions related to *biopiracy* and how the IPR regime (especially *via* biotechnology related patents) tended to legitimate the illegal or unlawful use of genetic resources and traditional knowledge (TK).

Through a series of high profile patent cases (Ayahuasca, Quinoa, Peruvian Maca, Neem and many others)⁹, the direct or indirect use of genetic resources and TK in inventions has been well documented. Sometimes with very questionable novelty and inventiveness, others without having complied with national regulations on access to ABS nor TK, these patents have raised

important questions regarding the fairness in the regular (or irregular) operations of the patent system world wide (especially in the US, the EU and Japan) and in patent search procedures in particular.

One of the first ideas raised in order to link the patent system with ABS and, thus, create positive synergies between CBD and TRIPs and promote fulfilment of the CBD benefit sharing objective, considered requiring patent applicants (specifically in the area of biotechnology) to provide patent authorities with evidence regarding legal origin of genetic resources or TK which might be part of the invention under analysis. The argument for this suggests that granting a legal right over an invention which may have been derived from an illegal act (illegal access to ge-

netic resources or TK), should be, as far as possible, prevented.

Although fervently supported by many mega diverse countries (and even included in legislation in Peru, Brazil, Costa Rica and others, including Denmark, though in the latter case restricted to disclosure of geographical origin) the key element in this proposal was to ensure that the major patent markets in the world (especially US, the EU and Japan) included this requirement of legal origin into their patent legislation. These *user measures* would ensure that the interests of countries of origin would be safeguarded by actions in countries where rights would be granted. Many industrialised countries have rejected the idea on the basis of it becoming, in practice, a substantive requirement for the processing of patents, in contravention with TRIPs standards and due to unnecessary complexities this additional requirement might bring to IPR offices worldwide.

Patent legislation in the Andean Community of Nations (Decision 486 on a Common Regime on Industrial Property - 2002) conditions the granting of IPR to respecting and not affecting the biological and genetic patrimony of Member States (article 3). Furthermore, patent applicants must provide with evidence of legal origin of genetic resources or TK used in an invention (ar-

ticle 26). Annulment of the patent is possible if these requirements are not met (article 75). In Peru, these same requirements are applicable to new plant varieties for which plant breeders protection is sought¹⁰.

Developing countries- countries of origin – on the other hand have argued this requirement is TRIPs compatible and responds to full disclosure needs, specific interests of biologically rich countries, it seeks coherence and mutual supportiveness among instruments in international law, etc¹¹. Furthermore, it is not more complex than the process of depositing micro-organisms in relevant facilities as required by the Budapest Treaty as a means to comply with disclosure requirements in biotechnological inventions related to micro-organisms.

User measures related to IPRs also refer to how databases may make TK available as a means to attack novelty claims in patent applications. The whole issue of registers and databases has been widely discussed in WIPO¹². Although recognised as a means to prevent biopiracy it poses a series of questions regarding PIC from communities as a condition for publicly disclosing information related to TK (even if already in the public domain), its effects of oral cultures and traditions, management and availability of the information, etc.

However, some of the potential disadvantages of an international ABS regime (in terms of substantial content and process and especially for biodiversity rich countries) may include:

- a) The need for a long (costly) and uncertain negotiation process, whose results may either differ only slightly from existing political positions (thus putting into question the cost / benefit of the whole negotiating exercise) or which may considerably depart from set ABS standards in the Bonn Guidelines, national legislation or other instruments.
- b) The development of an international regime which continues to place the burden of ABS on countries of origin (this would probably reflect existing policies, models and laws and include their practical limitations).
- c) A tendency to complicate even more an already complex issue and have a negative impact on existing policies and institutional approaches to ABS¹³, especially in the context where the CBD sets basic principles, the Bonn Guidelines are in force (even as a non binding instrument), the FAO International Treaty has been adopted and national and regional legislation is already being adopted throughout the world.
- d) Revisiting political positions on ABS which are quite well defined. It is difficult to envision an international consensus to embark on an negotiation process especially if a) a comprehensive treaty or protocol is the instrument under consideration and b) after many countries have only just recovered from the very convoluted FAO International Treaty negotiation process and experience.

- e) Require a formal recognition of a user and provider role with the subsequent need to adapt policies and regulations to the “user side of the equation”.
- f) The development of a regime in circumstances where limited in depth research has been undertaken regarding cost / benefits of a new negotiation process and the development of new international rules (where principles and compromises already exist : in the CBD, Bonn Guidelines, etc.).

4. Key issues to be considered if an international regime is to be developed.

What is “an international regime” may need further clarification. Options for an international regime may include a) development of an international treaty (or protocol to the CBD) on ABS or b) developing tools (i.e. through specific SBSTTA recommendations and COP Decisions) which ensure all CBD Parties adopt specific measures to realise the benefit sharing objective of the CBD. This would imply countries of origin and “user countries” adopting different types of administrative or legal measures with a view to ensure benefits derived from access to and use of genetic resources are adequately, fairly and equitably shared. In this latter case, one could argue an international regime already exists and what is needed is refining its content and operation.

