

Access and Benefit Sharing (ABS): Issues and Policy Options

Introduction

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There cannot be a more decisive moment for the conservation community, economists and social scientists to focus on issues of ethics and equity with respect to genetic resources than now. Be it the ongoing debates on the need to reward local communities for their conservation action or the raging challenges of food insecurity, access to resources and sharing the benefits of such access and subsequent use is the core of international environmental governance debate.

Though the issue of access and benefit sharing (ABS) under the Convention on Biological Diversity (CBD) has received attention during the past one and half decades, it still remains a technically challenging and legally complex issue. One clear problem with ABS debates has been the limited experience of dealing with the issues at national level and implementation of ABS provisions. Most of the discussions still continue to focus on political positions and advocacy in spite of us having the Bonn Guidelines on ABS adopted by Parties to CBD as early as 2002. Lack of implementation of Bonn Guidelines is clearly a missed opportunity.

Having been following the discussions under ABS for a long time, it is very interesting to see how various developments under these discussions have contributed to today's status. Beginning with the need to develop national regimes on ABS, the need to address issues of business and commerce in ABS, the importance of addressing ABS from

* The views expressed by the guest editor are his personal views and opinions and not that of the organization he represents.

ecosystem perspectives – especially the one on marine genetic resources, the role of clear understanding of tools such as certificates of origin, the need to include gender into ABS debates, the emerging discussions on role of regional trade on ABS and more recently the need to learn from other such similar processes (such as the one under the International Treaty on Plant Genetic Resources for Food and Agriculture) have all provided the much needed fuel to keep the engines of ABS discussions running.

What has been attempted in this special issue of Asian Biotechnology and Development Review is an attempt to capture the above debates from the expert's point of view. We are very fortunate to have such an assembly of experts coming forward to contributing their thinking into ABS dialogues and more so to mainstream them into debates ranging from biotechnology to development. Particular thanks are due to the co-chairs of the CBD ABS Working Group on ABS who contributed a think-piece on how they see the process progressing.

What we need now a global commitment to make ABS work and not just intentions of supporting the process. While we all agree that ABS is a complex and complicated issue, complexity should not be a cause for inaction! Let us hope that collective wisdom will prevail to move forward the negotiations of the international regime towards the target date of completing the negotiations by 2010 as agreed by the Ministers of Environment from countries who are Parties to CBD in Curitiba during COP 8.

The Question of Minimum Standards of Access and Benefit-sharing under the CBD International Regime: Lessons from the International Treaty on Plant Genetic Resources for Food and Agriculture¹

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Abstract: With the international regime on ABS currently under negotiations to fulfil the third objective of the Convention on Biological Diversity (CBD), this article considers the possible relationship between the emerging international regime and the FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), especially its benefit-sharing components, paying special attention on the lessons learned from the implementation of the ITPGRFA. In particular, it assesses whether some lessons learned from the ITPGRFA Multilateral System's implementation (MLS) may advance discussions on related international cross-sectoral issues in genetic resources. These issues include the question of whether an International Regime on ABS should expressly provide for international standards, such as mandatory minimum standards for access to genetic resources and benefit sharing in material transfer agreements (MTAs).

Keywords: International Regime; Access and Benefit Sharing; International Treaty on Plant Genetic Resources for Food and Agriculture.

Background

The Earth Summit, held in Rio de Janeiro in 1992, gave rise to three key multilateral environmental agreements. One of these binding agreements is the Convention on Biological Diversity, which was ready for signature on June 5, 1992 and went into effect on December 29, 1993. With its 193 Parties as of 2008, the CBD seeks to establish a comprehensive international programme for the sustainable management of biological resources.² It covers all types of biological diversity except for human genetic material.³ The Convention's three main objectives, which are stated in Article 1, are:

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the conservation of biological diversity; the sustainable use of its components;⁴ and the fair and equitable sharing of the benefits arising from the use of genetic resources.⁵

During the negotiations of the CBD, developing countries with a rich endowment in natural resources and crop diversity bargained with developed countries offering access to their genetic resources in return for “debt relief, royalties, technology transfers and research data”.⁶ However, the implementation of CBD’s third objective has proven to be particularly problematic.⁷ In 2002, the perceived failure of the so called “grand bargain”⁸ and, in particular, poorly regulated access, lack of fair and equitable benefit sharing, and claims of misappropriation of genetic resources were all factors, which contributed to the UN World Summit on Sustainable Development (WSSD) call for action to “negotiate within the framework of the CBD, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources.”⁹ Following the call, the Conference of the Parties (COP) of the CBD at its seventh meeting in 2004 decided to mandate the Working Group on ABS, with collaboration of the Working Group on 8(j), to negotiate an international regime on access and benefit-sharing with the aim of adopting an instrument/instruments to implement the provisions in Articles 15 and 8(j) and the three objectives of the Convention.¹⁰

Benefit Sharing Principles under the CBD and the FAO-ITPGRFA

Article 15 of the CBD regulates access to genetic resources by, *inter alia*: reaffirming the sovereign rights of States to their natural resources; stipulating that Parties shall endeavour to facilitate access to genetic resources; providing that access shall be subject to prior informed consent (PIC) and granted on mutually agreed terms (MAT); and requesting Parties to take measures to share benefits from the utilization of genetic resources, on MAT.

Eager to participate in the sharing of benefits arising from the use of genetic resources and associated traditional knowledge (TK), biodiversity-rich countries have started the development of national and regional ABS regimes. Although their implementation does not appear to have generated the expected benefits so far,¹¹ such laws were perceived as a factor contributing to freeze long-running cross-boundary

movements of plant genetic resources with potential negative consequences on agriculture and food security.¹² This is because the CBD promotes the development of a regime of contractual rules for the exchange of biological resources, which is based on bilateral contracts.¹³ However, these bilateral contacts may not be appropriate for crop research for two main reasons: first, countries are enormously interdependent in terms of plant genetic diversity, and second, a very high number of breeding materials is necessary to breed a new plant variety. Thus, in many cases, transaction costs associated with bilateral negotiations for access to the crop biodiversity – and related intellectual property rights over the material, if any – from numerous different sources may be sufficient to discourage plant breeding efforts.¹⁴

The CBD also addresses *ex-situ* conservation, which is referred to in Article 9 as “the conservation of components of biological diversity outside their natural habitats.” Under this provision Parties are encouraged to acquire, conserve, store and manage materials in national and international *ex-situ* collections. However, since the CBD only applies to genetic resources that are provided from *in-situ* conditions or have been acquired in accordance with it, international *ex-situ* collections formed before its entry into force are not governed by the Convention. As early as in 1989, the legal uncertainty regarding the status of these collections triggered the development of the International Network of *ex-situ* collections under the auspices of FAO. Before the adoption of the FAO International Treaty on Plant genetic Resources for Food and Agriculture (ITPGRFA), the bulk of materials held by this network, which comprises the International Agricultural Research Centers (IARCs) of the Consultative Group on International Agricultural Research (CGIAR), were managed in accordance with a non-legally binding instrument called International Undertaking on Plant Genetic Resources (IUPGR) as well as the *in trust* Agreement between the CGIAR Centers and FAO.¹⁵ In November 1994, following a request from the CBD, the FAO Commission on Genetic Resources for Food and Agriculture (CGRFA) started negotiations to bring the IUPGR in conformity with the CBD and, in particular, its ABS provisions.¹⁶ However, further developments under the IUPGR, that led to the adoption of the ITPGRFA, were delinked from the CBD discussions for various reasons.

The International Treaty on Plant Genetic Resources for Food and Agriculture not only is the remarkable outcome of this negotiating

process, but also responds to concerns arising in connection with the application of bilateral access rules to crop biodiversity.¹⁷ Part IV of the ITPGRFA establishes a Multilateral System of Access and Benefit Sharing through which its Contracting Parties have decided to facilitate access to the 64 most important crops and forages to ensure worldwide food security.¹⁸ Such resources are listed in Annex I of the ITPGRFA.¹⁹

In June 2006, the Governing Body of the ITPGRFA at its first session established the level, form and manner of equitable benefit sharing payments to be implemented through a standard contract called Standard Material Transfer Agreement (SMTA). The SMTA does not require a burdensome mechanism to track individual accessions, while it ensures that benefits flow back to the Multilateral System (MLS) if a product based on MLS materials is commercialised. In particular, a continuous chain of SMTAs between providers and recipients ensures that the benefit sharing obligations of the ITPGRFA are passed onto any “person or entity” that develops a product (*i.e.* seeds) derived from the Multilateral System.²⁰ Under the ITPGRFA and the SMTA, benefit sharing includes monetary (Article 6.7) as well as non-monetary benefits (Article 6.9)²¹ and voluntary contributions (Article 6.8 and Article 6.11). If certain legal requirements are met, compulsory benefit sharing payments of 1.1 per cent of the gross income from the sale of seeds (minus 30 per cent to allow for sale costs) must be paid by recipients to the Multilateral System.²² In particular, the commercialised product (*i.e.* the seeds whose sale is relevant for the benefit sharing provision of the SMTA) must: (a) incorporate the material received from the MLS and (b) shall not be freely available for further research and breeding, because of patent protection or otherwise. Beyond the physical incorporation of the material into a new product, in cases where no physical transfer of material is involved, the link established in Article 6.10 of the SMTA between the assignment of relevant IPRs and the transfer of recipients’ benefit sharing obligations to the assignee suggests that “the incorporation into a proprietary product of patented information, which results from research and development carried out on MLS materials, may give rise to benefit sharing payments *per se*”.²³

Apart from its many technicalities, the Multilateral System, which is implemented through the use of standard contracts, presents numerous and considerable advantages for agricultural research: (i) the SMTA reduces transaction costs, because it does not require *ad hoc* negotiations

between providers and recipients of PGRFA; (ii) it provides some scope for flexibility in handling derivatives, which are “under development,” and in particular, it allows for additional conditions to be attached to their transfer (Articles 6.5 and 6.6); and, (iii) in the case of non-compliance by recipients with the SMTA, it provides for binding international arbitration (Article 8.4(c)) and confers upon FAO, on behalf of the Governing Body, third party beneficiary’s rights to represent the interests of the Multilateral System.

The particular importance of the ITPGRFA for the international ABS regime negotiations under the CBD stems from two main facts. First, to date the ITPGRFA is the only legally-binding international instrument that implements the ABS principles of the CBD. However, its ABS provisions only apply to a subset of plant genetic resources relevant for food security and sustainable agriculture, which are defined in accordance with a number of cumulative criteria. Such criteria are determined as follows: (i) the PGRFA concerned must be expressly included in the list, which is annexed to the ITPGRFA; (ii) they must be used in breeding, research and training food and agriculture; and (iii) they shall not be encumbered by third parties’ rights and other interests, in the sense that they should be under the management and control of Contracting Parties and in the public domain. Second, because of the above, any new instrument or instruments, which might be developed with the view to being adopted by CBD Parties, may need to cover all the benefit sharing instances not expressly regulated by the ITPGRFA, while not precluding the potential expansion of the latter, in particular, with respect to crops not yet included into its Multilateral System of ABS.

Finally, “the important contribution” of the ITPGRFA and its continuing relevance for the negotiation of the International Regime on ABS is emphasised in COP Decision VII/19D, which refers to it both in its preambular language – where the ITPGRFA is the only treaty to be mentioned apart from the CBD – and in the list of elements, which shall be considered for inclusion in the international regime.²⁴

Recent Developments relevant for the International ABS Regime Negotiations

The negotiation of an International Regime on Access and Benefit Sharing under the Convention on Biological Diversity made some progress so far during the fifth and sixth meetings of the *Ad Hoc* Open-

ended Working Group on Access and Benefit Sharing (ABS), which were held respectively in Montreal, October 8-12, 2007, and in Geneva, January 21-25, 2008.²⁵ In particular, the sixth ABS meeting marked a considerable step forward thanks to an innovative approach for consensus building. Actually, the contact group temporarily agreed to set aside negotiations on contentious issues concerning the nature and scope of the international regime and engaged in constructive discussions on its main components.²⁶

The main result of this approach is that “for the first time since the launching of the process, no Party questioned the general need for an international regime,” allowing to move forward into substantive discussions and text-based negotiations.²⁷ As a consequence, the official outcome document, which was adopted by the Working Group, is a solid basis for future negotiations.²⁸ Such negotiations must be concluded “at the earliest possible time before the tenth meeting of the Conference of the Parties.”²⁹ During the upcoming ninth meeting of the COP to be held in Bonn, Germany, in May 19-30, 2008, time might not allow the Parties to advance discussions on substantive items of the international ABS regime-related agenda. However, this meeting will be crucial to decide important process-related issues, including the number of ABS Working Group meetings prior to COP 10 and funding.³⁰

Work in Progress: The International Regime on ABS

The draft “Recommendation on Possible Elements of a Decision on Access and Benefit Sharing” for consideration of COP 9 is basically the outline of the international regime’s structure and is divided into four main parts, namely: “Objective,” “Scope,” “Main Components,” and “Nature” of the International Regime.³¹ Without giving prejudice to the eventual nature of the international regime or any of its elements, being this paper confronted with the task of identifying potential lessons from the implementation of the ITPGRFA, it wonders what specific elements of the FAO Multilateral System and the SMTA can provide a basis for furthering the ABS discussions under the CBD. Because of the legally binding nature of the ITPGRFA, the following discussion is based on the assumption that relevant comparable elements of the international ABS regime could be accomplished in a legally binding setting. This assumption is necessary merely to facilitate the comparative analysis that follows, hoping that it might be acceptable to the reader

in the light of the above disclaimer. Rather than dismissing the possibility to discuss binding elements, which might be controversial, an attempt is made to identify the reasons why stumbling blocks could emerge, which might impede to extend solutions that appear to work in the context of the ITPGRFA.

Lessons Learned from the ITPGRFA

An information document prepared for COP 9³² considers the role of IPRs in technology transfer in the context of the CBD and underlines “the importance of specific bilateral arrangements, in particular ...material transfer agreements or bio-prospecting agreements, in defining each party’s rights, interests and obligations.” Then, it continues, “Without giving prejudice to the appropriateness and suitability of a wholly bilateral approach ...and, conversely, to the need for overarching principles and legal obligations that would provide a surer safeguard for the equity and legitimacy of specific arrangements ...the design of such arrangements seems to be an important factor for ensuring that they operate to generate new technologies and new benefits, shares those benefits equitably, and respects the interests and concerns of the resource providers.”

On these premises, the role of the Standard Material Transfer Agreement (*i.e.* the specific bilateral arrangement, which implements the benefit sharing provisions of the ITPGRFA) and “the way it can be used to keep track of transfers of materials and to link their use to benefit-sharing is a very useful precedent” for the ABS Working Group to consider (SGRP, 2007: p. 3). In particular, the CGIAR Centres (2007: p. 3) suggest that “the SMTA functions as a certificate of source, with the source or origin of the PGRFA being the MLS itself.” Thus, the SMTA functions not only as a certificate of source or compliance with the ITPGRFA, but also as an essential mechanism for its implementation.

The key question is whether an International Regime on ABS should expressly provide for international standards, such as mandatory minimum standard terms for access to genetic resources and benefit sharing in material transfer agreements (MTAs) and the issue of how to define and manage derivatives and their products thereof, as well as potential impacts of such international regulatory mechanisms on the overarching objectives of the Convention. Some may observe that the practical possibility to introduce into the International Regime on ABS

a set of multilaterally agreed standards to be implemented though the use of private contracts, in the wake of the model adopted by the ITPGRFA, depends on the willingness of Parties to accept a bargain along the following lines. This bargain is likely to present a trade-off between the inclusion of international standards on access to genetic resources, which appears to be on top of the user countries' agenda and a range of other important issues, such as: an international definition of misappropriation; some minimum standards to deal with benefit sharing; the issue of derivatives; and an appropriate mechanism to encourage, monitor and enforce compliance with national ABS legislation, including though an "internationally recognized certificate of origin/source/legal provenance."

As regards compliance, at least one study has specifically considered the implications of ABS monitoring and enforcement through the use of private contracts, including private international law aspects that concern the applicable law to the SMTA in the context of dispute settlement.³³ In addition, a dedicated Expert Group has discussed in detail the options for a certificate of origin.³⁴ Therefore, the concluding part of this paper focuses on the ABS-related terms in the SMTA that regulate the issue of derivatives and it wonders how these terms can be useful for international ABS regime development under the CBD.

Derivatives and misappropriation are terms, which are not expressly defined either in the ITPGRFA or in the SMTA. Before the adoption of the SMTA, Fowler *et al.* (2004: pp. 663-4) "sought to bring clarity to these issues by proposing how the 'germplasm and related information' covered by the FAO-CGIAR Agreements should be interpreted and by describing a number of options for minimum requirements for taking out intellectual property protection on derivatives and components of designated germplasm." However, the authors note, "the FAO, the CGIAR and the international community ...may choose to retain the *status quo* in which the question of what can and cannot be done with designated germplasm is left unanswered. Choosing not to deal with the subject is itself a choice, though perhaps not the best one."

Because it creates legal uncertainty, the SMTA built-in 'constructive ambiguity' or 'strategic vagueness' concerning the extent to which IPRs should be allowed to cover materials derived from the Multilateral System

is not desirable. The same argument may possibly apply to the forthcoming ABS regulation under the CBD International Regime. However, in the context of the ITPGRFA, the above was a compromise necessary to build consensus on other aspects of the SMTA on which such consensus could be reached. More importantly, the absence of an express definition of derivatives does not impinge upon the clear-cut legal identification of derivative products for the purpose of benefit sharing, including mandatory payments. The incorporation requirement both in the definition of “Product” and in Article 6.7 of the SMTA does not leave scope for doubts regarding the fact that any product, whose commercialisation may trigger benefit sharing payments, must qualify as a derivative in the strict sense that it must contain the material received from the Multilateral System – or its genetic parts or components. In addition, the SMTA makes no reference to any particular percentage of MLS material to be incorporated into the final plant variety; therefore, there are no minimum levels of incorporation to define derivative products for benefit sharing purposes. This is the balance struck in the SMTA.

In the context of international ABS regime discussions, the critical question revolves around the issue of whether the incorporation requirement used in the ITPGRFA could be successfully employed to identify derivative products for the same benefit sharing purposes discussed above. Unfortunately, the direct application of the incorporation requirement into a context other than plant breeding may prove difficult. This is because the creation of new plant varieties inherently reduces to an activity, which makes use of multiple genetic parts and components that contain “functional units of heredity.” On the contrary, many gene products at the sub-organisms level, non-DNA molecules and proteins do not contain such “functional units of heredity;” therefore, they may fall outside of the system. This might be the case, for instance, of natural product discovery in the pharmaceutical sector. Thus, the incorporation requirement might need some further qualification to comprise categories of products, which are based on genetic resources, because product discovery would not occur without their use, although the genetic information is not eventually contained in the product. In these respect, it might be useful to further elaborate the relationship between biological resources and genetic resources as functional elements³⁵, which may comprise both “the tangible biological

material ('micro-tangibles') and the intangible asset (the genetic information)."

Turning the attention to the concept of misappropriation, under the ITPGRFA any use of MLS materials would qualify as misappropriation, if it violates the conditions established in the SMTA, including any illegal transfer of the original material and its derivatives – which may be either "Products" or "PGRFA under development" – as well as derivative intellectual property rights. The report of the Expert Group on an internationally recognised certificate (2007: par. 26 and 41) has also emphasised that: "transfers to third parties should require maintenance of the link with the certificate and the mutually agreed terms applying to the resources." It has also noted that "additional implementation challenges and costs may be related to the coexistence of genetic resources inside and outside the system." Therefore, the complementarity between the SMTA and a certificate of compliance under the CBD International Regime is a factor, which may contribute to reduce costs from materials being exchanged outside the system.

Finally, as to the issue of establishing minimum benefit sharing conditions, monetary payments of 1.1 per cent of the gross sale of any derivative products, in accordance with the ITPGRFA, should be taken as the baseline for minimum standard payments for access to genetic resources covered within the scope of the International Regime. The above percentage was agreed by the Parties of the ITPGRFA having in mind both the nature of plant breeding, which is less capital intensive than other research and development (R&D) activities in biotechnology, and the relatively low value of each potential contribution of a PGRFA to the final product; therefore, such percentage should be acceptable as a minimum standards for other biotechnology sectors in which the use of genetic resources may have more promising applications in terms of economic returns from R&D.

A Note of Caution

Rose (2003: p. 362) provocatively questions whether "the paper used over seven years of negotiations," which were necessary to develop the ITPGRFA, was "worth the trees." Koester (2002: p. 103) responds that "when faced with the question 'have we really accomplished anything?', the only answer is: what would be the condition of our biodiversity if

these conventions did not exist?" He makes an important point indeed, which is valid also in the context of the international ABS regime negotiations.

In Rose's opinion, "the answer is yes," it was worth, because the ITPGRFA "will operate to ensure availability of PGRFA, simplify transfers, promote fairness in benefit sharing, and direct some benefits towards PGRFA conservation." If all the above is being accomplished thanks to multilateral cooperation on biodiversity conservation, that is indeed a great success. However, to the extent that the ITPGRFA sets global rules, which impact on scientific research and plant breeding, the former can be considered a success story only because the affected scientific community eventually endorsed the proposed solutions – or at least could leave with them.³⁶

In the same vein, it will be necessary to carefully ensure that the regulation that is being proposed under an International Regime on Access and Benefit Sharing gives due consideration to the practical way in which trans-national collaboration actually takes place in the research community (see, for example, Jayaraman, 2008). At this point of negotiations, one of the risks that all ABS policymakers should be taking care of is that "legislation and practice that seeks to implement the CBD do not unduly restrict the legitimate use of genetic resources, discouraging scientific research." (UK Commission on Intellectual Property Rights, 2002: Chapter 4). In this respect, it might be appropriate to increase efforts to distinguish between commercial and non-commercial research, and to set facilitated standard access conditions for those who do not seek access for commercial purposes.³⁷ However, if the potential for developing a commercial product exists, the ABS International Regime should not prevent genetic resources, which have been acquired in accordance with non-commercial terms, from being used in a commercial research programme. This may occur under a new set of mutually agreed terms that reflect a different balance of benefit sharing obligations. Therefore, a chain of MTAs would be necessary to maintain the link between the provider and any subsequent recipient of genetic resources and their derivatives. This mechanism could be essentially based on the development cycle model used within the FAO Multilateral System.³⁸

Endnotes

- ¹ This article is based on a UNU-IAS working paper, which was prepared with support from the United Nations University-Institute of Advanced Studies (UNU-IAS) Biodiplomacy Programme. The author is extremely thankful to Graham Dutfield, Sam Johnston, Duncan Matthews and Balakrishna Pisupati for their feedback on earlier versions of this article. All errors and opinions expressed are of the author.
- ² Glowka et al. (1994); Koester (2002).
- ³ Biodiversity is the variability among living organisms. This covers: (a) genetic resources, (b) the portfolio of animal and agricultural species developed throughout the world and (c) the diversity of ecosystems.
- ⁴ Article 2 of the CBD defines the term “sustainable use” as the use of components of biological diversity in a way that does not lead to its long-term decline and that meets the needs of present and future generations.
- ⁵ “Genetic resources” are defined as genetic material of actual or potential value that contains functional units of heredity.
- ⁶ Blakeney, 2002: 27-9; see also Chandler (1993).
- ⁷ UNU-IAS (2003), p. 14, reports that only 50 countries either have “adopted or are in the process of adopting measures to exercise and secure their sovereign rights over genetic resources.” See also: Chambers (2003) at p. 316.
- ⁸ Siegele (2008).
- ⁹ Paragraph 44(o) of the Johannesburg Plan of Implementation.
- ¹⁰ Paragraph 1 of CBD COP Decision VII/19D; previous key developments on ABS policy-making under the Convention on Biological Diversity include, inter alia: a decision by the Conference of the Parties at its fourth meeting (COP IV) establishing an expert group on ABS in 1998; a decision by COP V establishing the Open-ended Working Group on ABS in 2000; the adoption of the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of their Utilization at COP VI in 2002. The above list, however, is not exhaustive; for a complete overview and analysis of recent developments leading to the international ABS Regime negotiations see: Hodges and Daniel (2005), and IISD (2008).
- ¹¹ IUCN (2006) reports: “Since 1993, considerable, although still insufficient, progress has been made in implementing CBD obligations and principles especially through national laws and obligations. However, the effectiveness of national and regional measures has proven to be limited resulting in WSSD’s call for an international framework.”
- ¹² Managers of CGIAR Centres frequently attributes the significant decline in the rate of acquisition of new materials by most of Centres’ genebanks in recent years “to the highly politicised nature of access and benefit sharing issues at international, national and regional levels.” See: Halewood and Sood (2006)
- ¹³ Queen Mary Intellectual Property Research Institute et al. (2000), pp. 54-74. The conventional access agreements thus developed are called Material Transfer Agreements (MTAs).
- ¹⁴ Chiarolla (2006).
- ¹⁵ The text of the IUPGR, which was adopted in 1983 by Resolution 8/83 of the FAO Conference, is available at: <http://www.fao.org/ag/cgrfa/IU.htm>. In 1983, given the global interdependency of all countries in terms of crop diversity, FAO Countries endorsed the creation of the FAO Global System for the Conservation and Utilization of Plant Genetic Resources for Food and Agriculture. The Global System is composed by several tools, which include specialized international bodies and agreements, plant germplasm collections, scientific networks and an early warning system. Further information is available at: <http://www.fao.org/FOCUS/E/96/06/06-e.htm>. The component of the Global System that provided the formal

framework for international action to promote the conservation, sustainable use and availability of crop biodiversity was the IUPGR. In particular, Article 5 of the IUPGR recognised the principle of unrestricted access to plant genetic resources in the following terms: "It will be the policy of adhering Governments and Institutions having plant genetic resources under their control to allow access to sample of such resources, and to permit their export, where the resources have been requested for the purposes of scientific research, plant breeding or genetic resources conservation. The sample will be made available free of charge on the basis of mutual exchange or on mutually agreed terms." See also Andersen (2005).

¹⁶ In 1992, the Conference of the Parties of the CBD recognised that the regime developed under the Convention on Biological Diversity was not well suited to PGRFA and handed this issue over to the FAO. See Resolution No. 3 of the Nairobi Final Act.

¹⁷ The Treaty was adopted by the FAO Conference on November 3, 2001. It entered into force on June 29, 2004 and has 116 Parties (information updated until March 2008). See in general: Moore and Tymowski (2005).

¹⁸ Bellon (2006).

¹⁹ While the ITPGRFA encourages facilitating access to all plant genetic resources for food and agriculture, only PGRFA which are under "the management and control of the Contracting Parties and in the public domain" will be automatically included into the MLS (Article 11.2). However, such resources must be used only for the purpose of utilisation and conservation for research, breeding and training for food and agriculture, being other uses, such as chemical, pharmaceutical and/or other non-food/feed uses regulated in accordance with the CBD.

²⁰ Article 12.4 of the ITPGRFA states: "the recipient of PGRFA shall require that the conditions of the MTA shall apply to the transfer of PGRFA to another person or entity, as well as to any subsequent transfer of those PGRFA."

²¹ Visser et al. (2005).

²² Article 6.7 of the SMTA states: "In the case that the Recipient commercializes a Product that is a Plant Genetic Resource for Food and Agriculture and that incorporates Material as referred to in Article 3 of this Agreement, and where such Product is not available without restriction to others for further research and breeding, the Recipient shall pay 1.1% (less 30%, to allow for sales costs) of the Sales of the commercialized Product."

²³ Chiarolla (2008: p. 4).

²⁴ See, in particular, the Annex to Decision VII/19D(d)(xxii) under "relevant elements of existing instruments and processes."

²⁵ The terms of reference for the ABS Working Group are contained in the Annex to Decision VII/19D, which sets out a number of agreed parameters for the negotiation. These parameters concern, in particular: (a) the process, which shall be based on a gap analysis; (b) the nature of the international regime, which revolves around the questions of whether the latter should include one or more instruments and whether it should be legally-binding or not; (c) its scope, which includes access to genetic resources and sharing of benefits, as well as traditional knowledge; and (d) a list of elements, which shall be considered for inclusion in the regime, comprising references to relevant existing instruments and processes. See: Scott (2007).

²⁶ Such components are listed in the Annex to Decision VII/19D, including inter alia: measures to ensure benefit-sharing (i), (ii), (iii), (v), (vi), (xiii), (xiv); measure to facilitate access (iv); measures to ensure compliance with PIC and MAT (ix), (x), (xi); protection of traditional knowledge (xv), (xvi), (xviii); compliance mechanisms (xx), (xxi); measures to facilitate implementation of the regime (viii), (xix), (xxii); relevant elements of existing instruments and processes (xxiii); and others.

- ²⁷ IISD (2008: p. 10).
- ²⁸ CBD (2008a: and Annex, pp.11-20).
- ²⁹ This deadline is established in CBD COP Decision VIII/4A, par. 6. In addition to renewing the mandate of the Working Group (WG) and setting the above timeframe for the negotiation, this Decision, in section C, established a Group of Technical Experts on an internationally recognised certificate of origin/source/legal provenance, which meet in Lima, Peru, in January 22- 25, 2007. See: CBD (2007). The Group of Technical Experts considered the possible rationale, objectives and the need for an internationally recognised certificate of origin/source/legal provenance; defined the potential characteristics and features of such an internationally recognised certificate; analysed the distinction between the options of certificate of origin/source/legal provenance and implications for achieving the objectives of Article 15 and 8(j); and identified associated implementation challenges.
- ³⁰ CBD (2008b: Item 4.1. par. 79).
- ³¹ CBD (2008a).
- ³² CBD (2008c: par. 189).
- ³³ Chiarolla (2008).
- ³⁴ CBD (2007).
- ³⁵ Tvedt and Young (2007: p. 63-5).
- ³⁶ The CGIAR Centers report that over the first eight months of 2007 “a total of 97,669 samples were distributed under the SMTA” and “only three potential recipients have refused explicitly to accept materials under the SMTA.” See: FAO (2007), par. 7-8.
- ³⁷ As regards the question of how to draw the line between commercial and non-commercial research, this paper has noted that within the FAO Multilateral System monetary benefits must be shared, if an IPR restriction limits the facilitated access to a derivative research product. Thus, in general, users’ applications for IPR protection are a useful element to distinguish between commercial and non-commercial research, because they are a clear indication of the intention to develop and commercialise a product to be sold on the market, including in the form of licensing.
- ³⁸ Chiarolla (2008).

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Trade, Particular Free Trade Agreements and Access to Genetic Resources and Benefit Sharing: Exploring Some the Linkages¹

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Abstract: This article highlights the potential relationship between Trade in general, and FTAs in particular, and the negotiations on an international regime for access and benefit-sharing within the context of the CBD, and identifies some questions requiring further scrutiny. In particular this article addresses the linkages between Trade (in particular) FTA and ABS in the context of the disclosure of origin of genetic resources in IPR applications and the restrictions on intellectual property rights (IPR) applications for inventions derived from genetic resources for which an access permit was granted and the relationship between ABS and investment and services rules in FTA.

Keywords: Access and benefit sharing; Convention on Biological Diversity; Intellectual Property Rights; Free Trade Agreements; World Trade Organization.

Introduction

A growing number of bilateral and regional free trade agreements (FTAs) incorporate provisions relevant to biodiversity. Meanwhile, there are ongoing negotiations on an international regime governing access to and the equitable sharing of benefits from genetic resources derived from biodiversity under the Convention on Biological Diversity (CBD). While there are clear linkages between the two sets of regimes, scant research has been conducted on the implications – both positive and negative – of the trade and intellectual property provisions included in FTAs on the international regime for access and benefit-sharing (ABS). This article highlights the potential relationship between Trade in general, and Free Trade Agreements (FTAs) in particular, and the

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negotiations on an international regime for access and benefit-sharing within the context of the CBD, and identifies some questions requiring further scrutiny. Despite the theoretical speculations, it is still uncertain if and how FTAs might have an impact on the negotiating dynamics and country positions with regard to the international regime. More time and analysis will thus be needed in order to identify the potential impact of Trade and FTAs on the negotiations and final outcome of an international regime for ABS.

A growing number of bilateral and regional FTAs incorporate provisions relevant to biodiversity as it is explained below. Meanwhile, there are ongoing negotiations on an international regime governing access to and the equitable sharing of benefits from genetic resources derived from biodiversity under the Convention on Biological Diversity (CBD). While there are clear linkages between the two sets of regimes, scant research has been conducted on the implications – both positive and negative – of the trade and intellectual property provisions included in FTAs on the international regime for access and benefit-sharing (ABS) related to biodiversity. Most of the analysis undertaken so far has focused on the issue of disclosure requirements.

Disclosure of Origin and International Trade: Are FTAs Restrictive or Supportive?

Rules governing access and benefit-sharing are linked to intellectual property rules (and trade rules) in several ways, some of these include:

- ABS rules may pose restrictions on intellectual property rights (IPR) applications for inventions derived from genetic resources for which an access permit was granted. For example, the Biodiversity Law of Bhutan requires prior notification, and India's Biodiversity Law requires prior written authorisation.
- ABS-related rules may require the disclosure of the origin of the materials in an IPR application that concerns or makes use of accessed materials in an invention (incorporated in ABS or Biodiversity Laws, for instance in the Andean Pact Decisions 391 and 486; the Costa Rica Biodiversity Law; the Provisional Measure of Brazil).

One of the measures suggested in order to achieve a synergistic relationship between the CBD and intellectual property systems (in particular, the WTO TRIPs) was the disclosure of the origin of genetic resources or associated traditional knowledge in intellectual property

right applications, particularly in patents. For several years the CBD, the World Trade Organization (WTO), the World Intellectual Property Organization (WIPO), and other agencies through their reports have insisted on the need to promote disclosure of origin in IPR applications.²

The Conferences of the Parties to the Convention have also addressed the relationship between IPR and biodiversity. For example, at the III Conference of the Parties, Decision III/15 (access to genetic resources) requested the Executive Secretary to cooperate with the WTO through its Committee on Trade and Environment in order to explore the extent to which there may be links between Article 15 of the Convention and the TRIPs. Decision III/17 also recognized, among other things, that further research is required in order to understand the relationship between the provisions of the TRIPs and the CBD, particularly those points relating to technology transfer and the conservation and sustainable use of biodiversity, fair and equitable benefit-sharing, protection of traditional knowledge, etc. The IV Conference of the Parties (1999 Bratislava), in addition to reiterating a number of previous calls from past COPs, emphasized the need to ensure consistency in the implementation of the Convention and the TRIPs, in order to increase mutual supportiveness between both regimes and ensure that biodiversity-related concerns receive IPR protection (IV/15). The V Conference of Parties (2000, Kenya), in Decision V/26, requested the WIPO and UPOV to properly take into account the relevant provisions of the Convention in their work, including the impact IPR might have on the conservation and sustainable use of biological diversity and particularly on the value of traditional knowledge. Subsequently, it invited the WTO to bear in mind that the TRIPs and the CBD are mutually related and called for a more in-depth exploration of that mutually supportive relationship. COP Resolution VI/24/C 1, *"The Role of IPR in the Implementation of Benefit-Sharing Agreements"*, invited the governments and Parties to promote disclosure of the origin of genetic resources in intellectual property right applications when the protected material consists of or makes use of genetic resources in its development. The aim of this disclosure is to help track compliance with prior informed consent and the mutually agreed conditions on which access to those resources was granted. Numeral 2 contains the same invitation regarding associated traditional knowledge. At the VII Conference of the Parties, Decision VII/ 19 requested the Working Group on Access and Benefit Sharing (WGABS) to identify aspects related to

disclosure of the origin of genetic resources and associated traditional knowledge in IPR applications, including aspects related to the certificate of origin/source/legal provenance. It also asked the WIPO and UNCTAD to prepare studies on disclosure of origin in IPR applications, based on a list of topics that need addressing.

The Bonn Guidelines also refer to this topic when they indicate that user country measures should take into account measures to promote disclosure of the origin of genetic resources and the origin of knowledge, innovations, and practices in intellectual property right applications (16.d.ii).

Main Elements of the Disclosure Proposal

It is not surprising that the requirement for disclosure of origin / proof of legality of access in intellectual property applications should be the object of intense political and legal debate. Although different legislations contain references to this requirement, they differ in terms of their consequences.³ Some of the biodiversity or intellectual property laws contain the obligation to disclose the origin of genetic material utilised in inventions or plant varieties, or even to present proof of the existence of prior informed consent or a certificate of origin that establishes the legality of access to the genetic material or associated traditional knowledge. This stipulation would help to support compliance with the CBD provisions on access to genetic resources and benefit-sharing.

In most cases, the European laws that have introduced this requirement refer only to the obligation to disclose the origin or, in the case of Norway, to prove the existence of PIC (only for genetic materials, not for traditional knowledge). However, these laws do not affect the existence of intellectual property rights as such, but rather fall within the penal or civil domains. Likewise, few laws on plant breeder rights, especially in India, consider this situation.

As Correa (2005) states, "Although the purpose of this obligation and its rationale seem clear enough, and there is substantial – though not unanimous - support for it to be established, the conditions and circumstances of this obligation and how it will be applied need to be more precisely defined..." The scope and conditions of application of the obligation should be consistent with its purpose, and care should be taken not to impose a disproportionate burden on the applicants and the institutions in charge of their applications".⁴

However, other aspects should be taken into account when considering the inclusion of disclosure of origin in the International Regime negotiations:

- a- The instrument has a limited impact on the prevention of misappropriation or biopiracy, and should, therefore, be accompanied by other complementary mechanisms. For example, in a number of documented cases of misappropriation through patents, the geographical origin of the resource was mentioned. In order to improve the quality of the granting of patents and other intellectual property rights, search systems in order to determine if the inventions are novel are needed. These complementary mechanisms have been explored by the WIPO Intergovernmental Committee on Genetic Resources and Intellectual Property, Traditional Knowledge and Folklore.
- b- Consideration should also be given to whether countries have the ability to effectively monitor patent applications and patents granted in order to determine if there has been misappropriation of materials. Even if misappropriation is detected, it is doubtful that the countries have the economic and financial capacity to invalidate patents in foreign jurisdictions, considering the long and costly process involved. This situation points once again to the need to study other user country measures, for example, those that facilitate access to justice, as required to achieve the objectives of the CBD.
- c- One way to prevent misappropriation is to improve access to information existing in the public domain, and make it available to the technical staff in charge of reviewing patents to aid them in determining if they are novel and if prior art exists. This is one of the aspects the WIPO has been working on through the Intergovernmental Committee.
- d- Finally, although these provisions have been included in some countries' patent laws or in their biodiversity or related laws, it is also advisable, strictly at a national level, for the countries to begin introducing a new statutory obligation into their access or related laws: namely, the requirement for an access applicant to disclose the origin or source of the resource at the time access is granted if the access applicant presents a patent application. Although it is not possible to categorically state whether or how the patent offices will take these legal or contractual provisions

into account, or whether they will take action against an applicant that does not comply with them, this measure merits consideration. Incorporating this provision will require that actions be taken at a national level, which should not wait for the conclusion of international negotiations on the Regime or the WTO discussions.

Disclosure and FTA

With regard to free trade agreements, concerns have been raised that in some cases their IP provisions may limit or preclude the opportunities to introduce disclosure of origin requirements. For example, the language used in the US-Central American Free Trade Agreement (CAFTA), states that “Each party shall provide that a disclosure of a claimed invention shall be considered to be sufficiently clear and complete if it provides information that allows the invention to be made and used by a person skilled in the art, without undue experimentation, as of the filing” (article 15.9.9). Doubts have been raised as to whether this text implies a restriction on additional information being requested when the patent is disclosed. For legal and technical reasons the author does not agree with this interpretation. However, it deserves to be mentioned as a suggested potential implication of the FTA on the disclosure requirements.

FTAs have generally not incorporated a mandatory requirement for the disclosure of origin in the substantive IPR Chapter of the Agreement. However, the issue has sometimes been addressed elsewhere. For instance, in the case of the US-Peru FTA, the following elements have been agreed in a side letter:

- a) Recognition of the importance of traditional knowledge (TK) and biodiversity, as well as their contribution to development.
- b) Recognition of the importance of a) prior informed consent from the appropriate authority; b) equitable sharing of benefits from the use of TK and genetic resources; c) promoting quality patent examination to ensure the conditions of patentability are satisfied.
- c) Recognition of the fact that access and benefit sharing can be adequately addressed by contracts.

Despite the recognition of the issues in the side letter, the text agreed is essentially on uncontroversial matters (e.g the importance of TK). In other words, the side letter does not address or respond to the more controversial aspects of disclosure of origin. Therefore, these provisions may not have an impact on critical issues discussed in the negotiations on an international regime.

ABS and Investment/Services Disciplines

The relationship between ABS and investment and services rules in FTAs is also of interest. For example, research services – including biodiversity-related research – is mentioned in the services chapter of CAFTA.

There may be legal implications of considering bioprospecting as a service and investment disciplines in FTAs may also be applicable. A common discipline in investment provisions is the prohibition (or restriction) of “performance” and other requirements placed on the investor and the investment. Arguably, such restrictions could limit the rights of countries to require, as part of ABS rules or procedures, technology transfer from the potential user of the genetic resources. Such technology transfer has been noted as an important benefit in the biodiversity context. Whether in fact this mandatory requirement for a foreign company imposed in the context of an ABS permit would constitute a violation of the investment disciplines remains unclear.

Nevertheless, a common feature of FTAs is a provision providing that, in case of contradiction between the investment chapter and other chapters, the latter prevail. Thus, the environmental chapter, which requires compliance with environmental laws in the country – including any access law or biodiversity law – would prevail over conflicting investment disciplines. A potential solution would be to require the investor/access applicant to comply with any technology transfer or other benefit sharing provisions in the context of the ABS permit. Any condition imposed on the applicant/investor would thus have its legal basis in the CBD and domestic environmental law.

From a legal perspective, some authors have pointed out the implications of considering “bioprospecting” as a service and the applicability of the investment disciplines contained in the FTA; in this regard, the prohibition (or restriction) of “performance” and other requirements to the investor and his investment can be mentioned; e.g. limiting the rights of the Country, as part of the access procedure, to require technology transfer from the potential user of the genetic resources (a benefit sharing condition before access is granted). This mandatory requirement imposed on a foreign company in the context of an ABS permit, could constitute a violation of the investments disciplines.

Finally, it is important to point out another implication of FTA’s investment provisions. The investment Chapter usually requires Parties to provide National Treatment to a foreign investment (under certain

circumstances and exceptions carefully negotiated and listed). A concern has been raised because some ABS laws discriminate between nationals and foreigners, creating a more favourable procedure for foreigners (e.g. India, Brazil, Sarawak). At this stage in the IR negotiations it is unclear to what extent, if any, the “access component” of ABS will be included. However, at least some proposals (e.g. those of the EU) have been put forward making a clear reference that ABS should not discriminate between nationals and foreigners.

Certificate of Origin/Compliance and Trade Disciplines⁵

One element ABS negotiations have focused on in order to respond to the call for user country measures, and to contribute to solving problems related to the monitoring and traceability of genetic resources, is by developing some form of certificate of origin/source/legal provenance – more recently named ‘certificate of compliance’.

The idea of the certificate is to prevent or minimize problems generated by the existence of two different jurisdictions for ABS arrangements – that of the place where the material is collected and that of the place where research and development activities are carried out. The existence of an internationally recognized document would make it possible to check the legality of access at the place where the activity (patent, product approval, etc.) generates value, and to discover the subsequent use of the resources and the origin of the corresponding benefit-sharing. At the same time, this supposedly⁶ would favour the creation of simpler access systems in provider countries, in that existing control mechanisms would be applied, via the certificate, in the later stages of research and development, thus helping to make the regulations on access to genetic resources more flexible. In this way, monitoring and regulation would be less strict during the access phase and stricter during the research and development phase, where control or check points would be established. This implies that the documentation would need to pass through the various buyers, but the monitoring points would be reserved only for certain milestones in the research and development process, such as those related to product approval, IPR applications, publications, the presentation of funding proposals, etc.

Many aspects still need to be clarified before this system can become operational, including (Fernández, 2004):

1. The designation of national authorities to issue certificates that are mutually recognized

2. The identification of conditions for verification of and compliance with the certificates, that is, the determination of which materials they would apply to, for what purposes, and at what moment or stage they would be verified
3. Exemptions
4. Provisions for cases in which it is not possible to identify the origin of the genetic resources, including benefit-sharing
5. Differential treatment of different sectors
6. Dispute settlement mechanisms
7. The creation of an international certificate register
8. How countries that are not parties to the IR will be handled
9. Provisions related to the resources contained in *ex-situ* collections prior to the Convention

Other aspects of interest could include:

1. Focus on what the certificate corresponds to: species, genes, specific biological samples, derivatives, etc.
2. Transaction costs of the certificate.
3. Different types of certificates: origin, legal provenance, source.
4. Characteristics of the system: simplicity, flexibility, avoidance of complex procedures.
5. Considerations regarding the product supply chain, etc.
6. Ability to comply with the objectives of the CBD, especially conservation.
7. Economic impacts and implications of the certificate for different actors (botanical gardens, etc.)
8. Content of the certificate.
9. Sanctions for non-compliance.
10. Lack of legislation on access.
11. Procedures for control and use of the Clearing House.
12. How to ensure that additional barriers are not created for the non-commercial exchange of resources.
13. Compatibility with international trade regimes,⁷ etc.

Depending on the certificate's final design, some rules of the trade system (WTO or FTA) might apply to it, especially those related to technical barriers to trade. For instance, if the certificate is going to be checked at customs and if the legal consequences of not showing the same are the prohibition of the entry of the genetic resources- for which the certificate should have been issued - into a country. However, the

potential implications of such rules on the certificate need to be better understood.

Capacity Building

Studies on the implementation of national ABS laws confirm the difficulties provider countries face in adequately complying with their current legislation. In the opinion of the author, in order to achieve CBD objectives, the importance of national frameworks and their application should not be neglected. This topic is closely related to capacity building. From this perspective, the international regime should contribute decisively to ensure the best possible application of existing legal frameworks on ABS, the strengthening of legal certainty and the creation of national capacities for that purpose.

FTAs often contain provisions on environmental cooperation (including capacity building activities) either in an Environment Chapter and/or in an Environmental Cooperation Agreement to be ratified separately. In each case, preliminary priorities have been set out for cooperation and capacity development in different areas or fields. ABS could be considered one of these areas and receive financial and other support from trade partners. These programmes could support capacity building activities under the international regime.

Discrimination against Countries without user measures in Place:⁸ Flexibility through Governmental Reciprocity and Trade Implications

One step that source countries can consider, as a means of finding an appropriate standard of flexibility in addressing post-access monitoring and oversight, is the concept of reciprocity.

A source country might consider adopting legislation under which special ABS special procedures are only available for users operating under the jurisdiction of a country that has adopted certain measures. This approach might eliminate a common problem where applications that had been refused, because the authorities felt that did not have adequate guarantees or were uncertain of how exported material might really be used.

This solution should address the legal possibility for a country providing genetic resources to condition the granting of access to the existence of appropriate measures in the user country (User Measures). To condition the granting of access or to establish more favorable

procedures, in the cases in which measures of this nature exist in the User Country, also has implications from international trade.

Often it is argued that the purpose of user measures is to provide an incentive for countries of origin to develop more flexible ABS rules and procedures and thus facilitate access in line with the CBD objectives. This was a 'key conclusion' of the first panel of experts in ABS: "Flexibility in providing countries is related to the extent that user countries and organizations implement measures that provide incentives or establish control mechanisms in order to secure the interest of providers over their resources."⁹

Description of the Measure

The proposed measure consists in introducing a mechanism that would provide for the existence of an additional, reciprocal and expedited access procedure (AREP) that would only be available for those countries who have effectively adopted user measures (including but not limited to the certificate of legal provenance and disclosure requirement).¹⁰

The issue of what exactly could be simplified (e.g. procedural or substantial issues) in the expedited procedure and how this would be determined has to be further explored. However, the mere existence of such mechanism would itself greatly assist those countries interested in developing effective access regimes. Additionally, this should be coordinated with the ongoing capacity-building efforts.

The measure is 'additional' in that it should not overrule the authority to determine access. Thus, the proposed alternative procedure would coexist with the general or standard procedure for ABS, which could then have more protective conditions.

However, the main advantage of the measure is that it could facilitate benefit sharing, so sending a much needed signal. First, as flexibility would increase so would the access activity and consequently the chances to generate benefits to share. Second, for any given country, it is more likely that benefit sharing will become significant in an aggregate manner rather than in an isolated way. Thus, as flexibility would take less time to be part of the system this would shorten the time for significant transactions to occur. As a result, significant benefit sharing would be facilitated.

In being available only to Parties to a binding instrument, for example, the measure would contribute in attracting signatories. If the international regime is to realize its potential in becoming the main

legal structure regulating ABS and is to bring some degree of order and predictability to germplasm flows, it must attract wide adherence. The use of this kind of incentive has been successfully tested in relation to other Multilateral Environmental Agreements (MEAs).

The mechanism would require substantial information from National Focal Points (NFPs), which could be incorporated into databases of countries and user measures held in the CBD Clearing-House-Mechanism (CHM). The information would then be available for National Competent Authorities (NCAs) who would verify upon the eligibility of applicants and decide upon granting AREP.

National Experience in Discussing the Measure

The idea of introducing, in addition to the standard access procedure, certain expedited/simplified access procedures for nationals of jurisdiction where user measures have been adopted, was discussed within the environmental public sector in Mexico, during the deliberation of the Draft National ABS Law. In the end the Ministry of Environment was not persuaded due to misunderstandings over the exact limitations posed by international trade obligations and an over-dimensioning of the issue of discrimination. The general trade concern was over the discrimination that the measure entailed, without any further elaboration.

The Seychelles constitutes a good example of a country for which oversight and control of users will be nearly impossible. The Seychelles is not primarily a "user" of GR, and will probably not be able to build the level of infrastructure to monitor, test, or take other actions that impose restrictions on users. Its draft law, however, attempts to remedy these deficiencies, through the use of two kinds of provisions, legal mandates (basic user measures) and reciprocity. These provisions were included to give users and user countries an idea of the minimum that is expected from other countries in return for access and the right to use genetic resources.

These user provisions are very basic statements, however. In general, they simply require Seychellois who are utilising the genetic resources of other countries to

- Comply with the laws of the source country (Article 32);
- Comply with the terms and conditions of any relevant permit or contract (Article 33); and

- Notify the source country when the resources have been accessed (Article 34.)

For purposes of access legislation, however, a much more important provision is that which addresses questions of legal reciprocity and unconscionable terms and conditions. In this connection, Article 36 of the draft law states that

The provisions of this Part shall only apply in respect of the laws or other terms and conditions of access or utilisation of foreign jurisdictions providing equivalent or reciprocal protections to those contained in this Part, and shall not be enforceable where any relevant terms and conditions are declared unconscionable.

Both clauses of this provision are of interest legally. First, the reciprocity clause appears designed to create an incentive for user countries to adopt “user measures.” In essence, it says that “if you don’t protect our genetic resources from unauthorised exploitation, we won’t do the same for you.” Presuming that other source countries (with larger genetic-resource industry and research bases) follow this example, such an incentive might indeed develop. At the same time, that clause suggests that all that user countries must do is provide three of four unenforceable single sentence mandates, in order to meet their responsibility under Article 15.7.

In addition, the second clause might be interpreted to be an authority to declare foreign law invalid – another provision that might have negative reciprocal impacts, if a user country were to adopt and enforce it.

Trade Concerns: The Limitations

A wide variety of trade measures (TREM’s) have been used in MEAs, either amongst parties or against non-parties. This includes reporting requirements on trade flows, labelling or other identification requirements, requirements for movement documents (such as permits or licenses, or systems of prior notification and consent), and export and/or import bans.

Particularly those TREMs aiming to provide means of enforcing a MEA (i.e. measures amongst parties and against parties) can give rise to considerable trade concerns. This is because they entail a discriminatory practice that might be incompatible with a basic tenet of the world trade system: *non-discrimination*. Non-discrimination is promoted mainly by operation of two principles: most-favoured-nation (MFN) and

national-treatment (NT). The former requires Member Countries to extend the best treatment granted to like products from any other Member (Article I of GATT). The latter requires Members to extend the same treatment to domestic and imported like products (Article III of GATT).