As an example of the different approaches to the international regime, the Group of Like Minded Megadiverse Countries, in the Cancun Declaration (2002) called for the “... *creation of an international regime to effectively promote and safeguard the fair and equitably sharing of benefits arising from the use of biodiversity and its components*”, which contrasts substantially from paragraph 44(o) of the Plan of Implementation of the WSSD which refers to an international regime to “... *promote and safeguard the fair and equitable sharing of benefits arising out of the utilisation of genetic resources*”. The latter is much more closely linked to article 15 of the CBD whilst the former may

include issues as varied as environmental services provided by biodiversity, thus with much broader and complex implications

Scope, use of terms and definitions. Experience with current ABS policies and laws at the national and regional level (even with the Bonn Guidelines), seems to indicate that there is still a very broad range of interpretations regarding key concepts such as “access to genetic resources”, “users”, “providers”, “prior informed consent”, etc, and, furthermore, in relation to the scope and ambit of ABS rules and regulations. This presents a particularly complex challenge in terms of either agreeing on the need for clear and defined concepts or, alternatively, agreeing on the need for very broad concepts which allow Parties with enough flexibility to interpret precise meanings on a case by case situation. One complex aspect for example, relates to how genetic resources are considered: whether in terms of a physical entity or as a source of information. Both may imply a set of different legal implications.

Baseline research and understanding regular research needs and practices of key stakeholders. Past ABS policy development experiences have also shown considerable gaps and limitations in the “non legal” knowledge regarding how the “genetic resources market” operates and what are the needs of key stakeholders (including indigenous peoples on one hand and taxonomic and private, corporate interests on the other).

For example, it is quite surprising that only in 1999 was the first more or less comprehensive study on the market for genetic resources finalised¹⁴, after many laws and legislation on ABS had already been developed and enacted and many more drafts were on the drawing boards and in the making. Baseline research is a key need if sound policies (and laws) are to be developed and, especially, implemented whether these are reflected in a treaty, a protocol or other measures. Though seemingly obvious, this factor is often sidelined and implicitly understated.

Final comments.

The idea of a comprehensive treaty or protocol should not underscore the possibilities of other measures and instruments which may achieve the needed goals of ensuring a fair and equitable sharing of benefits from access to and use of genetic resources. COP Decisions – based on SBSTTA Recommendations or work of the *Ad Hoc Open Ended Group of Experts on ABS* – may provide with clear and specific indications on user measures currently required without the need of negotiating an international instrument *per se* (in terms of a protocol or treaty).

To achieve benefit sharing from access to and use of genetic resources clear, simple, flexible rules

which act as incentives for collaboration and joint partnerships are critical. These rules should combine basic ABS legislation in countries of origin and the adoption of a set of clear rules in user countries (represented possibly by user institutions) in the area of IPRs, import legislation, CITES procedures, etc.

Finally, if it is agreed an international treaty is required (or a protocol), the question of *why it is needed* must have been thoroughly responded and discussed (limitations of national legislation should not be the only justification). What is the *qualitative* difference an international instrument will generate in regards to implementation of CBD ABS principles should also be assessed, *vis a vis*, the use of the existing framework (with adjustments and strengthening).

In this regard, we would propose that a wholly new international instrument is only relevant and worth the effort if :

- a) the regime focuses on agreeing on full disclosure in patent applications obligations,***
- b) the regime focuses on agreeing on universal obligations on certification of origin or provenance,***
- c) the regime focuses on specific measures and obligations to ensure compliance and monitoring of genetic resources (and TK) flows.***
- d) the regime places emphasis on benefit sharing and technology transfer provisions in particular.***

Final notes

- 1 The *Ad Hoc Open Ended Working Group on Access and Benefit Sharing* meeting for the second time in Montreal in December 2003, has made specific recommendations –though most are in brackets– in regards to the international regime (Recommendation 2/4 of the Working Groups report from Montreal). These will be considered by COP VII in Malaysia.
- 2 Given the physical / informational nature and features of genetic resources, national legislation is limited in: ensuring compliance of access contracts, enabling effective monitoring measures and tracking and, ultimately, enabling a degree of control in regards to the use of these resources.

- 3 For an analysis of the overall justification for the need for an international regime see: Group of Like Minded Megadiverse Countries. *Elements to Advocate for an International Regime on the Fair and Equitable Sharing of Benefits Derived from the Utilization of Genetic Resources*. Reference document prepared by Alberto Glender, Technical Secretary of the Group of Like Minded Megadiverse Countries. Expert Meeting, Montreal, November 2003.