However, GATT also contains general exemptions by virtue of which a Party can deviate from its basic obligations under certain circumstances, including the obligations not to discriminate. Pursuant to Article XX, measures aimed to protect the environment can be validly pursued under paragraph (b) on protection of human, plant and animal life and health; and paragraph (g) on protection of exhaustible natural resources. There are some conditions that have to be met in order to be able to benefit from these environmental exemptions. The measure must be the less restrictive to trade, must be related to the environment, and must not be, according to the “ chapeau” , a disguised restriction on international trade, or applied in a manner which would constitute a means of arbitrary¹¹ or unjustifiable discrimination between countries where the same conditions prevail. Thus, in addition to the MFN and NT principles, discrimination is addressed in the T&E scenario through the chapeau of article XX.

In the same vein, in the environment field the international community has committed to avoid measures that constitute a means of arbitrary or unjustifiable discrimination.¹² Note however, that the consensus in both fields is limited to the excesses since clearly not all form of discrimination is *arbitrary or unjustifiable*.

In relation to potential trade implications of the measure, considering some of the understandings produced over the debate of MEA-WTO relationship, as well as the terms of the environmental exemptions embedded in the GATT and the inclusion of the notion sustainable development in the international trade system, it can be concluded that the proposed measure should be considered WTO compatible.

In sum, it can be safely argued that the measure proposed in this paper poses no major problems of WTO compatibility, considering:

- The precedents found in other MEAs and in the International Treaty for Plant Genetic Resources for Food and Agriculture.
- The terms of the exceptions of the Article XX of the GATT and its interpretation; and

Box I: Links between the International Regime on ABS and FTAs

IR component	FTA Implications
<ul style="list-style-type: none"> ● Benefit-sharing/ Traditional knowledge 	<ul style="list-style-type: none"> ● Promotion of mechanisms to support/ recognise the importance of benefit-sharing (Side Letters addressing the issue). ● Side Letters and other relevant provisions reaffirming the importance of TK and biodiversity for development. ● In some commentators opinion potential restrictions on disclosure included in IPR Chapters. ● Restrictions on the type and modalities of benefit-sharing requirements imposed on bioprospecting (investment disciplines and their applicability with regard to ABS activities). However, primacy of Environmental Chapter of FTA could solve this restriction, allowing the investor's requirements (e.g. tech transfer) in the light of the obligation to enforce environmental laws (biodiversity related laws).
<ul style="list-style-type: none"> ● Access 	<ul style="list-style-type: none"> ● Promotion of mechanisms to support/ recognise the importance of PIC from the competent authority (Side Letters addressing the issue). ● Prohibition of discrimination between foreigners and nationals (ABS activities considered as services or investments¹³). However, primacy of the Environmental Chapter of FTA and recourse of other Treaty's provisions and exceptions could solve this restriction.
<ul style="list-style-type: none"> ● Support compliance with Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) of provider countries. 	<ul style="list-style-type: none"> ● Technical Barriers to Trade rules (or the reaffirmation of the WTO disciplines found in FTA) and their impact on a potential certificate of origin/compliance (depending on its final structure; design; check points; legal consequences of non presentation of the certificate; etc). In accordance to some commentators disclosure of origin restrictions.
<ul style="list-style-type: none"> ● Capacity Building 	<ul style="list-style-type: none"> ● Environmental Cooperation Agreements and capacity building in priority areas, including potential activities in ABS-related areas.

- The understandings that have emerged during the long debate of the relationship between MEAs and the WTO rules.

Some Concluding Remarks

This article has highlighted a number of links between Trade (focusing on FTAs) and the international regime for ABS that is currently being negotiated under the CBD (see Box I). Despite the theoretical speculations, it is still uncertain if and how FTAs might have an impact on the negotiating dynamics and country positions with regard to the international regime. So far, this has not seemed to be the case. With regard to the substantive content of the proposals submitted by the different countries or by regional groups in the negotiations, it is difficult to link the modifications of recent country proposals to the content of their FTAs (especially because the proposals do not include specific negotiating language).

More time and analysis will thus be needed in order to identify the potential impact of Trade and FTAs on the negotiations and final outcome of an international regime for ABS.

Endnotes

- ¹ Parts of this article are based on a previous article of the author, published in Biodiversity and regional and bilateral trade agreements: Implications for access and benefit-sharing negotiations, Bridges Trade and Environmental Review, Issue No. 3, ICTSD, Geneva, March 2008
- ² Concerning technical and legal aspects of disclosure of origin, readers are referred to the following studies which, in addition to being comprehensive, present some differing conclusions on various aspects: WIPO, Technical Study on Patent Disclosure Requirements Related to Genetic Resources and Traditional Knowledge, Study No 3, 2005; Sarnoff, Joshua and Correa, Carlos, Analysis of Options for Implementing the Disclosure of Origin Requirements in Intellectual Property Applications; UNCTAD, February 2006; Rojas, Martha et al., Disclosure Requirements, op. cit.; Sarnoff, Joshua, Compatibility with Existing International Property Agreements of Requirements for Patent Applications to Disclose the Origins of Genetic Resources and Traditional Knowledge and Evidence of Legal Access and Benefit Sharing, available at www.piipa.org; Ho, Cynthia, Disclosure of Origin and Prior Informed Consent for Applications of Intellectual Property Rights based on Genetic Resources. A Technical Study of Implementation Issues. Final Report, July, 2003; and, Hoare, Alison, Background Paper for the Chatham House Workshop: "Disclosure Requirements in Patent Applications - Options and Perspectives of Users and Providers of Genetic Resources." 9-10th February 2006, Energy, Environment and Development Program, Chatham House.
- ³ For example, Brazil, the Andean Community, Costa Rica, India and Egypt, among others.
- ⁴ Correa, Carlos, Alcances jurídicos de las exigencias de divulgación del origen en el sistema de patentes y derechos de obtentor, Research Documents, Initiative to Prevent Biopiracy, Year 1, No 2, August 2005.

- ⁵ It is not my intent to develop the idea of the certificate in depth. For further detail, see the following documents: Dross, Miriam and Wolff, Franziska, *New Elements of the International Regime on Access and Benefit Sharing of Genetic Resources: the Role of Certificates of Origin*, BFN. Bonn, 2005; Fernandez, Jose Carlos, *The Feasibility, Practicality and Cost of a Certificate of Origin System for Genetic Resources: Economic Considerations*; in *Yokohama Round Table: Toward Fair and Equitable Benefit Sharing: Instruments for the Effective Implementation of the Bonn Guidelines under the Convention On Biological Diversity*; Yokohama, Japan, 11 March 2005; Tobin, Brendan, Cunningham, David and Watanabe, Kazuo: *the Feasibility, Practicality and Cost of a Certificate of Origin System for Genetic Resources*, working paper submitted to the Secretariat of the Convention on Biological Diversity, February, 2005.
- ⁶ An analysis of the causes behind processes to reform the implementation of ABS laws can be found in, Gatforth, Kathryn and Cabrera Medaglia, Jorge, *Factors Contributing to Legal Reform for the Development and Implementation of Measures on Access to Genetic Resources and Benefit-Sharing*, publication pending.
- ⁷ On this last aspect, cfr. Louafi Salim, Morin, Jean Frederic, *Certificates of Origin for Genetic Resources and International Trade Law*, IDRRRI, 2004, first draft.
- ⁸ This section is based on a previous draft of the book Cabrera Medaglia, Jorge y Christian López Silva (2007). *Addressing the Problems of Access: protecting sources, while giving users certainty*. Gland, Suiza: UICN.
- ⁹ Report of the Panel of Experts on Access and Benefit-Sharing, UNEP/CBD/COP/5/8, 2 November 1999, Conference of the Parties to the Convention on Biological Diversity, Nairobi, parr 151.
- ¹⁰ A somewhat similar measure was suggested at the First Panel of the Experts of the CBD. However, it focused on the conduct of persons, not State. The measure recommended only referred to voluntary instruments and it only suggested simplifying the PIC procedures. See Report of the Panel of Experts, op cit, Annex V.
- ¹¹ WTO panels have accorded special attention to flexibility in the application of the measure concerned. The more rigid and inflexible the application, the higher the likelihood that the measure is regarded as arbitrary and unjustifiable.
- ¹² As stated in Principle 12 of 1992 Rio Declaration and confirmed in paragraph 101 of the 2002 Johannesburg Plan of Implementation.
- ¹³ Few ABS laws provide a more favourable treatment to nationals in the process of granting of the ABS permit.

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Bioindustry and the Convention on Biological Diversity: Japan's Experience

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Abstract: In Japan, industry association and the government are working very closely to implement the ABS regime. This has yielded some very encouraging results which may provide guidelines for future policy options. The Japan Bio Industry Association, JBA, has been making efforts to build mutually beneficial relations with other countries as well that may provide genetic resources, by facilitating access to genetic resources and implementing fair and equitable sharing of benefits arising from the use of those resources.

Keywords: ABS, CBD, Japan.

Introduction

Since the Convention on Biological Diversity (CBD) entered into force in 1993, Japan Bioindustry Association¹ (JBA) has been steadily involved in the process of implementing CBD.

The Ministry of Economy, Trade and Industry (METI) is a competent national authorities on ABS in Japan. On behalf of METI, JBA has been implementing the access to genetic resources and benefit-sharing (ABS) provisions of the CBD, since 2002, in order to help the private sector and the scientific community to continue to build a win-win relationship with other countries. As part of this project, JBA has been participating in the meetings of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing (WG-ABS) as well as the Conference of Parties (COP) to CBD for discussion of ABS and other issues. JBA has also been making efforts to build mutually beneficial relations with countries that provide genetic resources, by facilitating access to genetic resources and promoting fair and equitable sharing of benefits arising from the use of genetic resources in an appropriate manner.

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Bioindustry and the Convention on Biological Diversity

Currently, the market size (domestic sales volume) of modern biotechnology products and services in Japan for 2006 was worth 1,847 billion Japanese Yen (JY) (approximately equivalent to US\$ 18 billion) per year.² The market has shown steady growth since 1989. If products of both conventional and modern biotechnology are combined, the market size in 2005 was JY 7,692 billion (approx. US\$ 77 billion). The size of the world pharmaceutical market in 2005 was US\$ 601.4 billion. Japan's share was approx. US\$ 66 billion (11 per cent of the world market), which is the second after the United States (44 per cent).³

Historically, Japan's pharmaceutical industry has strengths in microbial natural product-based drug discovery, as demonstrated by the world-wide blockbuster drugs such as pravastatin and tacrolimus. An example of more recent commercial success is micafungin. Some other compounds originating from Japanese natural products are currently being tested in the clinical phases.

There are several reasons for the Japan's strengths in microbial natural product-based drug discovery.⁴ Japan has traditionally developed fermentation industries using *Aspergillus*, *Saccharomyces*, and other microbes. This tradition helped to nurture expertise in applied microbiology. For example, more than 100 years ago, Jokichi Takamine, a pioneer in biotechnology in both Japan and the United States, developed and patented microbial enzymes for the first time in the world. Modern fermentation processes for amino acids and nucleotides have bloomed in Japan since late 1950s. Discovery and development of natural product-based drugs require a wide diversity of researchers in different disciplines. Success depends on well-organized collaboration between these experts rather than one genius. This type of research collaboration seems compatible with Japanese culture.

However, the percentage of small-molecule drugs worldwide that include those of natural product origin are envisaged to decrease substantially in the coming decades. On one hand, modern biotechnology-based drug discovery (for large-molecule drugs such as antibody drugs) attracted considerable attention of the corporate management in Japan. On the other, CBD has negatively affected corporate management's incentives for investment in natural product-based drug discovery, because of uncertainty about the regulatory procedures of a number of developing countries that are

potential providers of genetic resources. Major Western pharmaceutical companies either withdrew or reduced their focus in natural product-based drug discovery. Japanese pharmaceutical companies have been affected by this trend, but a number of them still manage to keep the function of their natural product drug discovery on a smaller scale. Continuous efforts are needed to keep the natural product drug discovery alive. In this sense, CBD-based collaboration with developing countries, such as efforts by Nimura Genetic Solutions in Malaysia, Mercian Corp. in Indonesia and HypHaGenesis Inc. in Vietnam, will be essential. MET and JBA have been implementing ABS provisions of the CBD, in order to help the private sector and the scientific community to continue to build a win-win relationship with other countries. The evolution of CBD-ABS implementation in Japan is described later in the section on development of Japan's ABS guidelines for users.

Experiences in Research Cooperation Projects on Conservation and Sustainable Use of Tropical Biodiversity between Japan and Southeast Asian Countries

Mutual understanding and trust are the basis to develop a good human relationship. Anticipating the advent of CBD-era, METI and JBA started planning bilateral research cooperation projects with Southeast Asian countries in early 1990s. We had a long-term objective to continue to develop good relationships with other countries. ABS was not an immediate target. The objective was to get to know each other in the upcoming CBD context.

The Bilateral Research Cooperation Projects between Japan and each of Thailand, Indonesia and Malaysia started in April 1993 and continued for six years until March 1999. The projects exchanged a total of 591 Japanese and Southeast Asian scientists, installed the most-needed equipment and instruments in the local research facilities, and sponsored domestic research programs. The Japan Bioindustry Association (JBA) carried out these projects entrusted by the New Energy and Industrial Technology Development Organization (NEDO) under the guidance of Ministry of International Trade and Industry (currently called METI).⁵

The research activities were mostly conducted by the scientists from universities and public research institutes. A total of 389 Japanese scientists were dispatched to the three Southeastern countries for on-

site collaborative research, whereas a total of 202 scientists from those three countries were invited to Japan for joint research or training for technology transfer. A variety of interesting results were gained in the research projects.⁶ The projects' cumulative budget was approximately 1 billion yen (approximately US\$ 10 million) over 6 years on Japan's side, including costs for personnel, equipment and instruments, research and training, and traveling. The JBA secretariat, in cooperation with its counterparts, worked out mutually acceptable, transparent and practical procedures for handling biological resources, including Material Transfer Agreements for scientific research purposes. The Bilateral Research Cooperation Projects helped all the participating countries to develop mutual understanding and confidence which became the foundation for the subsequent developments, including those described in the Section on Experiences of Japan's National Institute of Technology and Evaluation (NITE) in Research Cooperation in Microbial Taxonomy with Other Countries.

As policy relevant lessons, JBA learned that biological resource centers, as repository of biological materials and related information, have become an essential part of the scientific and technological infrastructure for each country in the era of Convention on Biological Diversity, and that they should therefore be strengthened. JBA also learned that involvement of industries would be essential in future cooperation projects on biological diversity, because industries have the actual capabilities to create benefits from utilization of biological resources.

In fact, after several years of preparation, some Japanese companies established its laboratories in these countries and have since been conducting research activities in compliance with the CBD and their national laws. In retrospect, the mutual understanding and trust that had been developed through the Research Cooperation Projects in 1990s were foundations for these developments

Objectives of the Arrangements

The primary objectives of the projects were;

- (1) To assist the participating countries in their own efforts to conserve and use biodiversity in a sustainable manner;
- (2) To train the participating scientists and help further develop their scientific skills through collaborative research with installment of state-of-the-art equipment and instruments in their countries.

Content and Implementation of the Arrangements

Japan-Thailand Project

As the basic agreement, Memorandum of Understanding (MOU) was concluded between NEDO, Japan and The National Science and Technology Development Agency (NASTDA), Thailand. Scientists and researchers from a number of national research institutes and universities of both countries participated in the joint research activities. The subjects of the cooperation projects were as follows:

- A. Taxonomic analysis, ecosystem evaluation and monitoring
 - 1.1 Feeding strategies of primates
 - 1.2 Improvement of microbial culture collection systems:
 - Use of classification/identification methods based on DNA
- B. Conservation of biodiversity through man-made ecosystems
 - 2.1 Interactions among different organisms within a man-made ecosystem
 - 2.2 Genetic diversity analysis of artificial ecosystems
 - 2.3 Socio-economic and ethnological analysis of an artificial ecosystem
- C. Use of bioresources
 - 3.1 Use of bioresources:
 - Screening of new bioactive substances found in plants and their applications
 - 3.2 Study of traditional use of plant resources

Japan-Indonesia Project

The MOU was concluded between NEDO, Japan and The Agency for the Assessment and Application of Technology (BPPT), Indonesia. Scientists and researchers from a number of national research institutes and universities of both countries participated in the joint research activities. The subjects of the joint research were:

- A. Taxonomic analysis, ecosystem evaluation and monitoring
 - 1.1 Microbial culture collection systems
 - 1.2 Plant conservation techniques:
 - (1) Conservation of plant diversity
 - (2) Tissue and cell cultures of tropical plant species
 - (3) Development of DNA techniques for the evaluation of biological diversity
- B. Utilization of tropical bioresources
 - 2.1 Utilization of microbial resources

- 2.2 Utilization of plant resources
- 2.3 Elucidation of symbiosis between plant and microorganism and its utilization
- C. Promoting the establishment of “Tropical Bioresources Industrial Development Center” in Indonesia

Japan-Malaysia Project

The MOU was concluded between NEDO, Japan and The Standards and Industrial Research Institute of Malaysia (SIRIM). Implementation of the cooperation project on Malaysian side was conducted by National Biotechnology Directorate (NBD), The Ministry of Science, Technology and the Environment (MOSTE) Malaysia. Scientists and researchers from a number of national research institutes and universities of both countries participated in the joint research activities. The subjects of the research cooperation were:

- A. Ecosystems and monitoring
 - 1.1 Biodiversity databases and gene banks
 - 1.2 Evaluation and monitoring of marine ecosystems
 - 1.3 Ecosystem evaluation and inventory development based on advanced technologies
- B. Utilization of tropical bioresources
 - 2.1 Screening and separation of bioactive compounds produced by microorganisms and plants
 - 2.2 Evaluation of therapeutic and toxic potentials of natural products

Experiences of Japan’s National Institute of Technology and Evaluation (NITE) in Research Cooperation in Microbial Taxonomy with Other Countries

Microbial resource centers are fundamental to preserving and harnessing microbial biodiversity and genetic resources. The availability of precisely identified and validated microbial resources is essential for scientific research and industrial and other applications. In many cases, microbial resource centers are centers of excellence for preserving microbial biodiversity and training microbial taxonomists. In recent decades, academia in Japan has experienced a conspicuous decline in number of taxonomic experts trained to discover, identify, describe and classify microbial biodiversity. For example, when professors in microbial taxonomy retire, the universities often suppress the posts, and recruit

researchers with disciplines more 'glamorous' than taxonomy. This trend has led to drastic reduction in graduate training in microbial biodiversity research. Becoming increasingly concerned about the situation, Japan's academia and industry together made a recommendation to the government that a national microbial resource center be established the function of which is to be adapted to the principles of the Convention on Biological Diversity (CBD) and the genomic era. In response to this recommendation, the Japan's government, in 2002, created a microbial resource center within the National Institute of Technology and Evaluation (hereafter referred to as NITE-BRC).

Organization of NITE-BRC

Within NITE-BRC, the functions of the microbial culture collection and genomic research are integrated to promote synergy and to add value to the microbial resources and associated data. The functional organization of NITE-BRC is as follows:

- Preservation and distribution of microbial resources as references
NITE-BRC collects, identifies, preserves and distributes potentially useful microorganisms and cloned genes to users to promote basic research as well as industrial and other applications. These strains serve as references for diversified purposes. As a separate entity, NITE-BRC also has a patent microorganism depositary in accordance with the Budapest Treaty.
- Microbial genome analysis
The function of microbial genome analysis group is integrated within NITE-BRC. Once genome analysis of a microorganism is completed, the results are released for public use in the "Database of the Genomes Analyzed at NITE" (DOGAN).⁷

Concept of International Collaboration and "Tsukuba Statement"

The concept of international collaboration that has been leading NITE-BRC is consistent with the 'Tsukuba Statement' issued by the Global Taxonomy Initiative (GTI) Programme of Work in Microbiology that took place in Tsukuba, Japan in October, 2003⁸ (see the box below). The GTI is a cross cutting issue of the CBD. In the Tsukuba meeting, delegates from Asian and Oceania countries participated.

Key points are excerpted from the Tsukuba Statement as follows:

- 1) Strategic inventory of microbial diversity should be developed in each country.

- 2) Taxonomists themselves should recognize the importance of their role for solving biodiversity problems. National governments should establish laboratories and institutes for applied microbial taxonomy.
- 3) Developed countries are requested to draw up and implement a plan for the advancement of microbiology in collaboration with developing countries.
- 4) Providers and users of microbial resources must respect and follow the CBD and the Bonn Guidelines. National governments should

Tsukuba Statement

Tsukuba, Ibaraki, Japan, 9 October 2003

Global Taxonomy Initiative (GTI) and Microbial Taxonomy⁹

1. For the purpose of accumulating knowledge on and the full understanding of microbial diversity, predicting its change, and assessing the impact of any change, and for the purpose of developing the technology and measures for sustainable use and the fair and equitable sharing of benefit, a strategic inventory of microbial diversity should be implemented in each country.
2. Taxonomists themselves should recognize the importance of their role for solving biodiversity problems. In order to sustain and advance microbial taxonomy and to prevent the loss of and increase the number of microbial taxonomists, national governments should establish laboratories and institutes for applied microbial taxonomy. Microbial taxonomists must exert all their powers to advance microbiology.
3. Recognizing the importance of microbial taxonomy for the strategic inventory of microbial diversity, developed countries are requested to draw up a plan for the advancement of microbiology in collaboration with developing countries and the plan should be implemented.
4. Providers and users of microbial resources must respect and follow the CBD and the Bonn Guideline. National governments should pay attention so that the CBD does not hinder strategic inventory of microbial diversity. Providers must accelerate acquisition of strains and specimens used for taxonomy. In particular, national governments should not excessively restrict the academic use of biological resources, especially type strains of bacteria and reference strains of fungi and algae. As much as possible of the information associated with these strains should be made available to the public.
5. In addition to the strains referred to above, the data from the inventory work in each country should be managed within database systems which support global networking, and which are effective for supporting the clearing house mechanism of transfer of microbes and guarantees continuity between generations.

pay attention so that the CBD does not hinder development of strategic inventorying of microbial diversity.

- 5) The data from the inventory work in each country should be managed within database systems which support global networking.

As stated at the beginning of this section, the availability of precisely identified and validated microbial resources is essential for scientific research and industrial and other applications. On a long term basis, microbial taxonomy is an essential tool to implement the three objectives of CBD, including ABS.

Experiences of NITE-BRC in Collaborative Research with Other Countries

NITE-BRC signed memorandums with governmental organizations in Asian countries; with Indonesia, Mongolia and Vietnam for collaborative research for the conservation and sustainable use of microbial resources, and with China and Thailand for collaboration between culture collections. The framework and content of the joint projects vary, on a case by case basis. The following is an example of collaborative research:

- Sharing of research results
- Installation of equipments for capacity building
- Collaboration in sampling, isolation and taxonomical characterization
- On-site workshops for technology transfer
- Hosting of researchers at NITE-BRC facilities for joint research and/or technology transfer

Note that, since this is a collaboration project between government institutes, the form of benefit sharing is non-monetary.

The Asian Consortium for the Conservation and Sustainable Use of Microbial Resources (ACM)

NITE contributed to the establishment of the Asian Consortium for the Conservation and Sustainable Use of Microbial Resources (ACM) with 12 Asian countries. The ACM is aimed mainly at the following activities:

- Human resource development and capacity building to manage culture collections of microbial resources for ex-situ conservation in each member country
- Establishment of the network of biological resource centers and

the database of culture collections of microbial resources with a common interface

- Development of the material transfer system to facilitate international collaborative research among the member countries in compliance with the CBD

These activities in the region have been useful for the streamlined and effective implementation of access to microbial genetic resources, benefit-sharing and capacity-building on the basis of mutual understanding and goodwill, consistent with the principles of CBD and the Bonn Guidelines.

Development of 'Japan's ABS Guidelines for Users'¹⁰

Soon after the adoption of the Bonn Guidelines in February 2002, JBA translated them into Japanese. Using the Japanese translation, JBA disseminated the Bonn Guidelines by organizing more than 8 public seminars in major cities across the country during 2003 and 2004. This helped to enhance the awareness of genetic resources users, i.e. companies and researchers, about the Bonn Guidelines.

As the Bonn Guidelines became better understood in Japan, a number of users expressed their views that descriptions of the Bonn Guidelines were often too general to be helpful for them to cope with their practical needs. They emphasized a need for user-specific and user-friendly guidelines. Taking these experiences into consideration, METI decided to develop user-specific guidelines on the basis of the Bonn Guidelines and the CBD. In consultation with experts from industry and academia, METI started working on such guidelines in cooperation with JBA in 2004. The Guidelines on Access to Genetic Resources for Users in Japan ("Japan's ABS Guidelines for Users" for short) were completed and published in Japan in March 2005.

The Japan's ABS Guidelines for Users aim to help both providers and users of genetic resources to build win-win relationships, and to minimize the risk of getting involved in problems, while ensuring business flexibility. To promote their dissemination, JBA held since 2005 more than 12 public seminars in 6 major cities across the country. Its English translation was completed in February 2006.

Governmental Support for Users of Genetic Resources

On the basis of the Japan ABS Guidelines for Users, METI and JBA have developed a number of tools to support users of genetic resources.

- Bilateral workshops and meetings with CBD officials of providing countries:
In order to promote development of partnership between users of genetic resources and providing countries, JBA, supported by METI, invited CBD officials (or experts) to Japan for information exchange at public workshops or meetings. They were requested to present information to the audience on their national policy, laws and regulatory systems relevant to ABS implementation. In some cases, JBA went to providing countries for information exchange. So far, JBA and METI have held such bilateral workshops or meetings with the following countries; Australia, Brazil, Bhutan, China, India, Indonesia, Malaysia, Mongolia, Myanmar, Nepal, New Zealand, Singapore, Thailand and Vietnam.
- JBA's specialized website for ABS-related information on providing countries:
JBA created a Japanese-language website specialized for disseminating information on ABS-related policy, laws and regulation of different countries, for users of genetic resources.
- JBA's Help Desk:
JBA has been involved in the CBD matters since 1993. Based on this experience, JBA gives, to users of genetic resources, advice on ABS matters to those who have questions or problems, free of charge and on a confidential basis. Since 2005, JBA has handled more than 90 cases of such consultation, as of April 2008.

Concluding Remarks

Our approach is based on mutual understanding and trust. We choose partners when both sides feel comfortable with each other from that perspective. So far, we feel that this approach has been working. The following statement is my personal view.

Social and economic situation is different in different countries. Therefore, domestic needs are different, national policy is different, and, in turn, laws and regulatory systems are different. However, even under these circumstances, different peoples can successfully collaborate if they identify a point of mutual interest. Key to success is mutual understanding. Steps for win-win partnership development would be as follows:

- 1) Understand each other's national situation.
- 2) Set a mutually agreed target, and jointly develop practical and

effective procedure for collaboration based on the national laws of the providing country, or the principles of CBD and the Bonn Guidelines if there is no such law.

- 3) Help each other to overcome risks, achieve the target and generate benefits.
- 4) Share the benefits in a fair and equitable manner based on the agreement made in 2.

Endnotes

¹ JBA is a non-profit organization dedicated to the promotion of bioscience, biotechnology and bioindustry. JBA was established in 1942 through the support of industry, academia and government. Today, JBA functions as a think tank and a platform for cooperation among scientists, technologists, corporate managers and policymakers.

² Nenkan (2007).

³ Sumida. and Okuda (2008).

⁴ ibid

⁵ The Tokyo International Forum on Conservation and Sustainable Use of Tropical Bio-resources, Results of the Bilateral Research Cooperation Projects Between Japan and Each of Thailand, Indonesia and Malaysia from 1993 to 1999, NEDO and JBA, November 9-10, 1998, Tokyo, Japan

⁶ ibid

⁷ Dogan (<http://www.bio.nite.go.jp/dogan/Top>)

⁸ WFCC Newsletter, No. 38, Global Taxonomy Initiative (GTI) and Taxonomy, January 2004, p.50 (<http://www.wfcc.info/NEWSLETTER/newsletter38/index.html>)

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¹⁰ Sumida (2008).

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Access and Benefit Sharing: Issues related to Marine Genetic Resources

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Abstract: Since the entry into force of the CBD in 1993, countries have struggled to find answers to several questions related to ABS issues and have spent considerable amounts of time, energy and money in understanding how to operationalise these principles. One critical area that is beginning to appear during the discussions under the international regime is the status of marine genetic resources with a particular emphasis emerging on genetic resources available in areas beyond national jurisdiction. This paper presents some key legal and policy issues that negotiators of the international regime on ABS need to consider in relation to marine genetic resources.

Keywords: CBD, ABS, Marine, Genetic Resources.

Introduction

One of the key innovations of the UN Convention on Biological Diversity (CBD) was the way it sets out key principles relating to Access and Benefit Sharing (ABS) in relation to genetic resources. For example, Article 15 of the CBD on Access to Genetic Resources states that each Contracting Party shall endeavor to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties. Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources. Each Contracting Party shall endeavor to develop and carry out scientific research based on genetic resources provided by other

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Views and opinions expressed in the paper are those of the authors and not the organizations they represent.

Contracting Parties with the full participation of such Contracting Parties. Moreover, each Contracting Party is required to take legislative, administrative or policy measures with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources.¹

At the same time, it is also one of the most contentious aspects of the Convention because of limited experience of countries in dealing with ABS besides ABS discussions spanning social, economic and cultural arenas. Since the entry into force of the CBD in 1993, countries have struggled to find answers to several questions related to ABS issues and have spent considerable amounts of time, energy and money in understanding how to address these questions. Though more than six years were spent on developing a voluntary set of guidelines on ABS (the Bonn Guidelines) in 2002 countries quickly moved on to the development of an 'international regime' on ABS with limited focus on implementing/using the Bonn Guidelines. In 2006 Parties to the CBD decided that they will have to complete negotiations for the international regime by 2010. However, this process of defining the nature, scope, objective and elements of the regime seems to be taking longer than expected.

One critical area that is beginning to emerge during the discussions under the international regime is the status of marine genetic resources with a particular emphasis emerging on genetic resources available in areas beyond national jurisdiction. This paper presents some key legal and policy issues that negotiators of the international regime on ABS need to consider in relation to marine genetic resources. The intention on the paper is not to provide a prescriptive idea for the negotiations, but provide an information compilation which may provide useful to negotiators to consider when finalizing the international regime on sectoral issues such as marine genetic resources and links to other multilateral negotiation processes.

Marine Genetic Resources

In recent years the question of the status of genetic resources of marine areas both within and beyond national jurisdiction has been a subject of debate in the forums associated with the Convention on Biological Diversity, the International Seabed Authority, the United Nations Informal Consultative Process on the Law of the Sea, the annual debates

of the United Nations General Assembly on Oceans and the Law of the Sea, and more recently, in the deliberations of Ad Hoc Open-ended Informal Working Group to study issues relating to the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction. Discussions in these forums has focused on three main issues pertaining to both areas within and beyond national jurisdiction: access and benefit sharing in relation to marine genetic resources; the establishment of marine protected areas (MPAs); and the regulation of mineral prospecting operations at hydrothermal vents sites and, more generally, of environmental impacts of human activities in open and deep ocean areas². In addressing questions associated with access and benefit sharing in relation to marine genetic resources the international community should be mindful of the consequences for integrated oceans governance of failing to recognize the linkages between those issues.³

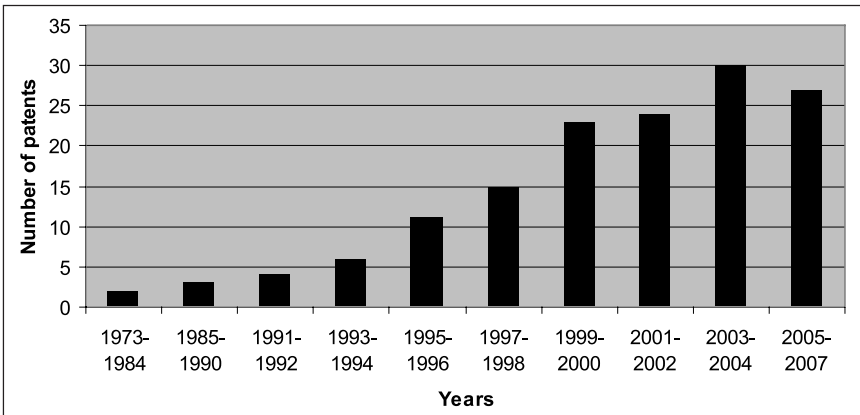
Marine Prospecting

While there is a considerable divergence of views within the international community as to the precise meaning of the term “bioprospecting”, at least in the context of marine genetic resources the term “bioprospecting” is more accurately defined as including the entire research and development process from sample extraction by public scientific and academic research institutions (which are generally but not exclusively funded by governments), through to full scale commercialization and marketing by commercial interests such as biotechnology companies.⁴

The focus of research on marine genetic resources is gradually becoming broader and also encompasses deep sea genetic resources as well as genetic resources from other areas beyond national jurisdiction such as Antarctica. According to a recently published study⁵ at least 135 patents relevant to marine genetic resources were filed in the period from 1973 to 2007 (see Figure 1 below). The search undertaken for the purposes of that study was conducted using simple key words including the terms ‘marine genetic resources’ and should therefore be considered as purely indicative.

The patents identified in that study were classified according to categories reflecting six domains of application: chemistry, pharmacology, cosmetics, food, agriculture and health care.

Actual patenting activity is probably much greater than that limited search suggests. For example a subsequent study published in 2008 identified

Figure 1: Number of Patents involving Marine Genetic Resources filed from 1973-2007

Source: Vierros et. al 2007.

at least 20 patent and or patent applications based on or derived from marine sources in the Arctic alone.⁶ These patents fell into seven broad categories of potential or actual use including medicines or pharmaceuticals, animal health care products (including aquaculture), food technology, enzymes with industrial applications, enzymes with life science research application, cosmetics and skin care, and nutraceuticals (including dietary supplements and other health products.⁷

It is very difficult to clearly quantify the monetary value of marine biotechnology due to the lack of clear global data.⁸ Although there have been a number of studies on the commercial value of marine biotechnology, it is difficult to accurately place a figure on the commercial value of marine biotechnology due to variations in assessment methodologies.⁹ Some studies have attempted to give a global view of the marine biotechnology industry. For example, one recent study estimated that in 2004 marine biotechnology globally was valued at 2.2 billion excluding aquaculture, seaweed and processing related industries (Douglas-Westwood Limited 2005). Other studies have focused on specific market values of industries commonly using marine genetic resources and approximate annual sales of selected marine-based products.¹⁰ One cancer-fighting agent alone sourced from marine sources is estimated to have annual sales of US\$1 billion in 2005.¹¹ Another recent study estimates that in 2002, global sales of marine biotechnology products, including anti-cancer compounds, antibiotics and antivirals, were estimated at about US\$2.4 billion.¹²

Despite all of these studies there has so far been no single authoritative valuation of the marine genetic resources and their commercial uses and there is little if any clear data on the commercial use of marine genetic resources sourced from marine areas beyond national jurisdiction. Unlike the debate surrounding climate change there has so far been no “Stern Review” for the oceans and marine genetic resources in particular. Moreover, an eventual monetary valuation of marine genetic resources should take into account the values of the services of deep sea ecosystems.¹³ Such a review is long overdue.

Legal Issues Concerning the Commercial Use of Marine Genetic Resources

Marine genetic resources found within areas of national jurisdiction are to be accessed and used according to the relevant provisions of the 1982 Law of the Sea Convention (LOSC), the CBD and other relevant international agreements. The LOSC does not provide a definition of the term ‘marine areas beyond national jurisdiction’, but it is generally accepted that the term ‘marine areas beyond national jurisdiction’ refers to the two discrete jurisdictional zones referred to in the LOSC known as the ‘High Seas’ and the ‘Area’. Following the provisions of Article 86 of the LOSC the ‘High Seas’ may be regarded as all parts of the sea that are not included in the exclusive economic zone, in the territorial sea or in the internal waters of a State, or in the archipelagic waters of an archipelagic State. The ‘Area’ is defined in Article 1(1) of the LOSC as “the sea-bed and ocean floor and subsoil thereof, beyond the limits of national jurisdiction”. Uncertainty exists as to the extent of coastal State jurisdiction over marine genetic resources on the continental shelf beyond the Exclusive Economic Zone (EEZ). This uncertainty relates primarily to the sovereign rights of the coastal state over the so called sedentary species under LOSC. But as this subsidiary issue has received little attention in the international debate so far this question is not addressed in this paper (for further examination of this issue see publications such as (Allen 2001), (Korn et. al 2003) and (Leary 2007)). For the purposes of this paper the term ‘marine areas beyond national jurisdiction’ may be regarded as referring to all parts of the sea that are not included in the EEZ, in the territorial sea or in the internal waters of a State, or in the archipelagic waters of an archipelagic State including the water column and the Area.

It is worth noting that in marine areas beyond national jurisdiction two separate legal regimes apply to the 'High Seas' and the 'Area'. As a matter of customary international law and under the LOSC it is generally accepted that marine genetic resources are freely accessible to all, that is to say access to and the sampling of marine genetic resources in the High Seas is regarded as a legitimate exercise of freedom of the High Seas. In that regard it is worth noting that the list of High Seas freedoms listed in Article 87(1) of the LOSC are not exhaustive and for present purposes it is worth noting that "freedom of the high seas" includes, "*inter alia*" "freedom of navigation", "freedom of scientific research" and "freedom of fishing".

The position with respect to the 'Area' is more complex. It is generally accepted that access and benefit sharing in relation to the genetic resources of the Area is unregulated. Such activities fall outside the operation of the main international legal regime applicable to the deep sea established by Part XI of the LOSC and the 1994 Implementation Agreement in relation to Part XI of LOSC (the Part XI Agreement).¹⁴ These treaties established a very detailed international regime governing exploitation and benefit sharing in relation to the mineral resources of the Area. Principally this regime vests the International Seabed Authority with a mandate to regulate the exploitation of the mineral resources of the 'Area'.

However, the genetic resources of the deep sea do not fall within the 'resources' to which that regime applies.¹⁵ This is because the definition of 'resources' contained in Article 133(a) of LOSC limits the International Seabed Authority's mandate to "all solid liquid or gaseous mineral resources in situ in the Area at or beneath the sea-bed, including polymetallic nodules". As such the International Seabed Authority only has a mandate to regulate exploitation of those mineral resources. Its mandate does not extend to the genetic resources of the 'Area'. However, the International Seabed Authority has recently expressed a desire to address issues associated with the sustainable management of deep sea biodiversity to the limited extent that its mandate allows (principally with respect to mining).

There has been some debate in various international forums as to whether deep sea genetic resources and or marine genetic resources more generally in areas beyond national jurisdiction should be regarded as the common heritage of mankind [sic], as that term is used in LOSC. In the case of marine genetic resources in the High Seas it is unlikely that this is correct as this is inconsistent with such resources being subject to High Seas freedoms.

In the case of the genetic resources of the Area the common heritage of mankind [sic] status of genetic resources as distinct from deep sea mineral resources is disputed. Regardless of whether or not these resources are regarded as or subsequently designated as the common heritage of mankind or not, this still does not address the core issue of the absence of regulation of access and benefit sharing in relation to these resources in areas beyond national jurisdiction. Even if marine genetic resources were regarded as the common heritage of mankind there is still no mechanism provided for in LOSC to regulate access and benefit sharing in relation to these resources.¹⁶

It is also worth noting that certain marine species found in the Area possess pelagic larval life stages, which implies that, for a certain period of their life cycle, these resources are to be found in the water column. Issues related to different stages of the life cycles of marine genetic resources (which may be pelagic or benthic, depending on the species in question) are currently not adequately reflected in the international discussions on these resources.

Perhaps even more significant than the debate as to the applicability or otherwise of the concept of the common heritage of mankind is the role played by patents in the exploitation of marine genetic resources. The grant of a patent in relation to development of biotechnology from marine genetic resources is the key legal act in the bioprospecting process.¹⁷ Unlike other resources of the ocean such as minerals or fish, in the case of marine genetic resources often one small sample can be developed into a new product, while in some areas of research often the final commercialized product is based on a derivative and no subsequent sampling of the original organism is required. This is not always the case though, as some research on certain new drugs requires harvesting of large quantities of the marine organisms. Ultimately only the person who holds the patent on the new product developed can lawfully exploit that product or license others to exploit the product. Thus even if a third party could obtain another sample and reproduce the initial biotechnological product, that third party's ability to exploit that product would be subject to the patent rights held by the first party to patent the product.¹⁸

Importantly, it is worth noting that the grant of a patent is essentially a sovereign act of a nation State, albeit to an extent subject to international treaties such as the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the

Purposes of Patent Procedure (the Budapest Treaty).¹⁹ This is especially significant in the case of biotechnology derived from genetic resources sourced beyond national jurisdiction because regardless of where the original genetic resource is sourced, the grant of a patent is always something that occurs within a State's jurisdiction. This means that the rights of a patent holder are determined by the domestic law of the State in which the patent was granted (subject to that State's international legal obligations including obligations under TRIPS and the Budapest Treaty). Thus rights in relation to patents (as opposed to the question of access rights) are not affected by the absence of a specific regulatory regime in areas beyond national jurisdiction.²⁰

Key Issues that the International Community Needs to Address with Respect to Genetic Resources from Areas beyond National Jurisdiction

The core issue of course is whether or not benefits associated with exploitation of marine genetic resources should be shared by the entire international community, not just by the wealthy developed states with the capacity to exploit such resources, which remain difficult to access, technologically and financially.²¹ Once the international community reaches a consensus with respect to the need for access and benefit sharing to be regulated then arguably the single most important step will be to link that regime to international and domestic regimes dealing with the grant of patents with respect to marine genetic resources.²²

One author has proposed that this might be achieved with minimal change to the existing patent system.²³ This proposal suggests that benefit sharing in relation to such resources might be achieved by means of royalties payable in relation to patents granted in relation to deep sea and other marine genetic resources sourced from areas beyond the limits of national jurisdiction. Thus it has been suggested that this could be achieved by establishing a form of trust fund with royalties to be made payable to that trust fund. The payment of royalties could be made a condition of the grant of the patent which would be imposed under domestic law. In addition to existing disclosure requirements, those depositing microbes in type culture collections under the Budapest Treaty might also be required to identify the exact geographical location of where the microbe is sourced thus making it possible to identify whether or not the proposed benefit sharing regime applies.²⁴ Much of the scientific literature reviewed for the purposes of this and previous

studies have contained information on the location where the original samples were taken from, often identifying precise co-ordinates of latitude and longitude. Although this is not always the case.

It is important to note that the proposal noted above would only extend to genetic resources sourced from areas beyond national jurisdiction as those within national jurisdiction already fall within the regime recognized by the CBD. A few parameters for the proposed royalty have also been suggested and should also be noted. Firstly it has been suggested that a good benchmark figure may be similar amounts paid under access and benefit sharing arrangements within national jurisdiction.²⁵ Secondly it has been suggested that it would be preferable that any such royalty be linked to the actual sale of products derived from such genetic resources. This would minimize the royalty becoming a disincentive to research and development.²⁶

Questions also need to be considered in relation to the environmental impact of activities such as marine scientific research which provide the samples for research and development. It is not yet clear whether the scale of the environmental impact of such activities warrants regulation. Clearly further detailed scientific research on the nature and scale of such activities is required.²⁷ Before any regime is imposed to regulate the environmental impact of marine scientific research, if in fact such a regime is warranted in the first place, it is important that there is close examination of the impact of such a regime on scientific research. Ill conceived and hasty regulation runs the risk of setting back very valuable scientific research.²⁸ At a minimum, as earlier studies have noted (eg (Vierros et. al 2007) and (Leary 2007)) any regime must be developed in consultation with the scientific community who are both stakeholders and advisors to policy makers.

However, as evidence is emerging that marine scientific research does have some environmental impact (especially at sites that are repeatedly visited) a precautionary approach would mandate that the international community consider seriously the nature and scale of its impact, and the extent to which regulation is warranted.²⁹ There are precedents for the sustainable management of the environmental impact of science beyond national jurisdiction. The most obvious example is the mechanisms of the Madrid Protocol to the Antarctic Treaty which is primarily implemented via domestic legislation of contracting parties. The Madrid Protocol is a suitable model for regulating the environmental impact of scientific research in areas beyond national jurisdiction

including the deep sea.³⁰ Compliance with an environmental impact assessment mechanism modelled on the Madrid Protocol might be enhanced if compliance with any such regime was made a condition of receiving government funding for scientific research as already occurs in several jurisdictions.³¹ Such an environmental impact assessment regime might also be incorporated into regimes for the management of MPAs in areas beyond national jurisdiction.³²

Issues under CBD

The other main treaty of relevance to these issues is the CBD. However, the CBD appears to have only a limited application to activities in areas beyond national jurisdiction. In a meaningful practical sense the CBD would only appear to apply to activities beyond national jurisdiction to the extent that States regulate the activities of their own nationals. So far no State regulates the activities of its nationals with respect to the genetic resources in areas beyond national jurisdiction.³³

Under Article 4, the jurisdictional scope of the CBD is limited to components of biodiversity found in areas within the limits of national jurisdiction. Deep seabed and other marine genetic resources in areas beyond national jurisdiction are therefore excluded from the CBD's scope. However, the CBD applies to processes and activities, regardless of where their effects occur, carried out under the jurisdiction or control of states within or beyond areas subject to national jurisdiction. As observed by Arico and Salpin (2005) "it follows that activities undertaken in the High Seas or the Area, including navigation, scientific research, bioprospecting, exploration, exploitation dumping and tourism, fall within the scope of CBD if they are carried out under the control or jurisdiction of a CBD Party".

As Arico and Salpin (2005) go on to observe

"Under Article 22, the CBD does not affect the rights and obligations of Parties deriving from existing international agreements, except where the exercise of those rights and obligations would cause serious damage or threats to biodiversity. Since the exploitation of marine genetic resources in areas beyond national jurisdiction including those of the seabed implies value-addition, several articles of CBD could provide a basis for States to regulate bioprospecting activities of their own nationals in relation to such resources. These articles include Articles:

- 8 (d) on protection of ecosystems and species, *in situ*
- 9 (d) on the regulation and management of collection of resources
- (c) on the identification and monitoring of processes which have or likely to have significant adverse impact
- 8 (l) on the management and regulation of processes and activities having significant adverse impacts and
- 14 (a) and (c) on environmental impact assessments and exchange of information regarding activities having significant adverse impacts.

These provisions provide a basis for development of impact assessment guidelines, technical standards, monitoring activities and setting thresholds for collection and use of marine genetic resources".³⁴

According to Arico and Salpin (2005) a study carried out analyzing CBD Decision II/10, was presented at the 8th meeting of the Subsidiary Body on Scientific Technical and Technological Advice (SBSTTA) of the CBD in March 2003. It outlined relevant provisions of the CBD and UNCLOS, and concluded that

"neither the United Nations Convention on the Law of the Sea nor the Convention on Biological Diversity provides a specific legal regime for commercially-oriented activities relating to marine genetic resources on the High Seas and in the Area," and stressed the need to develop a legal regime to regulate them. A similarity between the objectives pursued by the international community both under UNCLOS and the CBD was noted, since both instruments aim at the conservation of marine biodiversity and attempt to ensure sustainable use of its components. The study stressed that while the CBD further aims at a fair and equitable sharing of the benefits arising out of the use of genetic resources, UNCLOS aims at an equitable sharing of benefits arising out of mineral resources from the Area. The following options to address bioprospecting for deep seabed genetic resources were examined: maintaining the *status quo* and leaving the exploitation of deep seabed genetic resources unregulated; applying the regime of the Area and its resources to deep seabed genetic resources, which would entail the application of the common heritage of humankind principle to deep

seabed genetic resources as well as their management by an international body for the benefit of all, and amending the CBD to bring deep seabed genetic resources within its framework." (Arico and Salpin 2005).

However, Parties to the CBD were divided on how to address the issue of marine genetic resources beyond national jurisdiction since SBSTTA 8. COP 7 of CBD through its Decision VII/5 called for rapid action to address threats to marine biodiversity in areas beyond national jurisdiction, including in relevant international fora such as the UN General Assembly. Establishment of Marine Protected Areas beyond national jurisdiction was also called for with cooperation from all relevant international agencies and processes.³⁵

In relation to deep seabed genetic resources beyond the limits of national jurisdiction, decision VIII/21 of the COP notes the biodiversity value of deep seabed genetic resources (VIII/21 paragraph 1) and recognizes the urgent need to enhance scientific research and cooperation on deep seabed genetic resources and to provide for their conservation and sustainable use (VIII/2 paragraph 2). The COP decision also emphasizes the urgent need for capacity building in developing countries relating to deep seabed biodiversity (VIII/21 paragraph 9).

Discussions under the Working Group on Access and Benefit Sharing are to cover issues of need for transparency in exchange of genetic resources and call for disclosure of origin of genetic resources in applications for intellectual property rights. Currently CBD, UNCLOS as well as other intergovernmental processes are unclear on how to address these issues.

Several studies concluded that any meaningful benefit sharing regime on deep seabed genetic resources can be effected only if such resources are brought under a regime similar to that governing the mineral resources of the Area under UNCLOS. Such an approach reflects the view taken by the G77 on the issue more than any of the other views expressed by non G77 States and other stakeholders to date. But as noted elsewhere in this paper this is by no means the only possible option for addressing the issue. The maintenance of a firm attachment to such an approach may make it very difficult for a clear resolution of the issue to be achieved. Perhaps a more flexible approach is warranted. The debate should perhaps focus on what is the best way to achieve an equitable distribution of benefits associated with bioprospecting in marine areas beyond national jurisdiction rather

than automatically jumping to the conclusion that there is but one solution to the issue.

In addition to the other models mentioned above lessons can also be learned from other regional instruments focusing on protection and use of marine environments including the Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR) that includes focus on cooperation and protection of marine environments of the High Seas and underlying seabed and sub-soil with provision of measure for protection of species and habitats; the Noumea Convention (Convention for the Protection of the Natural Resources and Environment of the South Pacific Region) that covers seabed activities; the Mediterranean Action Plan that includes maritime areas in the High Seas, beyond the national jurisdiction of the 22 Parties to the Barcelona Convention for the protection of the marine environment and the coastal region of the Mediterranean; the Antarctic Treaty System (ATS) that includes the Antarctic Treaty, the Convention on the Conservation of Antarctic Marine Living Resources (CCAMLR), the Madrid Protocol and the Convention on Regulation of Antarctic Mineral Resources Activities (CRAMRA), and the Intergovernmental Oceanographic Commission of UNESCO.³⁶

In addition several non-governmental initiatives such as the InterRidge Initiative that facilitates international and multi-disciplinary research associated with mid-ocean ridges, and the Micro-Organisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC) have contributions to make to defining the ABS provisions for marine genetic resources in areas beyond national jurisdiction.³⁷ National activities and experience such as Canada's Endeavour Marine Protected Area, the Lucky Strike and Menez Gwen Marine Protected Area of Portugal etc. also provide some examples of national interventions to deal with issues of access to marine genetic resources with limited focus on benefit sharing.³⁸

Recent Developments Relevant to Deep Sea Genetic Resources, including ABS

At a recently-held Strategic Planning Workshop on Global Ocean Issues in Marine Areas Beyond National Jurisdiction in the Context of Climate Change (Nice, France, January 23-25, 2008) held under the auspices of the Global Forum on Oceans, Coasts, and Islands and with the co-sponsorship of the Nippon Foundation, it was stressed that

“[w]hile there has been substantial progress in recent years in achieving integrated governance of oceans in areas under national jurisdiction and in regional seas areas, governance of areas beyond national jurisdiction remains largely sectorally-based, fragmented, and inadequate. This means that it is difficult to address inter-connected issues (such as the impacts of human uses on the environment, multiple-use conflicts among users, and responses to climate change effects) through an integrated and ecosystem-based approach. There are, moreover, significant differences of opinion among stakeholders regarding what actions need to be taken to improve governance in marine areas beyond national jurisdiction, especially regarding the question of distribution of benefits from the uses of biodiversity in these ocean areas” (Global Forum 2008a).³⁹

At the Nice Workshop, there were discussions about the usefulness of examining modes of benefit sharing which had been developed in other areas so as to inform future debates in the context of relevant fora, namely, the UN Working Group and the CBD. This was based on the consideration that providing an overview of the range of modes of benefit sharing represented a key step in the work of the Global Forum on improving governance of marine areas beyond national jurisdiction.