- 4 For example: Decision 391 of the Andean Community – Bolivia, Colombia, Ecuador, Peru and Venezuela (1996); Executive Order 247 of the Philippines (1996); Biodiversity Law 7788 of Costa Rica (1998); Provisional Measure 2,126 – 8 in Brazil (2001); Organization of African Unity Model Law (53 African countries) (2000);

- Biodiversity Act of Bhutan (2003); Bill on ABS of Nepal (2001). Many other countries have developed specific policies on ABS (in their National Biodiversity Strategies) and / or have also developed draft legislation on ABS.
- 5 Grajal, Alejandro . *Régimen de Acceso a los Recursos Genéticos Impone Restricciones a la Investigación en Biodiversidad en los Países Andinos*. INTERCIENCIA. Jan – Feb. 1999. Vol. 24, No.1 and Hoagland, E. 1997. *Access to Specimens and their Genetic Resources . An Association of Systematics Collections Position Paper* are two examples of scientists concerns regarding over zealous legislation which restricts possibilities and options for biodiversity research.
 - 6 It should be noted that numerous private and public institutions in developed countries (“to which” resources flow) have in fact designed and made public policies oriented at implementing ABS principles and the CBD in general. *Royal Botanical Gardens Kew* in the UK, *New York Botanical Gardens* in the US, the *International Cooperative Biodiversity Group Program* of the US, the *South African Council for Scientific Research*, to name just a few, have institutionalised ABS policies. For further details of these and many other institutional policies see: Ten Kate, Kerry and Laird, Sarah. 1999. *The Commercial Use of Biodiversity. Access to Genetic Resources and Benefit Sharing*. Earthscan Publications Ltd., London. Section 10.
 - 7 This representation of countries as providers of resources, *vis a vis*, countries using resources is clearly a simplification of an otherwise very complex situation. All countries are providers and users of resources – to a certain extent. In the context of agricultural genetic resources for example, interdependence has now been recognised as a critical feature in ABS discussions. The *FAO International Treaty on Plant Genetic Resources for Food and Agriculture* (2001) seeks to regulate ABS based on this concept of interdependence. The idea here is simply to highlight the fact that, in quantitative and qualitative terms, most research and development and the application of biotechnology is carried out in US, Europe, Japan, Australia and maybe a few other countries (including Brazil, India, China and Cuba as representatives of the developing world).
 - 8 One of the main advantages of the CBD may reside, precisely, on the fact that concepts and principles are quite general in their formulation, leaving flexibility to countries to implement them as the situation may require.
 - 9 For a specific review of these patents see: Dutfield, Graham. 2000. *Intellectual Property Rights, Trade and Biodiversity*. IUCN, Earthscan Publications Ltd. London. Chapter 5.
 - 10 For further analysis of Decision 486 see: Ruiz, Manuel. *The Andean Community’s New Industrial Property Regime: Creating Synergies Between the CBD and IPRs*. In: BRIDGES, ICTSD, Geneva, Year 4, No. 9, 2000.
 - 11 For a complete set of arguments for and against the use of this requirement see: Tobin, Brendan. 1997. *Certificates of Origin : A Role for IPR Regimes in Securing Prior Informed Consent*. In Mugabe, John, et.al.(eds). *Access to Genetic Resources: Strategies for Benefit Sharing*. Nairobi, ACTS Press. Carvalho, Nuno Pires de. 2000. *Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications without Infringing the TRIPs Agreement: The Problem and the Solution*. Washington University Journal of Law and Policy, No. 2, 371. Ruiz, Manuel. *The International debate on Traditional Knowledge as Prior Art in the Patent System : Issues and Options for Developing Countries*. South Centre, October, 2002 (available at <http://www.southcentre.org/publications/occasional/paper09/toc.htm>). Ho, Cynthia. *Disclosure of Origin and PIC for Applications of Intellectual Property Rights Based on Genetic Resources: A Technical Study on Implementation Issues*. Final Report, 2003, prepared for UNEP. Available as: UNEP/CBD/WG-ABS/2/INF/2.
 - 12 For an in depth analysis of the consequences of disclosing and systematising TK thorough databases see: Laird, Sarah (Editor). 2002. *Biodiversity and Traditional Knowledge. Equitable Partnerships in Practice*. WWF, UNESCO, Royal Botanic Gardens Kew,

Earthscan Publications Ltd. Loindon, Sterling VA. Chapter 4. Also, WIPO. *Composite Study on the Protection of Traditional Knowledge*. Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. WIPO/GRTKF/5/8, April, 2003. Available at : <http://www.wipo.int>

- 13 This could be the case for many research institutions and *ex situ* conservation centres which have developed specific ABS policies for their

research and development projects. It is in fact quite surprising that within the US – the most conspicuous non party to the CBD – many laboratories, companies, research centres, etc. have adopted rules and codes of conduct to guide their ABS practices, in accordance to CBD principles.

- 14 See: Ten Kate, Kerry and Laird, Sarah. *The Commercial Use of Biodiversity : Access to Genetic Resources and Benefit Sharing*. Earthscan Publications Ltd, London.

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