At the 4th Conference on Oceans, Coasts and Islands organized by the Global Forum (Hanoi, 7-11 April 2008), a number of such possible ABS models and tools were considered so as to further discussions on deep sea genetic resources. These models include: the IOC Abe-LOS Criteria and Guidelines on Transfer of Marine Technology; the ABS-Management Tool developed by the International Institute for Sustainable Development; The World Intellectual Property Organization contracts database; the CBD ABS case studies; the UNU-IAS Information Resources on Biological Prospecting; the OECD study on Valuation and Exploitation of Intellectual Property; the OECD study on Research Use of Patentable Knowledge: A Review; and the Call of the Earth Llamado de la Tierra and UNU-IAS publication on Pacific Genes and Life Patents, Pacific Experiences and Analysis of the Commodification and Ownership of Life – among others.⁴⁰

At the Hanoi Conference, the Co-chairs of the Global Forum Working Group on Governance of Marine Ecosystems and Uses in Areas Beyond the Limits of National Jurisdiction produced a report for consideration by the UN Working Group at its second meeting (New

York, 28 April – 2 May 2008). The report refers to current discussions in relation to access to genetic resources in areas beyond national jurisdiction and their potential for applications such as pharmaceuticals and industrial processes, as well as with regard to the sharing of the benefits arising from their utilization. The report suggests that these discussions should continue in an appropriate forum. In particular, the United Nations General Assembly *Ad Hoc* Open-ended Informal Working Group should be institutionalized as a regular mechanism that provides the forum to pursue discussions and make recommendations on issues related to marine biodiversity in areas beyond national jurisdiction, including the equitable and efficient utilization as well as the conservation of on marine genetic resources. Access and benefit-sharing, as well as capacity-building, should also be an important element of these discussions, and appropriate models of trusts that would operate on the basis of users' rights should be identified.⁴¹

Although moderate in length and scope, the discussions on genetic resources at the second meeting of the UN Working Group (New York, 28 April-2 May 2008) largely confirmed the directions of work suggested by the Global Forum WorkingGroup.

Future Options for ABS Discussions related to Marine Biodiversity

Given the need to conserve marine biodiversity, sustainably use the resources and share benefits of such use, it is important to understand the nature of the problem and this can only be achieved with further detailed study of these issues. While the CBD, UNCLOS, UNGA, ATS and others deal with issues of marine biodiversity they have so far had limited progress in linking up with each other to address issues of conservation, use and access issues for marine genetic resources. Political and administrative divisions continue to exist within each of these processes which in part appear to fail to consider a forward-looking agenda for sustainable use and ABS issues related to marine biodiversity. It is therefore important to consider the following as possible related questions or issues that need to be considered for discussion under all the above fora:

1. Discussions under CBD, UNCLOS and the related international forums need to be based on clear understanding of legal and compliance issues as well as national capacities to implement the

provisions. As such further studies are required on the capacity of all states on this issue.

2. Bioprospecting in marine environments is an emerging area of research for many countries. Environmental impacts of such actions are poorly assessed. Quantitative data and evidence to show the optimal levels of harvesting marine genetic resources is either lacking or purely anecdotal. In the absence of development of assessment tools on short and long term impacts of sourcing marine biodiversity it will be difficult for countries to assess the potential use of marine biodiversity for bioprospecting purposes. The biodiversity impact assessment and environmental impact assessment tools developed under the CBD may need to be extended for application and use in marine environments. A first step towards this goal might be a detailed study of the potential and actual impacts of bioprospecting in marine areas beyond national jurisdiction and their connections if any with other extractive uses of ocean resources.
3. Though several studies have indicated the growing commercial interests of using marine biodiversity, the economic potential of marine biological resources is yet to be ascertained. Valuation of marine biodiversity is therefore needed in order to assess the size of commercial and related markets for these resources. Simply put now is the time for a "Stern Review" for the Oceans.
4. Discussions under the Ad Hoc Open-ended Informal Working Group to study issues relating to the conservation and sustainable utilisation of marine biological resources beyond areas of national jurisdiction established by the UN General Assembly need to consider linkages with discussions under the CBD on development of an international regime on ABS. There have been some initial studies on possible options for ABS but there is limited analysis of such options. Scientific cooperation and technology transfer form the core of such options.⁴² These should be discussed in light of the commercial interests and confidentiality terms associated with use of marine biodiversity for commercial purposes.
5. A critical issue relating to benefit sharing is the interaction of any benefit sharing regime with national and international patent systems. A detailed study of how existing patent regimes interact with other relevant sources of law and policy is required. A second aspect of such a study should consider possible modalities for

interaction between patent regimes and each of the possible options for benefit sharing.

6. The nature and scale of partnerships between industry and scientific research institutions is unclear. Again what information that is available is largely anecdotal. A detailed study on the nature and extent of these partnerships, together with a study of the legal arrangements and modalities of operation of existing partnerships would help inform on-going debate on this issue, especially having regard to the close link between so called pure [sic] marine scientific research and bioprospecting.
7. Discussions both within UN and outside need to address the need for establishing an institution or process or modify an existing institution or process with a mandate to adopt conservation measures, authorise and receive access requests (if closer examination of possible options suggest this is desirable), and possibly negotiate benefit sharing arrangements, deal with technology transfer and information exchange and feed into various national, regional and international fora.

The need for such institutions or processes will however very much be determined by what form of regulation if any the international community deems desirable. There should not be regulation just for regulations sake, but instead future consideration of options should be focussed on the desired outcomes which in turn will point the way to suitable options. It is absolutely fundamental to the success of any future regime that it is outcomes focussed and is not to bureaucratic. The last thing we need is for a future ABS regime for marine areas beyond national jurisdiction to effectively put a brake on future scientific and commercial advances. Most importantly any future regime must be built on the key pillars of sustainable use and conservation of biodiversity that underlie the CBD. These principles are fundamental to the future of marine biodiversity in areas beyond national jurisdiction for present and future generations.

Conclusions

Issues identified and discussed in this paper are a clear result of limited and sometimes conflicting interests of international negotiation processes. Some of the issues that are emerging seem to stem from the advances made in scientific and technological fields that necessitate global and regional agreements to be responsive to such changing and emerging needs of countries and institutions.

It is of critical importance that international negotiations under various institutions should be based on on-the-ground realities in terms of governance options, capacities of stakeholders involved, resources and timelines available to effect change and decision making based on a holistic understanding of the issues rather than sectoral opinions. It is hoped that all the stakeholders who are either parties to the discussions or who will be affected by the decisions will understand the inter-linkages on the main dimensions of ABS identified in this paper when making decisions and drawing up protocols and action plans to conserve, sustainably use and share the benefits of genetic resources both within and beyond areas of national jurisdiction.

Endnotes

¹ Article 16 on Access to and Transfer of Technology states that each Contracting Party undertakes subject to the provisions of the Article to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment. Access to and transfer of technology to developing countries shall be provided and/or facilitated under fair and most favorable terms, including on concessional and preferential terms where mutually agreed. In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights. Each Contracting Party shall take legislative, administrative or policy measures with the aim that Contracting Parties, in particular those that are developing countries, which provide genetic resources are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights, where necessary, through relevant CBD provisions (Articles 20 and 21) and in accordance with international law. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that the private sector facilitates access to, joint development and transfer of technology for the benefit of both governmental institutions and the private sector of developing countries. Article 19 on Handling of Biotechnology and Distribution of its Benefits states 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 for such research, and where feasible in such Contracting Parties. Each Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms.

² Vierros et. al (2007).

³ *ibid.*

⁴ Leary (2007).

⁵ Vierros et. al (2007).

⁶ Leary (2008a).

7 ibid.
8 Leary (2008b).
9 Leary (2008b).
10 Vierros et. al (2007).
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12 Ruth (2006).
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28 Leary (2007).
29 Leary (2007).
30 Leary (2007).
31 ibid
32 ibid
33 ibid
34 Arico and Salpin (2005).
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36 See Leary (2007); and Arico and Salpin (2005).
37 Arico and Salpin (2005).
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39 Participants in the Nice Workshop identified a variety of options for considering the special issues involved in the management of marine genetic resources, as follows:
- Identify: a) potential benefits from research and commercialization of marine genetic resources in areas beyond national jurisdiction; b) options for benefit sharing, including learning from case studies on best practices; c) modalities for promoting equitable use;
- Promote continued and focused marine scientific research;
- Identify means of data banking, knowledge management and sharing i.e. the biotech industry should provide information on where the samples of organisms identified to be of medicinal, industrial, other value, have been collected, for management and conservation purposes;
- Involve the biotech industry in the planning process;
- Facilitate government-to-government discussions, especially between developed and developing nations;
- Identify and assess management options, which are potentially applicable in addressing the threats to marine genetic resources, including codes of conduct, permits and environmental impact assessment, area-based management, and ecosystem-based management, for adoption across sectors and regions;
- Carry out economic analysis; analysis of comparative advantage;
- Form partnerships and formal agreements of collaboration, including memoranda of understanding.

^d Vierros and Wells (unpublished).

^e Global Forum (2008b).

^e See for example Intergovernmental Oceanographic Commission, 2005.

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Access and Benefit Sharing and the Biological Diversity Act of India: A Progress Card

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Abstract: Biological Diversity Act, 2002 was enacted in the parliament of India on 5th February 2003 and to implement the above act the National Biodiversity Authority was established in September 2003. Following this the Biological Diversity Rules 2004 were notified as well as various sections of the BD Act simultaneously. For effective functioning of the National Biodiversity Authority the Regulation/Guidelines /notifications were being prepared and notified based on priority. Since the BD Act is in force in India, the application for Access for Bioresources and associated Traditional Knowledge (for research and/or commercial use), Transfer of Research Results (Technology), approval for Patent (IPR) applications and Third Party Transfer of Bioresources were received regularly and approved by the National Biodiversity Authority in accordance with the BD Act. The nitty-gritty of the process of the approval of application for access of bioresources, the criteria for benefit sharing and the recent developments in the National Biodiversity Authority in connection with access and benefit sharing are shared in this paper for transparency in the ABS process.

Keywords: ABS India, Biological Diversity Act, 2002 progress till 2008.

Introduction

India is one of the 12 mega biodiversity countries of the world as well as one of the mega-diversity countries. Demographically, it is the second-largest populated country in the world and a majority of its population still directly depends on biological resources for their livelihood. With only 2.5 per cent of the total land area, India accounts for 8 per cent of the recorded species of the world which includes countless millions of races, subspecies and local variants of species and the ecological

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processes. India is very rich in terms of biological diversity due to its unique bio-geographic location, diversified climatic conditions and enormous eco-diversity and geo-diversity. India embraces three major biological realms, viz. Indo-Malayan, Eurasian and Afro-tropical and is adorned with 10 bio-geographic zones and 26 biotic provinces.¹

Plant Diversity

About 850+ species of bacteria, 14,500+ species of fungi 6,500+ species of algae and 17,500+ species of flowering plants are reported from India till today². At National level, the information on flowering plants has been documented in 24 Fascicles by the Botanical Survey of India in addition to eight volumes covering general aspects of flora of India, such as physiography; geology; climate; botanical history; phyto-geographical divisions; endemism; centers of diversity and phyto-geographical affinities; exotics; ethno-botanical, medicinal and plants of other economic value; plant based industries; wild relatives of cultivated plants; endangered plants, habitats and their conservation; protected area network; botanic gardens and the statistical analysis of the flora have been published.

Faunal Diversity

So far 89,451 species of fauna have been identified from India and insects alone account for 59,353 species. Amongst invertebrates, parasitic forms, Meiofauna and Soil Fauna (Annelida) exhibit a very high degree of endemism at species level. Overall, 34.90 per cent of insect species are endemic to the Indian region and more than 40 per cent of Indian leech, freshwater sponges and molluscs also show endemism. Among vertebrates, highest degree of endemism at species level is seen in Amphibia followed by Reptilia, Aves, Mammalia and Pisces.³ Fisheries in India play an important socio-economic role. More than six million fishermen and fish farmers in India depend on fisheries and aquaculture for their livelihood. The harvestable potential of marine fishery resources in the Indian Exclusive Economic Zone has been estimated at about 3.9234 mt. A total fish production of 8.09 million tonnes (3.26 million tonnes from the marine sector and 4.83 million tonnes from the inland sector) had been achieved at the end of the 2007.

Crop Diversity

India's preponderance of native tribal and ethnic groups has contributed significantly in the conservation and diversification of

biodiversity. Its cultural and ethnic diversity includes over 550 tribal communities of 227 ethnic groups spread over 5,000 villages. These people have traditionally protected patches of forests in the form of sacred groves dedicated to deities and more than 50,000 sacred groves have so far been reported from various parts of the country which harbour several species of flora and fauna. India holds a prominent position among the eight vavilovian centres of origin of cultivated plants, which is the geographic region where crops exhibit maximum diversity in terms of number of races and botanical varieties.⁴ In India, rice landrace variability exists both in indigenous crops as well as those introduced from other parts of the world. Today, about 166 crop species and well over 324 species of wild relatives of crop plants are recognized and utilized for food production. Wild edible plants account for nearly 1000 species serving various purposes: 145 as roots/tubers, 526 as leafy vegetables/greens, 101 for buds/flower, 647 for fruits and 18 for seeds and nuts.

Moreover, India has rich tradition of conserving nature and natural resources. Worship of trees, forests, rivers, ponds, mountains and association of animals and birds with gods and goddesses have contributed immensely to their conservation. Various traditional systems of *in-situ* conservation of natural resources have been organised and institutionalised. Therefore, a great challenge exists for India to conserve its rich biodiversity while ensuring economical and ecological security.

Multilateral Environmental Agreements on Biological Diversity and India's Responses

India has been playing a major role in the implementation of global, international, regional and national policies and programs related to environment, biodiversity, trade and intellectual property rights. Biological diversity and associated traditional knowledge are two important areas of focus for India, with links to sustainable development. With such a focus, India is Party to the World Heritage Convention (1972), Convention on International Trade in Endangered Species of Flora and Fauna (CITES) (1975), Ramsar Convention on Wetlands (1975), Convention on Biological Diversity (1992), Agenda 21 (1992), UN Framework Convention on Climate Changes (1992), UN Convention to Combat Desertification (1994), the Trade Related Intellectual Property Rights (WTO-TRIPs) 1994, Cartagena Protocol for Biosafety to CBD (2000), FAO International Treaty on Plant Genetic Resources for Food and Agriculture (FAO, 2001) and others.⁵ CBD is the

most comprehensive legal instrument that addresses the issues of access to genetic resources and benefit sharing with explicit links to issues related to traditional knowledge associated with genetic resources. Consequent to the ratification of CBD by India on 18th February 1994 and in pursuance of the Conference of Parties (CoP) decisions of CBD that followed, the Ministry of Environment and Forests - the national focal point of CBD, has taken steps to implement the CBD provisions by promulgating the Biological Diversity Act, 2002 (NBA) in Parliament of India. Recognizing urgent need to develop human resources, capabilities and legal and public policy to enable countries rich in Biodiversity to take an active part in the new economy associated with the use of Biological Diversity, a set of rules to implement the NBA were developed in 2004. India continued to play a crucial role in furthering global debates on ABS in several international fora including the World Intellectual Property Organisation (WIPO), the Trade Related Intellectual Property Rights (TRIPS) council and others. India also is the founding member of the Like-Minded Mega biodiverse Countries (LMMC) group that worked actively towards a decision to develop an international regime on ABS. In doing so, India continues to insist that the regime must be “legally-binding” for the effective implementation of the ABS requirements enunciated by the CBD.

Biological Diversity Act, Access and Benefit sharing

The Biological Diversity Act, 2002 India, primarily addresses the issues concerning access to genetic resources and associated knowledge by foreign individuals, institutions or companies, and equitable sharing of benefits arising out of the use of these resources and associated knowledge by the country and its people.⁶ The Act governs Access and Benefit Sharing (ABS) through a three tier system, National Biodiversity Authority (NBA), State Biodiversity Board (SBB) and Biodiversity Management Committees (BMC). The NBA deals with matters relating to requests for access to bioresources and associated traditional knowledge by foreign individuals, institutions or companies, and all matters relating to transfer of results of research to any foreigner; imposition of terms and conditions to secure equitable sharing of benefits, establish sovereign rights over the bioresources of India and approval for seeking any form of Intellectual Property Rights (IPRs) in or outside India for an invention based on research or information pertaining to a biological resource and associated traditional knowledge

obtained from India. SBBs deal with matters relating to access to bioresources by Indians for commercial purposes and restrict any activity which violates the objectives of conservation, sustainable use and equitable sharing of benefits. The mandate of the BMCs is conservation, sustainable use, documentation of biodiversity and chronicling of knowledge relating to biodiversity. BMCs shall be consulted by the National Biodiversity Authority and State Biodiversity Boards on matters relating to use of biological resources and associated knowledge within their jurisdiction. In order to safeguard the interests of the local people and to allow research by Indian citizens within the country, free access to biological resources for use within India for any purpose other than commercial use for Indian people has been given to *vaid* and *hakims* (= traditional physicians) and other citizens.

Provisions for setting up of Biodiversity Funds at Central, State and Local levels are provided (Sections 27, 32 and 42) in the Biological Diversity Act, 2002. The monetary benefits, received as fees and royalties for approvals by National Biodiversity Authority is deposited in National Biodiversity Fund and used for conservation and development of areas from where resources have been accessed.

National Biodiversity Authority

The Biological Diversity Act of India, 2002 and the Biological Diversity Rules, 2004, is implemented by the NBA established by the Government of India under Section 8. The National Biodiversity Authority also performs functions such as laying down the procedures and guidelines to govern the activities such as access and benefit sharing and Intellectual Property Rights, in accordance with the Article 8 (j) of the CBD. The authority also coordinates the ABS activities of the SBB and BMC by providing them with technical assistance and guidance. NBA advises the government on matters relating to the conservation of biodiversity, sustainable use of its components and equitable sharing of benefits arising out of the utilization of biological resources, select and notify the areas of biodiversity importance as biodiversity heritage sites under this act and perform other functions as may be necessary to carry out the provisions of the act. The NBA on behalf of the Government of India takes measures to protect the biological diversity of the country as well as oppose the grant of intellectual property rights to any foreign country on any biological resource obtained from India or knowledge associated with such biological resource.

The establishment of the ABS provisions and their effective implementation in the territorial jurisdiction of India is dealt with in the Biological Diversity Act 2002 (Sections 3, 4, 6) and in the Biological Diversity Rules 2004 (Rule 14-20). This act provides for regulated access to biological and genetic resources by bonafide end-users for different purposes, including scientific research, commercial uses, biosurvey, bio-utilization, conservation and other sustainable uses, etc. The overall implementation of the Act is governed by three functional bodies viz. NBA, SBB, and BMC. NBA is the national competent authority to discharge all decisions pertaining to ABS, including prior informed consent process, approval for access and transfer of biological resources and scientific research results and technologies to foreign citizens, companies and non-resident Indians (NRIs), prior approval for applying for IPRs based on biological resources or traditional knowledge obtained from India, fixing criteria for benefit sharing, approval of third – party transfer of accessed biological resources and traditional knowledge, and several other matters related to ABS.

Access to Biological Resources and Associated Traditional Knowledge under the National Biodiversity Act

The Act stipulates norms for access to biological resources and traditional knowledge based on three ways:

- (i) Access to biological resources and traditional knowledge to foreign citizens, companies and NRIs based on ‘prior approval of NBA’ (Section 3, 4, 6 of the Act and Rule 14-20).
- (ii) Access permits to Indian citizens, companies, associations and other organizations registered in India on the basis of ‘prior intimation to the State Biodiversity Board’ concerned (Section 7 of the Act).
- (iii) Exemption of prior approval or intimation for local people and communities, including growers and cultivators of biodiversity, and *vaid*s and *hakims*, practicing indigenous medicines (Section 7 of the Act).

The key procedures to be followed for access to biological resources and traditional knowledge are dealt with under Rule 14 of the Biodiversity Rules 2004. These provisions are laid down to ensure effective, efficient and transparent access procedures through written agreements and applications in prescribed formats. Applicants seeking access to biological resources and traditional knowledge are required to

submit an application in FORM I⁷ along with an application fee of INR 10,000/-.⁸ Once the application is approved for access, an agreement has to be signed by the applicant for access of bioresources.

The NBA through appropriate consultation mechanisms, approve the applications and communicates its decision to grant access or otherwise to the applicant within a period of six months from the date of receipt of the application. The Authority is required to communicate the grant of access to the applicant in the form of a written agreement duly signed by an authorized official of the Authority and the applicant. The rule 14 also stipulates the Authority to provide reasons in writing in cases of rejection of an application and give reasonable opportunity to the applicant to appeal. The Authority shall publicise the approval granted through print or electronic media and also shall monitor the compliance of the conditions agreed to at the time of accordance of approval of grant for access, by the applicant.⁹ The access procedures are only regulatory in nature, not prohibitive in any manner to any applicant irrespective of their nationality, affiliations, origin, etc. Since inception, NBA has received more than 260+ applications for access, transfer of bioresources and patent protection. Fee has been paid to National Biodiversity Fund as per the BD Rule 2004 depending upon the type of applications.¹⁰

Revocation of access or approval

Revocation of access or approval granted to an applicant will be done only on the basis of any complaint or *suo moto* under the following conditions: (i) violation of the provisions of the Act or conditions on which the approval was granted, (ii) non-compliance of the terms of the agreement, (iii) failure to comply with any of the condition of access granted and (iv) on account of overriding public interest or for protection of environment and conservation of biodiversity (Rule 15, Sub rule 1). After having withdrawn the access permit, the Authority is required to send an order of revocation to the concerned Biodiversity Management Committee and the State Biodiversity Board for prohibiting the access and to assess the damage, if any, caused and steps to recover the damages (Rule 15, Sub rule 2).¹¹

Restrictions for access to biological resources

The Act imposes certain restrictions on request related to access to biological resources and traditional knowledge if the request is on: (i)

endangered taxa, (ii) endemic and rare taxa, (iii) likely adverse effects on the livelihood of the local people, (iv) adverse and irrecoverable environmental impact, (v) cause genetic erosion or affect ecosystem function and (vi) purpose contrary to national interests and other related international agreements to which India is party (Rule 16, Sub rule 1).¹²

Procedure for prior approval of transfer of research results

The Act does not permit any person to transfer the results of any research relating to biological resources obtained from India for monetary consideration to foreign nationals, companies or non resident Indians (NRIs) without the prior approval of the Authority (Section 4). Approval for such transfers shall be done on the basis of an application to authority in FORM II¹³ along with the payment of an application fee of INR 5000/-. The Authority within a period of three months from the receipt of an application shall take a decision on it. As in the case of access permits the Authority shall communicate the approval for transfer of research results to the applicant in the form of a written agreement duly signed by an authorized official and the applicant. The authority shall communicate the reasons in case a request for transfer of research results is not granted and shall give reasonable opportunity and time to the applicant for an appeal, if any (Rule 17, Sub rules 1-6).

Procedure for Prior Approval before Applying for IPR: (Section 6 of the Act and Rule 18, Sub rules 1-6)

All the conditions for granting approval for transfer of research results shall be applicable to any person desirous of applying for a patent or any other intellectual property rights, based on biological resources and knowledge obtained from India. The format for making such applications (FORM III)¹⁴ is annexed to the Biodiversity Rules 2003.

Procedures for Third Party Transfer of Accessed Biological Resources or Knowledge: (Rule 19, Sub rules 1-6)

The Act permits transfer of accessed biological resources or associated knowledge to a third party on the basis of the prior approval of the Authority through a process of submitting an application in FORM IV¹⁵ along with the payment of an application fee of INR 10,000/-. The other procedures remain the same as those stipulated for access to biological resources and traditional knowledge under Rule 14.

Criteria for Benefit Sharing

The Act, according to Section 21 and Rule 20 of the Biodiversity Rules,¹⁶ insists upon including appropriate benefit sharing provisions in the access agreement and mutually agreed terms related to access and transfer of biological resources or knowledge occurring in or obtained from India for commercial use, bio-survey, bio-utilization or any other monetary purposes. The National Biodiversity Authority is in the process of developing a guideline based on the provision of the Biological Diversity Act, 2002 and the same will be notified with the specific details of benefit sharing formula in an official gazette on a case-to-case basis. While granting approvals for access, NBA will impose terms and conditions so as to secure equitable sharing of benefits. These benefits *inter alia* include:

- a) grant of joint ownership of intellectual property rights to the National Biodiversity Authority, or where benefit claimers are identified, to such benefit claimers;
- b) transfer of technology;
- c) location of production, research and development units in such areas which will facilitate better living standards to the benefit claimers;
- d) association of Indian scientists, benefit claimers and the local people with research and development in biological resources and bio-survey and bioutilization;
- e) setting up of venture capital fund for aiding the cause of benefit claimers;
- f) payment of monetary compensation and other non-monetary benefits to the benefit claimers as the National Biodiversity Authority may deem fit.

The Biological Diversity Act provides for setting up of biodiversity funds at national, state and local levels. Benefits will be given directly to individuals or group of individuals only in cases where biological resources or associated knowledge are accessed directly through them. In all other cases, monetary benefits will be deposited in the Biodiversity Fund which in turn is used for the conservation and development of biological resources and socio-economic development of areas from where resources have been accessed. The time frame and quantum of benefits to be shared shall be decided on case-to-case based on mutually agreed terms between the applicant, authority, local bodies, and other relevant stakeholders, including local and indigenous communities.

One of the suggested mechanisms for benefit sharing includes direct payment to persons or group of individuals through district administration, if the biological material or knowledge is accessed from specific individuals or organizations. In cases where such individuals or organizations could not be identified, the monetary benefits shall be paid to the National Biodiversity Fund. Five percent of the benefits shall be earmarked for the Authority or State Biodiversity Board towards the administrative service charges.

The ABS procedures stipulated under the Biodiversity Act, 2002 are in line with the provisions of international laws and policies, particularly CBD and the Bonn Guidelines. The entire procedures as described in the Act can contribute substantially to facilitate an international regime of ABS on genetic resources and traditional knowledge.

Some Recent Developments under the NBA

The implementation of different sections of the Biological Diversity Act is the major task of NBA. Guidelines on Collaborative Research Projects (under Section 5 of the BD Act) involving transfer or exchange of biological resources or information relating thereto between institutions, including government sponsored institutions of India and such institutions in other countries has been prepared and notified.¹⁷ Establishment of Designated National Repository (DNR) (Section 39) is an essential part of the infrastructure for biodiversity conservation. DNR consists of service providers and repositories of preserved specimen consisting of all fauna, herbarium (dried plant material for research), the living cells, genomes of organism, and information relating to heredity and the functions of biological systems. DNRs also contain collections of culturable organisms (e.g. micro-organisms, plant, animal and human cells), replicable parts of these (e.g. genomes, plasmids, viruses, cDNAs), viable but not yet culturable organisms, cells and tissues, as well as databases containing molecular, physiological and structural information relevant to these collections and related bioinformatics." National Biodiversity Authority India has prepared guidelines on Designated National Repository and it is in the process of notification. The other guidelines such as access to bioresources or associated knowledge for research or for commercial purpose by foreigners (Section 3 of the BD Act) and determination of equitable benefit sharing arising out of the use of accessed biological resources, their by-products,

innovations and practices associated with their use and applications and knowledge (Section 21 of the BD Act), transfer of results of any research relating to any biological resources occurring in or obtained from India for further research or for commercialization (Section 4 of BD Act), intellectual property rights of invention based on any research or information on a biological resources obtained from India (Section 6 of the BD Act), biological resources normally traded as commodities (Section 40 of the BD Act), and areas of importance as Biodiversity Heritage sites (Section 37) are in the process of notification under the Act.

Conclusions

India's National Biodiversity Act and Rules form the core of India's commitment to implementing the CBD. Focus of the Act is broader than presented in this article. However, implementation of the Act requires human resource, institutional, financial capacities that still need to be strengthened along with much needed increase in awareness of public at local level in order to make the Act relevant and useful for conservation and development.

Efforts are underway to ensure the experience of India's implementation can be adequately reflected in the global negotiations on development of the international regime. In this regard, we welcome opportunities to share our experiences on development and implementation of the Act and Rules to all those interested. While national actions are based on national priorities, global influences they can make are enormous.

Endnotes

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- ³ <http://envfor.nic.in/>
- ⁴ Vavilov (1926).
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- ⁹ <http://www.nbaindia.org/approvals.htm>
- ¹⁰ http://www.nbaindia.org/approvals/status_approvals.htm
- ¹¹ <http://www.nbaindia.org/rules.htm>
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- ¹³ <http://www.nbaindia.org/applications/ruleform17.htm>
- ¹⁴ <http://www.nbaindia.org/applications/ruleform18.htm>
- ¹⁵ <http://www.nbaindia.org/applications/ruleform19.htm>

¹⁶ <http://www.nbaindia.org/rules.htm>

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The International ABS Regime Negotiations: A Business Opportunity?

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Abstract: The growing trend in the pharmaceutical industry for developing plant based drugs triggered a major global debate on access to genetic resources and sharing of benefits from these initiatives. The World Summit for Sustainable Development (2002) has shifted the global debate from Bonn Guidelines to CBD where negotiations are on at the Ad Hoc Open-ended Working Group on Access and Benefit Sharing. There are several important challenges before this group on which lot of clarity is required.

Keywords: Keywords: genetic resources, access and benefit sharing (ABS), biotechnology, Convention on Biological Diversity (CBD), biotechnology, Bonn Guidelines

Recent expert statements suggest that biotechnology is replacing pharmaceuticals as the driver for commercial research on genetic resources and, further, that this trend could accelerate in the future.¹

What is indisputably clear at this moment is the fact that genetic resources continue to fuel important process and product development in the biotechnology sector worldwide. Indeed, the potential value of genetic resources has not escaped the attention of some governments and companies. The search for new compounds in the wild, "bioprospecting" as some define it, could be worth US\$ 500 million by 2050.²

As the search for commercially promising genetic resources and their derivatives continues, the policy and regulatory environments

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around access and benefit-sharing of genetic resources (ABS) are in a state of flux – with governments moving to protect their national interests in light of their international obligations under various Conventions, Agreements and processes. Much of the debate and energy on ABS is centered in the UN Convention on Biological Diversity (CBD).

The main provisions on ABS under the Convention are set out in Article 15. States have sovereign rights over their genetic resources, and so national governments have the authority to determine how material is accessed, but should facilitate access for environmentally-sound uses. Access should be granted only with the prior informed consent of providers and requires mutually agreed terms between providers and users. Research should be carried out with the full participation of, or carried out in, provider countries, and benefits from use should be shared fairly and equitably between the users and providers.

As with the rest of the CBD, individual governments decide how to interpret and implement the ABS provisions at the national level, as each country has its own legal systems, national authorities and stakeholders. Consequently, there is a wide variation in how countries are implementing ABS (and, it should be noted, potentially leading to confusion for both providers and users of genetic resources). To address this uncertainty, in part, a working group on ABS was set up in 2001 under the CBD, and in 2002 the Convention's Conference of the Parties adopted the voluntary Bonn Guidelines on access and benefit-sharing and the fair and equitable sharing of benefits arising from their utilisation. This tool provides guidance for governments and other stakeholders (such as institutions or companies) on the development of domestic laws and policies and steps in the negotiation of ABS contracts. The Guidelines provide some clarification on prior informed consent (including advice on a workable system, and information users should provide) and mutually agreed terms (what should be included, and examples of typical terms). The Bonn Guidelines also emphasise the need for ABS National Focal Points and Competent National Authorities to provide information on national procedures for access and benefit-sharing.

While a number of countries and companies are now using the Bonn Guidelines (and they appear as relevant today as when adopted in 2002), a new international regime on ABS under the CBD was called for in Johannesburg at the World Summit for Sustainable Development

in 2002. In response, negotiations on this regime are being out in the Ad Hoc Open-ended Working Group on ABS, which has a deadline of 2010 to complete its work on the elaboration and negotiation of the regime.

Myriad challenges are confronted and are to be resolved by the International Regime negotiators. Some of these challenges are highly complex and technical in nature, while others are largely political, but no less vexing. The following un-exhaustive list of questions will need answers in order to complete negotiations on the regime. What should the objectives of the international regime be? Should the Regime embrace both mandatory and voluntary measures? Are industry sectoral approaches tenable within the international regime? Should compliance be the principal focus of the regime? If and how should negotiators deal with traditional knowledge related to genetic resources? Is ABS ultimately about capacity needs and, if so, what is the role of the private sector in this regard? How to deal with intellectual property rights issues?

One of the greatest hurdles to be overcome in the international ABS talks is, in plain words, lack of awareness on the social, economic, legal and policy links within ABS. Upon our election as Co-chairs of the ABS Working Group in 2006 by the Conference of the Parties to the Convention on Biological Diversity in Curitiba, Brazil, we identified awareness building among the keys to “unlocking” the international regime talks. Awareness must be built within and amongst countries, and involve political leaders, government officials, stakeholders, indigenous and local communities and the general public. Industry engagement, including importantly the biotechnology sector, is a critical – not only in terms of improving understanding of national interest, but equally in terms of identifying practical options and concrete solutions to existing and proposed ABS-related policies.

In the past two years we have noted an encouraging trend toward greater industry involvement in the meetings of the ABS Working Group. Not only does the number of active industry participants appear to be increasing, industry representatives have risen to the universal challenge from the Co-chairs to the Working Group to engage concretely and constructively in the debate.

This is an important and encouraging step forward. But it is insufficient. The biotechnology sector, like other industry sectors, must further engage at both the national and international levels. As we all

know, good policy ideas and solutions, more often than not, are first generated at home.

In the longer term — beyond the participation of the biotechnology and other industrial sectors in the ABS negotiations themselves — are the role and core responsibilities of the private sector in implementing the international regime. Implementation will need to take place as a large-scale exercise with business acting in partnership with the public sector and the non-profit sector, and include investment in areas such as: (1) investing in R&D, often with public funding partnerships, in food security, public health, and the conservation of biodiversity; (2) promoting biotechnologies based on genetic resources and their adaptation to distinct local environments. This is an approach that recognizes the increasing role of businesses as repositories of the most advanced (bio) technologies and the most sophisticated management methods for large-scale influence in the fair and equitable distribution of benefits arising out of the environmentally sound use of genetic resources.

We continue to urge the biotechnology sector to further engage in ABS domestic and global ABS policymaking, both in the development of policy and rules and in their implementation. Biotechnology businesses have a critical role to play in ABS, both now and in the future.

The core issue in relation to ABS is the need for clarity in terms of do's and don't's for both providers and users of genetic resources. Unless this clarity is there, conservation actions will suffer with limited use of genetic resources by perspective users. With limited or no access to genetic resources, all debates on ABS are bound to yield no results.

Endnotes

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Making Access and Benefit Sharing Regime Equitable To Women

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Abstract: Gender is a factor that determines access to resources and benefit sharing. Due to gender inequity, women could be unfairly treated in the distribution and use of resources from biodiversity and genetic research. This is true for both the indigenous and non indigenous women particularly those who are poor. An ABS regime must recognize and address this iniquitous situation for women to ensure that they have a fair share in the benefits accruing from research and use of traditional knowledge. Mainstreaming gender in ABS regimes at the international and national levels is the strategy to achieve this objective. Policies and processes that address the special situation of women are needed for the implementation of any ABS regime so that women can truly benefit from any progressive governance on access and benefit sharing.

Keywords: gender equity, gender lens, gender mainstreaming, access and benefit sharing

Introduction

The Convention on Biological Diversity (CBD) brought a global focus on the governance of genetic resources by having access to these resources and benefit sharing as one of its founding principles. The major players in this debate are the users and providers of genetic resources where developing countries (mostly providers of genetic resources) have formed solidarity among themselves to focus the discussions on benefit sharing and the prevention of misappropriation of biodiversity resources.¹

This position taken by developing countries is called for given that for a long time, many corporations and research institutions based mainly in developed countries have sometimes taken undue advantage of their dominance in the global liberalized economy in the exploitation and use of biodiversity resources of developing countries. These are exemplified in products such as medicines and food derived from these resources that are inaccessible to many of the people in poor nations.

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Genetic materials and traditional knowledge that were taken without the prior consent of communities that hold these resources also abound in the debates.²

This iniquitous state of affairs has been complained about by communities and civil society groups which are concerned not only with the unfairness that is obtaining but also with the threat to the sustainability of the environment. Among these are organizations of indigenous peoples who are among the most directly affected by corporate encroachments into their ancestral domain where the remaining forests are still found.³

To redress this imbalance, more attention has been given recently by international bodies (e.g. the UN) to the participation of national governments and of local communities in the protection and sustainable use of biodiversity resources. This is seen for instance in various international declarations and bioethics guidelines that seek to ensure the free and prior informed consent of affected communities as well as their fair share in the benefits that accrue from research and product development.⁴

However, there has not been as much attention to the gender question in such discussions compared to the attention on inequities between rich and poor countries.⁵

This paper argues that gender should be mainstreamed in an international and even in national ABS regimes for both human and nonhuman genetic resources. No ABS governance can be truly fair if it fails to ensure the protection of women's rights in ABS arrangements. The subordinated and discriminated situation of women the world over makes it easy to overlook their interests in ABS negotiation and decision making. The paper ends with recommendations for ways of making ABS governance equitable to women.

Conceptual Clarification

Before proceeding to discuss the need and role for gender to be considered in ABS debates, let us clarify the key concepts used in this paper. These are: (a) gender; (b) gender equity; (c) gender mainstreaming; and (d) gender lens.

Gender refers to roles, status and identities constructed by society that impact the allocation of power, entitlements, opportunities and prestige between men and women.⁶ *Gender equity* means fairness and justice in the distribution of benefits and responsibility between men

and women. The advocacy for gender equity results from a recognition of the differences in power between men and women that determine their well being and development thus the need to rectify the imbalances between the sexes.⁷ To promote gender equity does not mean to “invert inequalities”⁸ or to make women dominate men but to correct historical and structural disadvantages and create a just society for all.

Mainstreaming gender in ABS governance is examining the implications for women of the policies, processes and structures that will be put up and ensuring that the interest of women are integrated in the governing system.

Mainstreaming gender in ABS governance is the logical step to take when there is the application of the gender lens in examining issues of access and benefit sharing. *Gender lens* is a perspective that considers gender to be a fundamental factor of social life since it creates imbalances in power, access to and control over resources between men and women as a consequence of gendered structures, processes and systems. This is a holistic perspective because it recognizes the interconnectedness of gender with other structures of inequity such as poverty and ethnicity in all levels of social life.

Why should Gender be Mainstreamed in ABS Regime

Gender issues are issues that burden the majority population of the world – the women. Why are gender issues primarily women issues? It is because political, economic and social inequities in virtually all societies in the world are suffered by women. Gender issues are issues of discrimination and marginalization that prevent women from benefiting equitably from the resources available in the family, the community, the state and society in spite of women being the main custodians of biodiversity at household and local levels.⁹

The more visible inequities are those that result from class-based differentials in power, opportunities and resources. The less visible and oftentimes overlooked inequities are gender-based inequities. While class-based inequities should not be tolerated and must be urgently addressed, there is as much urgency in addressing gender-based inequities because these have been responsible for the untimely death¹⁰, ill health and poverty of millions of women.

Women and girls constitute the greatest majority of the world's poor.¹¹ In the same social class, there is a higher rate of unemployment

among women compared with men.¹² The ratio of malnourished women to men is overwhelmingly high. Men dominate public decision making with women mostly relegated to the domestic sphere.¹³ This is the special situation of poor women that requires particular attention in every policy and programme.

There is need for policy and mechanisms that explicitly address gender-based inequities because of the tendency to conflate gender with social class inequities. For instance, in policy or programmes that focus on poverty reduction, there is a tendency to expect that the benefits will be enjoyed equitably by both men and women. The reality, however, is that within poor communities there are structures that rationalize the subordination and oppression of women. A good example of these structures are socio-cultural norms that model a good woman to be subservient and domesticated; of the ideal mother who subsumes her needs to those of her family.¹⁴ What is the implication of these norms and of the special situation of women to their share in benefits or access to products derived from biodiversity or human genetic resources? There are several serious implications.

First, the fact that among the poor, they are poorer, means that products developed from biodiversity or human genetic resources such as medicines could be inaccessible due to their poverty. While it can be reasonably argued that poor men too would not be able to afford these medicines, poor women's access is obstructed by two intersecting factors: poverty and gender based bias whereas that of men's access is obstructed only by poverty.

How does gender and poverty intersect such that access is more difficult for women? In poor households, women as a result of their socialization to the gendered norms of their society, under-prioritize their health needs when there are demands for the scarce economic resources of the household by other members of the family. They would sacrifice their own health condition in order that the needs of their children or husband could be met.¹⁵ The situation would be different for women in well-resourced households. Poor women, therefore, suffer the consequence of the impact of the combination of poverty and gender inequity.

Second, in decision making on the distribution of benefits, women could be excluded from participation. The fact that universally men dominate the public discussion and decision making is illustrated in many actual cases of negotiations and decision-making for benefit sharing of biodiversity, involving local indigenous communities or

governmental agencies where women, if at all they are participants, constituted only a small minority in the councils that represented their communities.¹⁶ There are socio-cultural, political and economic barriers in every society that preclude poor women's meaningful participation in matters of public concern.

The participation of women, even if they only constitute the minority could be meaningful if they are able to influence the process and outcome of decision making. It is not only their physical presence that is required – for this could simply be token participation. The quality of their participation is also essential.¹⁷

In other words, addressing the inequities suffered by poor communities does not necessarily result to addressing specific disadvantages suffered by women or their particular needs. An international ABS regime that attends to inequities between rich and poor countries or a national regime that attempts to protect vulnerable communities, without explicit proviso for women's participation and entitlements could be unfair to women.

Gender Issues in Indigenous Societies

The rapid expansion of the commercial global biotechnology industry poses particular threats to indigenous people. This is a driver of increased research on biodiversity resources, especially genetic resources for commercial products (e.g. cosmetics, health foods). The growth of this industry meant greater intrusion in indigenous peoples' areas in developing countries where much of the biodiversity genetic resources are found and used by local people. As is often the case, access to and benefit sharing in resources from biodiversity are issues confronting indigenous peoples who are faced with dilemma of lack of awareness and tools to be involved in decision making.

Is gender a relevant issue in indigenous societies? The egalitarianism characteristic of indigenous societies is fast becoming extinct due to changes brought about by their interaction (in many cases, imposed) with the dominant society.¹⁸ Hierarchical and consumerist values are making inroads in indigenous societies indicated in increasing reports of domestic violence, the transformation of women from equal partners in economic activities to dependents confined to household work and sexual abuse.¹⁹

Indigenous women suffer greater discrimination than other women. The combined effects of ethnicity, gender and poverty²⁰ make

them among the most marginalized and impoverished women. These are layers of discrimination that impact indigenous women's access to and control of resources.

However, indigenous societies are usually perceived as homogeneous, meaning that while they are considered to be highly vulnerable to exploitation and deserving of protection, there is no differentiation in the vulnerability and marginalization of men and women. This is a gender-blind perception. In reality, there are significant differences in the nature and degree of vulnerability and marginalization of men and women in these societies. These important differences can be identified and understood with the use of the gender lens.

Only very recently has there been a major international instrument, the UN Declaration on the Rights of Indigenous Peoples (UNDRIP) that explicit provision is made against the discrimination of indigenous women. However, like many other UN declarations, this instrument is not legally binding although because of its moral weight it can be used to advocate for indigenous women's rights in an ABS regime.

Using the Gender Lens in Constructing ABS Governance

In Yokohama is a holograph building designed by Hiro Yamagata. A prominent feature of this building is the solar cube. The building's colour, shape and visual impact change when the viewer moves from one spot to another. This is an apt metaphor to illustrate the importance of perspective in our understanding of things.

With out the use of a gender lens, vulnerabilities and inequities would be seen as similarly experienced; a gender lens will surface the differences between men and women. If the perspective is focused on poverty alone without its link to gender, then women's interests in access to and share in benefit from biodiversity and other genetic resources could be overlooked. If a gender lens is used, then women's concerns will be an integral part of the policy, mechanisms and structures of the access and benefit sharing governance whether from biodiversity or from human genetic resources, at the international and national levels.

Ways for Mainstreaming Gender in ABS Governance

There has been substantial progress in the past three decades towards international recognition and protection of women's rights in many social and human development programs. In health and human rights, good examples are the UN Conference on Population and Development

(Cairo 1994) declaration, the Convention on the Elimination of Discrimination against Women (1975), the World Conference on Women (Beijing, 1995) and the Millenium Development Goals (MDGs). In biodiversity conservation and protection, the Convention on Biological Diversity (Rio de Janeiro, 2002) stands out for its preamble that recognizes the need for the “full participation of women at all levels of policy making and implementation for biological diversity and conservation”²¹ There have been important initiatives for mainstreaming gender in the implementation of the CBD such as those done by UNEP, IDRC, GTZ, FAO and UNDP.

However, there is a gap between good intentions as expressed in these various global policies on one hand and implementation on the other. Despite advances in legal rights, the actual state of women’s rights is dismal.²² Therefore, efforts to realize these policy pronouncements at local, national, regional and global arenas should continue. The time is opportune to advocate for gender mainstreaming in ABS governance because the meetings and negotiations are taking place at the committee level.

The Office of the Senior Gender Specialist of the World Conservation Union (IUCN) has produced an excellent policy brief for mainstreaming gender in ABS as part of its advocacy for gender equity in the environmental sector.²³ The brief makes a strong case why women should be involved in the ABS governance. It also puts forward doable ways for mainstreaming gender. Among the basic principles underlying the recommendations are: (a) gender-sensitivity in designing, planning, consulting on the content and structure of the ABS regime; (b) provision of empowering environment for women to access and share in the benefits; (c) development of women’s capability to participate meaningfully; and (d) redressing gender inequity in the distribution and use of benefits.

ABS regime that upholds gender equity

The unity of process, content and outcome is what is needed now. The outcome of any project is usually affected by the kind of process that it utilizes. If the project (like the construction of an ABS regime) is inclusive and consultative, ensuring the meaningful participation (as explained earlier in this paper) of the marginalized and oppressed, the outcome of such a process will reflect the interest of these groups. On the other hand, if the consultation and negotiation are sensitive only to the voice of the dominant or articulate, much of the concerns of those

who have no voice will be excluded in the final outcome.

However, the method for encouraging women to participate should consider their subjective and objective situation. This means recognizing that women could subjectively believe they have no right or capability to participate. They could therefore refuse to participate even if they are entitled to participate. Or it could be that their objective experience has given them valid reason to fear the consequence of participating, as for example it would take time away from their multiple domestic responsibilities and cause domestic trouble.²⁴

The process for involving women should consider this reality as well as women's time constraints. It should be innovative to enable women who have no experience at all in this type of activity to speak. It might take time for some of them to voice their needs and aspirations.²⁵

Conclusion

It was shown that socio-cultural, political and economic disadvantages are suffered by women because of their gender. However these disadvantages are oftentimes overlooked even in well intentioned policies and programs that sought to address poverty and inequity. An ABS regime that ignores this reality will contribute to the perpetuation of gender inequity.

Gender issues are complex and deeply rooted in society. Women's disadvantaged position, their own subjectivity about their persona and roles as well as the barriers that keep them from meaningfully participating in negotiations and decision making about access and benefit sharing requires a nuanced, sensitive and holistic approach. Top-down, narrow, technical and male-dominated mechanisms will not encourage women to meaningfully participate and enable them to equitably share in the benefits.

Legislating poor women's meaningful participation is easier than implementing it. ABS governance both at the national and global levels should include mechanisms for building women's capability and helping them empower themselves through equitable access and benefit sharing.

Endnotes

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² Hamilton, Chris (2006).

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⁴ Alvarez Castillo F, Dafna Feinholz (2006).

⁵ Tobin B, Lorena Aguilar (2007).

- ⁶ Alvarez Castillo F. (2001).
⁷ Y.L. Wong (2000).
⁸ Tobin, Aguilar (2007).
⁹ Alvarez Castillo, Feinholz (2006).
¹⁰ Nobel laureate Amartya Sen calls this the phenomenon of the “missing women”, meaning that more than 100 million women have died prematurely due to unequal access to resources. See Sen A. December 1990. More Than a Million Women are Missing. *The New York Review of Books*. 37(20). Page Feature.
¹¹ Division for the Advancement of Women (DAW), Department of Economic and Social Affairs. 2000. *Gender Equality, Development and Peace for the Twenty First Century: the Feminization of Poverty*. New York:DAW/UN.
¹² N.E. Moss (2002).
¹³ PAHO (2003).
¹⁴ The patriarchal ideology of the family depicts women as dependents of men, their needs provided for by the men; women’s identities are in relation to their social and biological reproductive roles. See Howard J and J Hollander (1997).
¹⁵ Santow, G. (1995).
¹⁶ Illustrative examples are the San and Kani peoples’ negotiations for benefit sharing and allocation of funds relative to their biodiversity resources with business corporations and governmental bodies. The reports on these cases are available at <http://www.uclan.ac.uk/genbenefit>
¹⁷ In the Philippines, the increase in the percentage of women in the national parliament over the years is mainly a function of political dynastism where wives, sisters or daughters stand for elective positions when the male politicians in the family are prohibited by law to be elected to the same public office for more than three consecutive terms. The female relatives are there to keep the position for the family until the time that the male politician can stand be elected to the office again.
¹⁸ Kathrin Wessendorf (2004).
¹⁹ A good source on the current situation of indigenous and non-indigenous women in India is the 2-volume work of R Indira and Deepak Kumar Behera. Eds. 1999.
²⁰ Most indigenous peoples are the poorest in the world. See Wassendorf. Op cit.
²¹ Convention on Biological Diversity. UNEP/CBD: Preamble. Available at: www.biodiv.org/doc/legal/cbd-en.pdf. Accessed July 29, 2006
²² Molyneuz, Maxine (2002).
²³ Alvarez Castillo F. (2001).
²⁴ This risk of harm is not only a subjective fear of women. It could in fact be objectively a real threat. For example, in a project intended to capacitate women to become community leaders, some of the officials of the women’s organization that was formed during the project were battered by their husbands for neglecting their domestic duties by attending meetings and trainings. See Estandarte, N, Segovia, L and Alvarez-Castillo, F. 1999.
²⁵ An example illustrates this: during a study into women’s health needs, when they were asked about their health needs during interviews, the women talked only about the needs of their children, their husbands and their parents. It was only after probing that they began to talk about their own needs - for livelihood, reproductive health services, safe and accessible water, firewood, etc.
²⁶ In Galvez Tan J, F Alvarez Castillo et al. 2006.

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Monitoring Compliance under An International ABS Regime: The Role of An International Certificate Scheme

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Abstract: One area of compliance which has received significant attention over the years relates to a potential compliance monitoring tool viz. international certificate issued by domestic authorities. This paper provides a brief overview of existing proposals for an international certificate system and of the report of the Group of Technical Experts (GTE) established by the CBD to consider on the practicality, feasibility and costs of certificate proposals. In developing any certificate system the aim of negotiators should be to develop a bureaucratically light, inexpensive, flexible system. Work should focus first on identification of the elements and procedures for any regime, only then should attention be given to what any system will be called. In this way the system will define its own name and not vice versa. Certificates should be designed to provide the information necessary for monitoring at checkpoints

Keywords: ABS, Material Transfer Agreements, TK, CBD.

Introduction

Negotiation of an international ABS regime, which has stumbled along since 2004¹, got a much needed shot in the arm at the 6th meeting of the working group on ABS (WG ABS). Adoption of a novel working methodology enabled negotiators to agree on components requiring further elaboration with a view to their incorporation in an international regime. These components are set out in five blocks that comprise fair and equitable benefit sharing, access to genetic resources, compliance, traditional knowledge associated with genetic resources, and capacity.

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The inclusion by the WGABS of compliance as one of the principal components for elaboration of an international regime may prove a decisive step in the negotiation process. Compliance, an issue which has been surprisingly marginalized in debates on ABS over the years, is at the heart of developing country calls for negotiation of an international regime. This is, however, only a very preliminary step and compliance issues are likely to prove amongst the most controversial and challenging areas facing negotiators of an international ABS regime.

The 6th WG ABS identified three areas of compliance in which there is consensus regarding the need for further elaboration of measures². These include:

- 1) Development of tools to encourage compliance:
 - (a) Awareness-raising activities
- 2) Development of tools to monitor compliance:
 - (a) Mechanisms for information exchange
 - (b) Internationally recognized certificate issued by a domestic competent authority
- 3) Development of tools to enforce compliance

One area of compliance which has received significant attention over the years relates to what the 6th Working group has described as an international certificate issued by domestic authorities, a potential compliance monitoring tool. This paper provides a brief overview of existing proposals for an international certificate system and of the report of the Group of Technical Experts (GTE) established by the CBD to consider on the practicality, feasibility and costs of certificate proposals. It then suggests a model and highlights some of the challenges that will be faced in developing a functional international certificate system.

Certificates of Origin, Source, Legal Provenance or Compliance

Monitoring access to and use of genetic resources and traditional knowledge is considered crucial for effective ABS and TK governance. At present the collection, storage, use and transfer of such resources and knowledge is subject to an ad hoc system which often involves multiple forms of documentation. This includes government permits for the collection, export and import of resources, international obligations for sanitary and phyto-sanitary reporting, internal requirements of *ex-situ* collections, and reporting necessary to meet users demands. This plethora of documentation may provide a means to

track back and identify the country of origin or legitimate provider of resources. Too often, however, different standards in record keeping breaks the chain of custody, resulting in what may be considered a loss of identity of the resources. An inability to demonstrate the origin or source of resources affects the capacity of enforcement agencies to monitor resource use and to ensure it is legal and conforms to the terms and conditions for its use. This in turn diminishes possibilities for enforcing benefit sharing obligations under the CBD.

Proposals for some form of international standardized system to document genetic resources and/or TK emerged soon after the entry into force of the CBD. An initial proposal for a CITES style permitting system³, was soon followed by a proposal for what was termed "certificates of origin".⁴ The certificate idea in particular caught on and proposals now also exist for certificates of source, legal provenance and compliance.⁵

A certificate of origin⁶ would identify the country of origin of resources and provide evidence of PIC for its use.⁷ The CBD defines a country of origin as a country having resources *in-situ*, and for domesticated crops and animals, where they developed their distinguishing characteristics. Under the CBD provider countries includes countries of origin and countries which obtained the resources in accordance with the CBD (Pre-CBD collections would not be covered). The issuance of certificate of origin in cases where TK is involved would be subject to PIC of indigenous peoples or local communities.⁸ Certificates would be monitored through a system of checkpoints, such as intellectual property (IP) applications and product approvals procedures.⁹ A certificate of origin system would in effect transfer the burden of proof regarding rights to use resources from the provider to the user.¹⁰

Certificates of source were suggested as an alternative to those of origin due to concerns that identification of the geographical origin of resources could prove impossible.¹¹ Sources to be certified would include primary sources (such as the Contracting Party providing resources, and the Multilateral System established by the FAO-ITPGRFA), and secondary sources (such as *ex-situ* collections, databases on genetic resources and traditional knowledge, and scientific literature).¹² Certificates would be linked to obligations for disclosure of the source of genetic resources and TK in patent applications. Patent authorities would be obliged to inform competent authorities of countries identified

as the source of genetic resources and/or TK of relevant IP applications where the source is declared.¹³

Certificates of legal provenance focus on the legality of use rather than on the issue of where resources are obtained.¹⁴ They would provide evidence of the geographical origin of resources and of compliance with the access laws of the providing country.¹⁵ Certificates would be recorded in an international clearing house, with users obliged to maintain the link between the certificate and genetic resources.¹⁶ Certificates could be requested at specific check points related to grant of IP rights, product approvals, grant making, and journal publications. A recent paper suggests they may be worthy of consideration as a possible tool for distinguishing TK legally in the public domain from that which has fallen into the public domain as a result of breach of a contractual or fiduciary duty, or due to misappropriation.¹⁷

The most recent proposal is for what are termed certificates of compliance. The term, which has become immediately popular, is used in the proposal to apply to cases of compliance with domestic ABS regimes.¹⁸ This proposal favours a system of internationally recognised certificates rather than a globally harmonised certificate. Its proponents have argued against the establishment of checkpoints to monitor certificates and resource use. The proposal would exclude TK from any certification system.¹⁹

The potential of a certificate system to form a part of an international ABS regime led COP 8 to establish the GTE which met in Lima in January 2007. The Group's report identifies a number of features common to all four proposals, including: (i) a certificate would be a public document issued by a competent national authority; (ii) it would serve to provide evidence of compliance with national ABS legislation; (iii) it could be required for presentation at specific checkpoints in user countries (iv) all models could cover all genetic resources.²⁰ Furthermore, the group considered that a mandatory system would be restricted to the scope of the CBD, while a voluntary system might extend beyond the Convention; potential benefits of a certificate system were likely to increase with greater participation of parties at both the user's and provider's end; and a paperless system is favourable, however, any system should be flexible enough to allow for a mixture of paper and electronic formats.²¹ The Group took the position that due to its intangible nature TK poses practical difficulties requiring special consideration before development of a TK certification scheme.

The 6th WGABS took the decision to include an international certificate issued by domestic authorities within the areas for further elaboration with the aim of their inclusion in an international regime. To this end, it has been proposed that the WGABS be given a clear mandate to prepare a set of minimum standards and procedures for an international certificate system and to provide the results of its work for consideration by COP 10 in Japan in 2010.²²

Potential Elements and Procedures for a Certificate System

This section provides a brief overview of issues which the WBAGS and GTE may wish to take into consideration in the development of minimum standard elements and procedures for an international certificate system. This is an indicative list of issues for consideration and is not intended to be exhaustive. The issues for consideration set out below have been prepared based upon analysis of: all four certification proposals and the report of the GTE; existing harmonised documentation procedures such as those developed by the International Plant Exchange Network (IPEN)²³ and MOSAICC²⁴; case studies on documentation practices of *ex-situ* collections, including the Royal Botanical Gardens Kew, the Smithsonian Institution and INBio²⁵; innovative models for contractual procedures to govern resource management, such as those of the International Treaty on Plant Genetic Resources for Food and Agriculture²⁶, Science Commons²⁷, the Potato Park²⁸ and Yellowstone National Park; conclusions of a series of international expert meetings on certificates²⁹; as well as review of the writings of numerous commentators³⁰; statements by industry sectors; and reports prepared by international organisations.

The paper seeks to avoid the often unproductive debate over what any certification regime should be called, and focus attention instead on the objectives, nature, content and scope of a certification system. Leaving what it should be called to emerge from the nature of the system itself.

What is the Purpose of Certification?

In order to determine the purpose of certification it is first necessary to consider what certification is and what it is capable of. Generally a certification system serves as a system for confirming the accuracy of something, or guaranteeing the meeting of a standard.³¹ The certificate

itself may serve to provide evidence of a legal right such as in the case of a certificate of title to a car³², or act as a mark designating the quality or nature of goods or services as, for example, the “AAA Approved” sign found at hotels.³³

In the context of ABS and TK it has been suggested that a certificate system may certify such issues as the origin of genetic resources, the source which provided resources, their legal provenance, i.e. that they have been obtained in accordance with the CBD, and compliance with relevant ABS laws.

Scope

Certificates will need to be flexible to enable certification of anything from a single sample to multiple collections under a single ABS agreement. The CBD will need to define derivatives to ensure that as resources undergo transformation documentation will continue to be held linking transformed resources and the certificate which covers such resources. This should be held at least up to the stage when benefit sharing rights are exhausted.

Further work is required to determine whether certificate should cover associated TK, and/or whether a stand-alone system for certification of TK is appropriate.

Nature

Certificates if they are to play any serious role as a tool to monitor compliance, should demonstrate compliance with relevant ABS legislation of provider countries as defined under the CBD. To this end they will need to certify the origin, source, and/or legal provenance of resources. Certificates will need to provide evidence of PIC and MAT in order to provide legal certainty which will be the principal incentive for their use by industry and the research sector. Certificates will prove more useful if they raise a presumption of fair and equitable benefit sharing. This presumption will need to be rebuttable in cases of fraud, misrepresentation and other unfair trading practices.

A system of certificates may be either mandatory or voluntary. If mandatory it is possible that it may be restricted to resources covered by the CBD. A voluntary regime could also potentially be extended to pre-CBD collections and resources collected outside national jurisdiction, such as Antarctica, the high seas, and deep sea-bed (these will be discussed further below). An incentive based system would seek to promote use

based upon the benefits for users of legal certainty arising from certification.

With regard to TK certification should be based upon PIC of indigenous peoples and local communities, and should be made with due regard for customary law and practice.

Format

The certificate of origin proposal suggests a form of passport that accompanies genetic resources, either through their entire history from collection to use ('cradle to grave'), or only for certain transactions.³⁴ The GTE supports a paperless system, but recognizes the need for any system to incorporate paper based certificates as well due to differences in technological capacity of countries.

There is growing use by a wide range of actors of systems of unique identifiers, including barcodes, and digital object identifiers (DOIs) as a means to identify resources and aid in their future tracking. Where DOIs are in use, these are usually managed by an international online registry. Use of identifiers would enhance the possibilities for maintaining a link between resources and the certificate and terms and conditions applying to them. Such a linkage would reduce cost, complexity and enable instant verification and reduce the opportunities for the fraudulent use of false certificates.³⁵

Certificates may be designated as non-transferable; transferable upon agreement to be bound by the same terms and conditions as applied to the original access; or, transferable only upon due notification to the provider country or indigenous peoples or local community, and their acceptance of such transfer. Provider countries and indigenous peoples and local communities may develop online systems to administer such transfers.

Issuing Authority

Certificates would be issued by a competent national authority in a provider country, as defined by the CBD. Certificates of legal provenance might also be issued by international genebanks of the CGIAR system for transfers covered by the ITPGRFA; this would avoid the placing of bureaucratic constraints on transfers covered by the Treaty. Potential authorities for issuing certificates for pre-CBD collections and collections from outside national jurisdiction are discussed below. In order to avoid delays and further bureaucracy certificates should be automatically issued

upon completion of an agreement based upon mutually agreed terms (MAT) in compliance with national ABS laws. An exception would be in cases where the contract's validity itself is challenged in accordance with national law. Certificates should be issued with little if any charge.

In the event that TK is to be covered by certificates, these may be issued by a national authority to demonstrate compliance with national legislation regarding PIC and MAT of indigenous peoples and local communities, for use of their knowledge and resources. Procedures for certification of TK should be managed where possible by a competent national authority representing and/or administered by representatives of indigenous peoples and local communities.

Indigenous peoples and local communities may also seek to develop their own certification authorities to demonstrate compliance with their customary laws and practices. Community protocols establishing clear procedures for certification of compliance could help to empower community control over PIC and MAT procedures.

Distinction between Commercial and Non-Commercial Use

Any certification system should avoid creating unnecessary costs and deals for pure scientific research, which covers a majority of access applications. Certification procedures may usefully adopt a two-tier system for commercial and non-commercial research. Researchers would be obliged to return to the provider country or indigenous people or local community for further PIC and MAT in the event of a desire to move to commercial related research and development activities. The terms and conditions for access may, in some cases, allow for such a change in use subject only to notification, where subsequent commercial use is governed by standard terms and conditions established by the rights holders.

Standard Material Transfer Agreements

Adoption of online access contracting systems employing standard material transfer agreements (MTAs) could greatly facilitate access to resources and TK. Increased access will increase the possibilities for discoveries of scientific and/or commercial importance and benefit-sharing opportunities for rights holders. Online systems may allow for click-licensing. Shrink-warp licensing systems may also be envisaged where receipt of resources and opening of their packaging amounts to acceptance of contractual provisions. The use of standard MTAs would benefit providers in what may often be asymmetrical negotiations with

users. Online systems may be established with a minimum of infrastructure which would benefit developing countries, and indigenous peoples and local communities wishing to manage their resources and provide them for access to a wider market. A set of standard agreements for non-commercial and commercial research could be developed by the CBD as has been done under the ITPGRFA.

Provider countries and other rights holders may decide to limit online licensing to resources which are widely available, or which are considered to have little commercial value. Obtaining access to endemic resources and high value resources such as extremophiles may require face-to-face negotiations. Likewise, indigenous peoples and local communities may designate TK which may be accessed over the Internet and restricted knowledge which can only be accessed following face-to-face negotiations, if at all. Any decision to provide for online licensing of resources or TK would be the sole prerogative of relevant provider countries and indigenous peoples and local communities themselves.

The viability of online systems will depend to a large extent upon the existence of a robust system of user measures to ensure that contracts are complied with and where there is a breach there are effective and accessible remedies. Contract law alone will be insufficient to ensure protection of rights against third parties not party to a contract for use of resources. User measures such as disclosure requirements in IP applications will also be required to help prevent misappropriation of resources and TK.

Clearing House Mechanism

A clearing house mechanism may be established to provide for register and tracking of all certificates.³⁶ This would bring transparency to the system and enable both providers and users to identify valuable resources. This may assist provider countries to regulate more effectively their resources, both for commercial purposes as well as to direct more effectively their scarce funds for conservation purposes.³⁷ Where there is online management of resources these systems may be networked providing greater access to information on resource use complementing a CHM, or in essence establishing a virtual CHM, through remote nodes.

Checkpoints

A majority of certificate proposals envisage their use in conjunction with one or more commercial and/or non-commercial checkpoints such

as intellectual property and product approval application procedures, other statutory approvals procedures, as well as in grant making and publications.

Checkpoints should be linked to high end use of resources and should not burden non-commercial users with unnecessary and costly procedures.³⁸ Placing checkpoints late in the stage of research and development will reduce costs for provider countries of any system and place the costs more firmly upon the users. If checkpoints are to prove effective in creating incentives for users to seek out PIC and MAT they will need to have substantive effect on procedures for granting of intellectual property, product approval, etc.

The principal checkpoint proposed by certificate schemes is for disclosure requirements in IP applications procedures. Proposed disclosure requirements range from a transparency measure in the form of disclosure of source³⁹, to more substantive measures including disclosure of origin and of evidence of PIC.⁴⁰ Disclosure requirements in national law have now been adopted by both developed and developing countries, including Brazil, Costa Rica, Denmark, Egypt, Germany, Norway, New Zealand, Romania, Spain, Sweden, Switzerland, and India. At the regional level, the European Community has opted for voluntary disclosure while the Andean community has adopted mandatory obligations. At the international level proposals have been made for amendment of World Trade Organisation (WTO) TRIPS Agreement to include disclosure requirements, covering origin, PIC and fair and equitable benefit sharing. A majority of WTO member countries now support such proposals.⁴¹ Switzerland has proposed amendment of the Patent Cooperation Treaty to establish mandatory disclosure of source requirements.⁴²

Care will need to be taken to ensure any disclosure requirements are drafted in terms which reflect the rapidly advancing pace of technological change. Advances such as those such as genomics and bioinformation now enable significant use to be made of genetic information without the need for physical access to genetic resources themselves.⁴³ Disclosure requirements will need to be couched in terms which address such indirect use of resources.⁴⁴

Users providing a valid certificate should be presumed to have a legal right to use resources for the purposes identified on the certificate or related terms and conditions of contract. They should also be presumed to have complied with national requirements on PIC, MAT

and fair and equitable benefit sharing. This presumption as stated above should be rebuttable under certain circumstances.

Traditional Knowledge

Indigenous peoples and local communities are as yet undecided on the appropriateness of applying certification to TK. If certification is to occur consideration will need to be given to the potential and limitations of different types of certificate systems. Certifying origin would require identification of the originators of TK or its cultural origin; certificates of legal provenance for TK may provide means to distinguish information which has fallen into the public domain due to breach of contract or of a fiduciary obligation or as the result of misappropriation; certificates of source might apply to TK held in public or private databases which cannot demonstrate a clear legal title for their commercial use (in which case, access should be limited to non-commercial use). All certificates would, in essence, be a form of certificate of compliance demonstrating conformance with national ABS and TK laws and/or customary law and practice of indigenous peoples and local communities.

Considering the complex nature of TK systems, a special meeting of TK experts should be convened in order to weigh up the merits and drawbacks associated with applying any certification system to TK.⁴⁵

Pre-CBD Collections

Where genetic resources and knowledge are in circulation outside the scope of an international ABS regime and certification system this may undermine their effectiveness, creating legal uncertainty and loopholes for unscrupulous users. The CBD does not explicitly extend its provisions to pre-CBD collections, though some countries have argued that all post CBD transfers of resources should be carried out in compliance with the CBD's provisions on PIC and MAT.⁴⁶

The proposal for certificates of origin would, in effect, exclude pre-CBD collections held in countries other than the country of origin. The certificate of source proposal might allow for certification of resources from pre-CBD collections held in provider countries. It has been argued that as pre-CBD collections are not explicitly addressed by the CBD, they are legally held and could, therefore, be granted certificates of legal provenance.⁴⁷ The certification of compliance proposal would exclude all pre-CBD resources from coverage. The GTE has suggested

that resources which fall outside the CBD may be incorporated in a voluntary system of certification. Whatever form a certification system might take there are likely to be incentives and pressure for *ex-situ* collections with pre-CBD genetic resources to bring them within a system of certification.⁴⁸ One potential solution would be for institutions holding pre-CBD collections to adopt the approach of IPEN's Common Policy Guidelines⁴⁹ that require member institutions to treat both pre-CBD and post CBD collections in the same manner.

Commercial bioprospecting activities in Antarctica, the High Seas and the deep seabed remain largely unregulated. Discussions are now ongoing in various international forums regarding the development of measures to regulate bioprospecting activities in areas beyond national jurisdiction. It has been proposed, for instance, that the Antarctic Treaty System (ATS) might be extended to include regulation of bioprospecting.⁵⁰ If this is done the ATS could also assume responsibility for certifying the legal provenance of resources. Bioprospecting activities on the High Seas are at present subject to flag State jurisdiction.⁵¹ Therefore, the flag state may be entitled to certify the legal provenance of resources. This has the dangers of having the flag country act as both judge and jury of legitimacy of collections. With regard to deep seabed resources the mandate of the international seabed authority could be amended to cover bioprospecting activities. Alternatively amendment of the CBD might be sought to encompass bioprospecting of resources collected on the high seas and the deep seabed.⁵²

The lack of a clear regulatory framework and procedures for regulating commercial bioprospecting on the deep sea-bed has been seen as a deterrent to investment in such research on the deep seabed⁵³ and in Antarctica.⁵⁴ Bringing such resources within the ambit of an international ABS regime and certification system could help to bring greater legal certainty and boost investment. One potential means for doing so would be through disclosure requirements in IP legislation. A blanket requirement obliging IP applicants to disclose the origin or source of resources and provide evidence of a legal right for their use could be applied equally to resources covered by the CBD and resources which do not fall within its remit. This is not a decision which could be taken by the CBD alone. However, an amendment to TRIPS requiring disclosure of origin, PIC and fair and equitable benefit sharing could be framed so as to apply to all genetic resources wherever obtained.

Further analysis of the relationship of a certificate system with genetic resources which are not covered by the CBD is required, including

investigation of: (i) modalities of an international certificate system which could create incentives for voluntary inclusion of non-CBD resources; (ii) measures for mandatory application of a certification system to pre-CBD collections and/or genetic resources collected beyond national jurisdiction; (iii) options for exemption of resources from any system; (iv) measures to mitigate the impacts of trade in genetic resources outside any international ABS regime and certification system.⁵⁵

Capacity Building and Further Research

There is a need for further information on current practices in the documentation and management of resources and TK, in particular regarding the practices of industry and the research sectors as well as indigenous peoples and local communities. There is also a need for targeted case studies and pilot projects on implementation of certificates at the national level and across whole chains of use from cradle to grave. Funding for GEF medium sized projects on ABS capacity building could provide a means for carrying out of pilot studies.

Conclusions

Certificates have a potentially important role to play as a compliance tool in an international ABS regime. They are, however, only one of a range of tools which will be required to establish a functional regime. They cannot be expected to resolve all the problems associated with current ABS and TK governance. Certificates in themselves are not an enforcement tool but when linked to a system of checkpoints they may play a significant role in protection of rights over genetic resources and TK.

The WGABS and GTE should begin work to prepare a set of standard elements and procedures for an international certificate system to be considered by COP 10, in Japan in 2010. To inform its work the WGABS should promote the carrying out of case studies and pilot projects. COP should call upon GEF as well as governments, international organizations and aid agencies to make funding available in the short term for necessary research and capacity building in this area.

In developing any certificate system the aim of negotiators should be to develop a bureaucratically light, inexpensive, flexible system. Work should focus first on identification of the elements and procedures for any regime, only then should attention be given to what any system will be called. In this way the system will define its own name and not vice versa.

Certificates should be designed to provide the information necessary for monitoring at checkpoints. To this end consultation should be carried out with authorities who may be called upon to enforce any system such as customs, patent authorities, police, judiciary etc.

Analysis of certification proposals and a wide range of related projects and experiences demonstrate that certificates can be practical, feasible and cost effective. Efforts should be made to secure the full and effective participation of all rights holders and stakeholder groups in the design of a certification system.

Endnotes

- ¹ The WG ABS was given a mandate to negotiate an international regime on ABS and related traditional knowledge (TK) by the 7th meeting of the Conference of the Parties (COP) to CBD, held in Kuala Lumpur in 2004.
- ² UNEP/CBD/COP/9/6
- ³ Downes (1993).
- ⁴ Tobin (1994).
- ⁵ For general analysis of certificate proposals see Tobin, Burton and Fernández 2008, Ute and Wolff 2007, Barber, Johnston and Tobin 2003. For discussion of certificates of origin Tobin 1997 and 2000; on certificates of sources, Girsberger 2004 and 2004b; on certificates of legal provenance, Fernandez 2004, 2005 and 2007; and, on certificates of compliance, Australian submission to CBD 2007.
- ⁶ Certificates of origin were first proposed as part of a wider proposal for a system of disclosure of origin in patent application procedures. Tobin B. (1994).
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- ¹¹ Switzerland. (2003), available at http://www.wipo.int/edocs/mdocs/pct/en/pct_r_wg_5/pct_r_wg_5_11_rev.pdf
- ¹² Girsberger (2004).
- ¹³ *ibid.*
- ¹⁴ Fernández J.C. (2004), available at <http://www.canmexworkshop.com/papers.cfm>
- ¹⁵ Fernández (2005).
- ¹⁶ Fernández (2007).
- ¹⁷ Tobin, Burton, and Fernández (2008).
- ¹⁸ Australia (2007).
- ¹⁹ *ibid.*
- ²⁰ Report Of The Meeting Of The Group Of Technical Experts On An Internationally Recognized Certificate Of Origin/Source/Legal Provenance UNEP/CBD/WG-ABS/5/7
- ²¹ *ibid*
- ²² Tobin et. al. (2008).
- ²³ Gröger (2007).
- ²⁴ Desmeth (2007).
- ²⁵ Tobin, B., D. Cunningham, and K. Watanabe (2004).
- ²⁶ SGRP (2007), Available at http://www.sgrp.cgiar.org/Publications/SMTA_PolicyBrief_WEB.pdf

- ²⁷ See Buck, M. (2005).
- ²⁸ See: <http://www.parquedelapapa.org/>
- ²⁹ See Dedeurwaerdere et al. (2004), Ute and Woolf (2007).
- ³⁰ See generally attached bibliography.
- ³¹ <http://www.thefreedictionary.com/certify>
- ³² Certificate of title n. generally, the title document for a motor vehicle issued by the state in which it is registered, describing the vehicle by type and engine number, as well the name and address of the registered owner and the lien holder (financial institution that loaned money to buy the car). <http://legal-dictionary.thefreedictionary.com/certificate+of+title>
- ³³ See definitions at http://www.discusslaws.com/terms/161/certification_mark.html
- ³⁴ Tobin et. al (2004).
- ³⁵ Desmeth (2007).
- ³⁶ Fernández (2007).
- ³⁷ Tobin et. al (2008).
- ³⁸ Fernández (2004).
- ³⁹ Switzerland (2003).
- ⁴⁰ Tobin (1997).
- ⁴¹ Trips Council Once Again Marked by Divisions over Disclosure Amendment, Bridges Weekly, Vol12, No.10, 19 March, 2008, available at <http://www.ictsd.org/weekly/08-03-19/story4.htm>, last visited, 25 March, 2008.
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- ⁴⁴ Tobin et al. (2008).
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- ⁴⁶ Fernández (2007).
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- ⁴⁹ IPEN (2000).
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The Challenge of a New Regime: The Quest for Certainty in “Access to Genetic Resource and Benefit-Sharing”

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Abstract: The negotiations for an international regime on Access and Benefit Sharing (ABS) are beginning to pick up significant momentum after many years of work under the Convention on Biological Diversity (CBD). ABS regime is tangled with a myriad of issues still un-agreed regarding the nature of the ABS regime, the primary mechanisms for its operation, and especially, how the regime will be practically implemented and enforced. This article focuses on some of the key legal and related issues on ABS from the past experience and suggest some ideas for taking the negotiations forward.

Keywords: CBD, ABS, Genetic Resources, Scope, Definitions, Derivatives, Legal Status, Enforcement

This May, in addition to its extensive agenda, the Ninth Conference of Parties (COP) to the Convention on Biological Diversity (CBD) will hear the “next installment” of a long story – the saga of ABS. Spanning more than 18 years, the saga reflects the most difficult quest of the CBD – the effort to realize its third objective” of *the fair and equitable sharing of the benefits arising out of the utilization of genetic resources*. (the “benefit-sharing objective or “ABS.”) Work aimed at realizing a functional ABS system has been actively ongoing since 2004, pursuant to still unclarified mandates that were originally enunciated in 2002 at the Johannesburg Summit,¹ and later adopted by the CBD COP-7, which created the Ad Hoc Working Group on Access and Benefit Sharing (the

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“AHWG-ABS”) 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 on Biological Diversity and the three objectives of the Convention.*²

This article is designed to briefly summarises some of the complex issues of greatest important to the negotiations, and explains their current status and the attitude of the negotiations at present.³ It begins with a brief introduction to the issue, explaining why the issue exists at all and why solutions to its primary operating needs have proven so elusive up to now.

The simplest proof that ABS is complex is to notice that after 16 years, it still remains unclear to many who are otherwise supremely competent professional analysts of CBD matters. The brevity and simplicity of Article 15 was possible only because the CBD negotiators chose not to identify and agree on the details necessary for final agreement on what ABS is, how it functions and what its purposes are. All that is known is that ABS is the main tool for achieving the “third objective” of the CBD,⁴ and that Article 15 gives some hints about the basic framework that the parties envision for achieving that objective. The primary components of Article 15 call upon the parties to do the following

[to] endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties.

[to] endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties; [and]

*[to] take legislative, administrative or policy measures ... with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources.*⁵

To the non-lawyer or other person without legislative experience, these few sentences⁶ may suggest that ABS is simple: one person or entity (the “user”) obtains “genetic resources” from another person, entity or country (the provider) and in exchange offers “benefits.”⁷

Alas, as further discussed in a great many writings on the topic, this simplified view is not actually what the CBD says, and is far from simple, from a practical and legal perspective.

In addition to Article 15, there are many other “ABS operative provisions” in the CBD (including technology transfer, biosafety, sharing of opportunities and repatriation of information⁸), all of which depend on the Article 15 framework.⁹

Progress to Date towards Realizing ABS

After the CBD was adopted, the parties almost immediately recognized that significant work would be required, just to figure out what ABS is and how to implement it. . In the ensuing years, work has progressed in four phases:

- ***First phase – promotion of national implementation.***

During the first 8 years following adoption of the CBD, the emphasis of national and international efforts was based on the belief that ABS could easily be implemented, if developing countries would only adopt provider-side legislation. During this period, the number of developing countries that attempted to adopt ABS legislation was variously estimated at between 50 and 100 countries. In the end, only approximately 35 have adopted any instrument mentioning ABS, and only about 18-20 countries (10% of CBD Parties) have adopted any regulatory measures or practices.¹⁰

- ***Second phase – development of the Bonn Guidelines:***

Beginning with COP V, it was clear that the cause of ABS failure was more than just a lack of developing-country legislative action. Both countries and users began to recognize the ABS concept, and the lack of a functional ABS system was becoming an impediment to commercial and research access to genetic and biological resources. International efforts focused on creating support and guidance for developing countries and institutions, still based on the idea that only provider-side measures would be needed. Guidelines and model instruments began to proliferate from many sources (primarily industry associations and NGOs), leading the COP to take on the task of developing of a definitive set of Guidelines – the “Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization”¹¹ Following their promulgation in 2002, the Bonn

Guidelines met with differing responses from different groups. Ultimately, there has been no noticeable increase in the number of countries that have adopted legislation, nor in the effectiveness or enforceability of existing national ABS systems since the adoption of the Bonn Guidelines.

● ***Concurrent phase – negotiation of the International Treaty on Plant Genetic Resources, and other work¹²***

From the beginning, following the adoption of the CBD, FAO began to address the special application of ABS concepts to food and agriculture – especially the use of foreign germplasm in conventional crop variety development practices. In 2003, FAO adopted a new instrument, the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA.) The ITPGRFA does not cover all genetic resources but only “plant genetic resources.” It applies only when these resources are used “for food and agriculture.” In addition, its primary mechanism, the “multilateral system for access to and use of plant genetic resources for food and agriculture,” applies only to crops listed on Annex A to the Treaty, and only when the specific resources being accessed are held in national or international collections or are in the public domain.

● ***Current phase – international regime negotiations***

ABS implementation still lagged, however, due to uncertainties and legal problems. Eventually, in 2002's World Summit for Sustainability issued the first call for “the negotiation of an international regime on benefit-sharing”, which ultimately led to the current ABS regime negotiations within the CBD. These negotiations have spent much of the first six years focused on determining what is meant by “negotiation of a regime,” with some countries continuing to oppose negotiation of any instrument (presuming that more informal guidance and COP decisions will be sufficient) and others assuming that the “negotiation of a regime” means “negotiation of a CBD protocol.”

The most recent meetings of the Working Group appear to have finally moved beyond those initial disagreements, with serious discussions focusing on the kinds of instruments (generally protocol, model instruments and compliance standards) that can be used to make the regime functional. If the Parties formally agree to move forward on such a framework, they will have taken the first step towards creating a functional system that could be implemented across national

boundaries – *i.e.*, toward the realization of ABS. If adopted, however, these decisions will be only the first (relatively straightforward) step toward finalizing the regime. The next section will consider several of the complex open questions that must be addressed as the next step – determining what content will go into the proposed framework.

The Next Critical Issues to be Addressed

One general (and manifestly incorrect) assumption that is still sometimes put forward is the idea that ABS can be implemented with “only” two national actions: (1) all countries provide relatively universal “access” to their genetic resources, and (2) when someone (a user) utilizes genetic resources, the user country will ensure that a share in the benefits (financial and non-financial) arising from that use will go back to the provider of those resources. This creates an incomplete picture, for several reasons. The main reason is that at present there is no “agreed understanding” on the meaning of the basic elements of ABS. This lack has been recognized since the day the convention was adopted, and continues to be a major obstacle to ABS implementation,¹³ primarily because, without such understanding each country would have to find a way to enforce 190 different national ABS laws within its own national legal system.

The process of creating a unified international regime has many layers. The following discussion focuses only on the next layer.

Incomplete Performance: User Measures and Provider Measures

The specific cause (*i.e.*, on-the-surface reason) of the failure of ABS to date, is the fact that CBD Parties have not adopted and implemented ABS legislation.¹⁴ This deficiency has two sides. First, only about 18 developing¹⁵ countries have adopted any ABS law. Those countries’ laws focus only on the “provider side” – that is, they each address the process of granting permits and/or entering into contracts for collection and use of genetic resources from their own country.¹⁶

Second, *no country* has adopted any law implementing the CBD’s required “user-side measures”¹⁷ – that is, measures governing users under their jurisdiction who utilize genetic resources of foreign origin.¹⁸ The international regime can only be functional if all Contracting Parties adopt *both* user-side and provider-side measures.¹⁹ At present, the countries that are thought to have the largest number of users under their jurisdiction are unlikely to adopt any user-side measures until the

legal issues are clear and consistent so that national ABS laws (both user- and provider-side) give legal certainty to users, providers, courts and agencies.

Many people offer explanations for the failure to adopt ABS measures. Few of these have proven correct. Ultimately, the main reasons that seem to be supported by the facts are the following:

- Basic elements of the ABS concept remain unclear, making it impossible to adopt national ABS laws that are legally clear and implementable in countries which operate under the strict “rule of law.”²⁰
- The primary focus on “provider-side” measures means that nearly one half of every ABS transactions will be un-covered by any national law, enabling source countries to assert their rights.
- There is little or no incentive anywhere to encourage users or countries with significant number of users under their jurisdiction to take action toward implementing ABS. The ABS concept has not been a “give and take” between two sides. Countries/communities which see themselves as primarily providers expect benefits, but offering no obvious *quid pro quo* in the form of anything that appears desirable for users.

Taken together these points may explain the failure of ABS. Their relevance is clearest when one remembers that ABS is, by definition, an environmental social objective to be realized through the use of commercial law concepts of equity and benefit. Those concepts can only function when one has “legal certainty” about them, and when they are built on mutuality and agreement. The next section identifies many elements which have prevented countries from adopting commercially implementable ABS measures.

Incomplete Concepts

A legally certain ABS system must be based on certain primary agreements that will enable countries to adopt functional implementation measures. Even 16 years after the Convention was adopted, the ABS regime is still not clearly defined and agreed. While provider-side measures may take many different approaches, it is essential that they must meet certain agreed requirements, so that any user country can adopt a single cross-border mechanism to apply them.

Normally, a country cannot specify particular national legislative requirements to will apply to a particular kind of cross-border situations

until all Parties have agreed on uniform elements. Specifically, in ABS, all countries’ national law should be based, at a minimum, on agreement regarding (i) the coverage of ABS, (ii) the linkage between “access” and “benefit-sharing” and (iii) the manner in which the ABS relationship is completed or terminated.

Coverage: The primary concepts and their function in the system:

Normally, the “scope and coverage” of an instrument are built primarily through definitions. In ABS many concepts are misunderstood or subject to disagreement. The following discusses some of the most common definitional/scope concerns.²¹

a. “Genetic Resources”: As of this writing, neither the COP nor any country has adopted a workable integrated system that explains the meaning of “genetic resource” in a way that would allow a government official or court to apply it. Specifically, it is not possible to look at any item and state whether it is a “genetic resource,” which is covered by ABS, or a “biological resource,” which is not.²²

In the ABS negotiations, some parties assume that the meaning of “genetic resources” is or should be essentially identical to that of “biological resources.”²³ Under that view, the legal owner of any plant, animal, microbe or any sample is also a separate owner of its “genetic resources” which are thought to be the genetic resources of the entire species. This could mean that any purchase or collection of any single biological specimen (and/or the use of any biological material in a product –as an ingredient in a bakery cake, for example) would constitute “access” to genetic resources.²⁴

Another approach holds that the meaning of “genetic resources” is “the information contained in a DNA or biochemistry of a species, subspecies or variety.” Under this approach, the biological material would be “an expression” of the genetic resources, in the same way that a published book or CD is “an expression” of the intellectual/artistic concept contained in the text or music. Like the owner of the individual book, the owner of a specimen of a species would not necessarily have the right to grant legal “access” to commercial or other use of the informational resources contained.

Currently many discussions simply adopt both views, without integrating them. This approach may be acceptable in countries whose legal systems are applied flexibly, however, it’s inconsistency creates an

almost impermeable barrier to implementation in countries who operate under strict concepts of the “rule of law.”²⁵

b. “Utilization of Genetic Resources”: Another basic question which must be answered is “*When is the benefit-sharing system triggered, and what triggers it?*” Article 15.7 appears to require only two triggers for benefit-sharing: (i) a person or entity (user) “utilizes genetic resources” from another country, and (ii) some benefits “arise from that utilization.”²⁶ Unlike the “genetic resources” definition (which cannot be pinned down concretely), it is possible to create concrete, externally verifiable definitions of “utilization of genetic resources.” If the regime clearly defines “utilization of genetic resources,” that definition can enable legal and administrative processes to know with certainty which persons are subject to benefit-sharing obligations – *i.e.*, persons engaging in certain activities or types of activities (*i.e.*, genetic manipulation and perhaps the creation of new plant varieties) – and what those obligations are. A regime based on “utilization” could regulate these activities without the need for to create an externally verifiable definition of “genetic resource.”

c. “Benefits arising from the utilization of genetic resources”: Similarly, a system for requiring, enforcing and/or motivating benefit-sharing could be functional at the practical level, only if the Parties can agree on the criteria for know when “benefits arise” from the use of genetic resources. For example, it will need to identify

- a clear point at which collected data become “research results” to be shared under Article 15.7 and/or repatriated under Article 17.2, and how sharing is to occur²⁷, and/or
- clear points at which the user’s activities and results constitute a benefit (*i.e.*, is it only a “benefit” when money is paid for a product? If not, does filing a patent application constitute a benefit to be shared?? What about approving an item for production or marketing? Should “interim discoveries” which are not separately patented or marketed, be considered “benefits” to be shared?)

Linkage between Access and Benefit-Sharing:

Another question that is not yet clearly agreed is how “access” relates to “benefit sharing.” Formerly, the simplistic view of ABS has held that benefit-sharing applies only to genetic resources obtained through licensed bioprospecting in the source country.

A few source/provider countries, as well as most users, appear to feel that ABS responsibilities only apply where the user specifically obtained a genetic resource from the source country directly – *i.e.*, by direct bioprospecting under an ABS permit.²⁸ Under this theory, if the material is acquired from a third-party (a collector, academic researcher or other third party), the transaction is not covered by ABS, and no benefit-sharing would be required. This view would thus create a loophole, enabling any user to easily avoid the entire ABS issue, without any sharing of benefits or results, or indeed any notice regarding the use of genetic resources.²⁹

To close that loophole, it would be necessary to develop a consistent and legally functional rule regarding the ownership of genetic resources, and to apply it to all utilization of genetic resources from a foreign country, no matter how those resources were obtained.³⁰ It would be nearly impossible to implement this type of a rule, however, because current science does not have a means of tracking genetic resources which would enable a scientist to identify the country providing the genetic resource from a DNA analysis of the genetic material in a particular product. Moreover, many kinds of use of genetic resources are not direct use of biological or genetic material from the species. Instead, they are undertaken through *synthesis* of the genetic or biochemical components. Most important, the use of genetic resources usually occurs in private laboratories and other places beyond normal oversight.³¹

When does ABS end? Transfers, derivatives and Contract Completion

One area that is currently a topic of very hot discussion is the question of "derivatives." Within the regime negotiation this issue must link to a larger issue – how and when ABS rights and duties finally come to an end.

In commercial situations, legal certainty depends partly on knowing exactly what rights or duties one has under any law or contract, but it is equally important for all parties to know how and when those rights and duties end. For most parties to a contract, the value of the contract depends on the value (to them) of what they are giving, as compared with the value (to them) of what they are receiving. Normally, when a contract requires a continuing regular payment with no clear end-point, this greatly decreases the value of the contract to

the person who must pay. Moreover, most countries have national laws which state that no contract obligation may continue eternally.³² There are three key concepts which must be addressed in order to determine what the “end point” of the ABS relationship should be:

- derivatives (*when does change in the resource mean that the ABS relationship is finished?*),
- transfer (*how does the transfer of genetic material, ABS rights, and/or research results affect the responsibilities of the provider, original user and transferee?*) and
- completion (*at what point is the ABS contract “satisfied?”*).

None of these has been fully decided, however, the “derivatives question” has been subject of the largest amount of discussion up to now. This issue is complicated by the fact that the term “derivative” has many different meanings in law and many other meanings in non-legal situations.³³ Discussions within the ABS-regime negotiations appear to use many of these definitions, without distinction, so that one position is apparently based on one definition without specifying which, and is challenging another argument that is based on a very different definition.

Framework Questions: ABS as Property or Other Right

Even after clarifying the ambiguous concepts above, there is another primary layer of basic issues that must be addressed in the international regime. This layer focuses on the nature of the legal rights and relationship created by every ABS law and/or contract. There are four integrated components of this issue, which are very briefly summarized here: (i) the nature of genetic resources, (ii) the ownership of genetic resources, (iii) the control of genetic resources; and (iv) inconsistencies in the legal approach to genetic resources over the course of ABS.

— Nature of Genetic Resources

After defining genetic resources, it will be essential to determine their “legal status” – that is, to know “what kind of property?” or “what type of right?” genetic resources are. To date, the legal status/nature of genetic resources has not been completely or carefully studied.³⁴

As noted above, the term “genetic resources” may mean the genes themselves (*i.e.*, the physical genetic material taken from a particular specimen), or it may mean the genetic information contained in the genetic structure of the species. In some countries, it also means the “biochemical formulas” of the various fluids and solids within the

species. Ultimately, the agreed meaning will probably be some merger of these. Contrary to some simplistic solutions, there is no legal system or concept currently in use that deals with a property type or right that is sufficiently similar to genetic resources that we can use that system as a model for regulating the ownership or transfer of genetic resources.³⁵ Although many commentators assume that genetic resources are a type of property, it is equally possible to view “genetic resources” as a different kind of intangible property — a “legal right to use” genetic information.

— Ownership of Genetic Resources

After one determines what kind of property or right is involved, there is another essential question: *Who owns that property (the genetic resource) or who is legally authorized to grant rights in it?*³⁶ This question affects the user’s “legal certainty” – he will only have a legally valid ABS contract if it is signed by the rightful owner or other authorized person.. Normally, most countries and indigenous peoples have very well developed legal systems (traditional or codified) regarding property ownership, however, they normally have many different sets of rules depending on what kind of property is involved. At present, no country has specifically stated from a legal perspective, which national “property” regime governs genetic resources.

Virtually all countries have separate functional rules governing ownership of

- rights in land and permanently constructed improvements,³⁷
- movable property,³⁸
- common property,³⁹
- sovereign property,⁴⁰
- patrimony,⁴¹
- “intellectual property”⁴² and
- other kinds of “intangible property.”⁴³

Within these categories of property there may be dozens of specialized sub-categories, subject to separate, unique rules, including rules determining who may own (or control) them, how ownership is obtained and what limits or duties apply to owners. There is no “standard” for national laws on property rights.⁴⁴ Each country divides resources among these categories differently, and allocates rights and duties of ownership differently. Countries that have formally adopted ABS laws, must still clarify which property classification will govern “genetic resources,” in general.

At present, there is still a need for significant research into this legal question. Only one preliminary study has been undertaken, but its examination assumed that “property rights” refers only to land law.⁴⁵ A more rigorous legally oriented analysis will be necessary, to enable the regime to address this issue.

— *Can one Realistically Expect to “Control” Access to or Use of Genetic Resources?*

Many of the most vocal advocates addressing ABS (especially those addressing traditional communities and knowledge) appear to assume that, a country or community can and should *control* physical access to its genetic resources and/or traditional knowledge. In fact, however, like any other secret, if even one person obtains traditional knowledge (whether by communication or by testing) or genetic information (from a sample, from test results or in other ways), then it is no longer a secret. If the system is based on “control” of the resource, then it breaks down as soon as any user obtains genetic *material* or *traditional knowledge* without ABS compliance. The source country or community cannot physically prevent him from conducting tests and research on it nor from using what he knows.

Long before the CBD negotiations, most species, and indeed most kinds of traditional knowledge have been dispersed to a large number of people, agencies and institutions both inside and outside of the source country. To be meaningful, the ABS concept must address these holders, and clarify whether and how they are included within ABS. Administratively, the simplest way would be to consider ABS as a new obligation imposed on *users* who obtain benefits by using the genetic resources, no matter where those resources were acquired (even if indirectly acquired from an *ex-situ* collection or from a researcher who has previously removed the resources from the source country.)⁴⁶ This approach would require some kind of mechanism for accounting for foreign collections and collectors, within the system without placing undue burdens on them.

— *Inconsistencies in Legal Treatment of Genetic Resources*

Finally, there are some basic inconsistencies in the “legal life-cycle” of genetic resource ownership, which form serious obstacles to consistent ABS legislation and implementation at the national level. These inconsistencies are the largest, most insurmountable obstacle to ABS implementation at present: The easiest way to describe this inconsistency is in “the four-step paradox of ABS”:⁴⁷

- Step 1: There are many potential sources for most genetic resources:
 - *the gene sequences and biochemical formulas of an entire species (subspecies or variety) are duplicated in all of its members;*
 - *there is no way to maintain complete physical control all specimens of any natural species, and their use as samples for research, genetic analysis or biochemical analysis, even if the species is a narrow-range endemic.*
- Step 2: “Ownership” and/or the right to control or dispose of genetic resources, is disseminated among many separate, unrelated holders:
 - *For nearly every species, natural distribution extends to more than one country;*
 - *Under Article 15, every country in which a species is found in situ has sovereign rights in the genetic resources of that species;*
 - *Some countries have laws which disseminate the ownership of, genetic resource widely, giving separate ownership of a species’ genetic resources to every individual who owns any specimen of that species;*
 - *Despite this diffusion of ownership, a country (community, person) that owns even a single specimen of a species may grant access to its genetic resources without consulting any other country or person who has a parallel ownership of the genetic resources of that same species.*
- Step 3: The user of genetic resources may need only a relatively small sample, obtained from one provider, in order to be able to utilize its genetic resources.
 - *modern industrial and commercial development processes can often find ways to duplicate or synthesize a species’ genetic and biochemical elements based upon only a few samples or in some cases, no samples at all (if they receive detailed research data⁴⁸);*
 - *once the initial research and development is complete, the user will often need no further physical specimens from any source.*
 - *This will be true regardless of whether the user first obtained an ABS contract or permission or not.*
- Step 4: Following access, some users try to convert the non-exclusive genetic resource (legally held and potentially usable by a great many providers) into an exclusive resource, by patenting the naturally occurring gene, rather than only patenting their innovation or invention.⁴⁹

- *If they receive the gene patent, the users could prevent (or require a royalty on) every other person, country or entity from any further commercial or pre-commercial use of the gene. This would theoretically prevent use or other transactions by (i) the country of origin, (ii) other countries-of-origin of the same genetic resource, (iii) other holders in those countries, or (iv) other users who may seek access to that genetic resource in the future*
- *Arguably, this kind of IPR defeats the purpose of ABS (which was intended to provide an incentive for conservation and sustainability), since the financial or potential value of species will be devalued following the issuance of the patent, thereby diminishing the conservation incentive.⁵⁰*
- *This type of IPR would also defeat the purpose of patents, which has been described as encouraging and protecting innovation. By contrast, an IPR which restricts the ability of other innovators to use the species' naturally occurring building blocks in other new products would appear to be an impediment to innovation.⁵¹*

This paradox boils down to a simple question: *If the user obtain his right to genetic resources from one of a large group of holders, how can he rationally convert it into an exclusive right (patent of the natural gene or traditional variety) without permission from all other holders? Or stated another way, Why should the right of one person or community or country "win" over the identical right of others?*

A "Binding Regime"—the Enforcement Problem

Another major framework concept that must be formally addressed is "enforceability." This issue has often been spoken of as "the creation of a *binding regime*" (which leads to fruitless arguments and discussions over the meaning of "binding" and the fact that any commercial legal regime will have both binding and non-binding elements.)

Enforceability questions and "binding regime" arguments sometimes distract the negotiators from a much more important question – whether it is possible for any part of the ABS regime to be enforceable *as a practical matter*. Many (perhaps most) of the problems discussed above cannot be enforced in courts. Consequently, most ABS claims are tried only in "the court of public opinion" (the press, the internet and other forums) resulting in negative publicity and other harms to users, without ultimately providing any remedy to providers and source countries. This creates a spiral of increasing distrust, more administrative requirements (in an attempt to make the ABS

responsibilities stronger and more binding) and, often, increased costs and longer processing time in obtaining the rights to use genetic resources.

All of this leads to a basic truth known to all lawyers, government administrators and commercial entities: *If a system is non-functional or imposes insurmountable obstacles to the parties, it does not matter what the system says – whether it is “binding” or “enforceable” or not – nobody will use it.* No sector’s interests will be served if the ABS system becomes unusable or so unwieldy that it discourages or prevents users from seeking ABS contracts.

In fact, of course, a regime may not be “enforceable” or “binding,” unless it can be clearly overseen, externally validated, and legally understood and applied. It will not matter whether a law states that it is “legally binding” or that it must be legally “enforced,” if it is not practically possible for courts, agencies, the parties to a contract, NGOs or other beneficiaries to take legal action to enforce it. At present, most proposals for an ABS mechanism would not be “practically enforceable,”⁵² because there is no way to know whether the user is complying, and no practical way to obtain evidence of this.

For example, if a law or contract states that the user will contribute 0.1 % from every sale of a product that uses a genetic resource, how will that provision be formally implemented and enforced? In order to implement and/or enforce such a law, one of two things must happen. Either –

- the user will pay voluntarily, without oversight or enforceability; or
- if the user does not pay as required, someone (user government, provider government, provider, NGO or other party) must bring some type of legal action – seek agency enforcement, go to court, go to an arbitration or mediation board, or some other nationally recognized mechanism. No matter which mechanism he chooses, in order for the deciding body to force compliance, the complaining person must, at minimum –
 - know that a user has used certain genetic resources without obtaining or complying with relevant permission and benefit-sharing;⁵³
 - undertake measures (gain access to the user’s facilities or obtain definitive scientific tests) to obtain and document legally valid proof that such utilization has occurred;

- know and document proof that “benefits have arisen” and what those benefits are;
- bring an action against the user under law of a country with jurisdiction over the user, which law must specifically clarify what “genetic resources” are and that use of foreign-origin genetic resources is not permitted without benefit-sharing; and
- clearly identify which country is the source country of the genetic resource, in a manner that satisfies the legal requirements under that law.

These requirements may be different in different countries. The complaining party must meet the standards of the country of jurisdiction, which usually means that he will need to obtain the assistance of lawyers in that country or other persons who know its requirements.

This can be very expensive, but is only one of the ways that legal enforcement can be costly. Unfortunately, as a legal matter, the current view of the ABS regime places the burden of bringing action on the “country providing resources.” This effectively prevents legal enforcement in most cases. The regime cannot provide much benefit to developing or least developed countries, if it forces them to protect their rights, without alleviating the cost and technical limitations on their ability to do so.

For many reasons, however, it is not possible to shift this burden directly to the user country. ABS cannot be executed by a “command and control” system, because most utilization of genetic resources happens in private laboratories and other areas. Even the richest developed country will not have sufficient manpower to inspect all facilities, and to undertake the relevant scientific analysis to determine if they are using genetic resources. Even if they could, they would not be able to know which country the resources came from, without compliance from the user. Thus, it is almost impossible to document violations by evidence that would be acceptable in courts in most OECD countries.⁵⁴

To the author, it appears that the only way to create an effective and functional benefit-sharing system will be to adopt strictly overseable “incentive” and motivation measures, which encourage users to comply with benefit-sharing requirements.⁵⁵ In essence, the user must obtain something of value to himself, which will make it

worthwhile for him to comply, and to demonstrate his compliance with appropriate evidence.⁵⁶

Conclusion: Subsequent Steps

The foregoing is not a roadmap to the completion of the international regime, but only a list of the next layer of activity. Once the negotiations have gotten past the initial concerns set forth above, they will have agreed on the basis for the broad framework *on which to build the regime* – they will know, for example: (i) what kinds of specific measures must be adopted by all countries, and which must be addressed by the international instrument, (ii) what resources, activities and benefits will trigger the regime, (iii) who owns the resources and/or has the right to grant “access” to them or permit their utilization; and (iv) how the user’s rights under an agreement with one provider country, community or individual affects the interests of other providers/holders of the same genetic resource.

At that point, however, the result will not be a regime, but a framework for creation of a regime. The next layer of issues to be examined would include critical questions such as the following:

- How will the ABS regime effectively integrate with the wider objectives set out in Article 8j of the Convention?
- How will the international regime address “research users”, in a way that
 - will not create undue obstacles or inordinate costs for academic, conservation and other non-commercial researchers, AND
 - will not create a loophole that would allow commercial users to acquire and utilize genetic resources without ABS compliance?
- How can the international regime serve as a “pillar” of the CBD, helping to uphold the other two CBD objectives – conservation and sustainable use of biodiversity?⁵⁷
- How can the ABS regime can operate in harmony with the ITPGRFA,⁵⁸ and potentially develop a means of integrating with other international regimes of relevance?⁵⁹

Thereafter, there will still be another layer of negotiations will be required to create and fine tune the specific legislative requirements that will be imposed on countries, and the specific international requirements, systems and institutions that the Parties decide to adopt.

At that point, one key necessity at that point will be definition of the relationships of the various parties within ABS transactions. For example, the ABS regime will need to

- clarify the concepts of
- “country providing genetic resources” (variously shortened to “source country” or in some cases “provider country”),
- “country of origin” (which is quite different in meaning from “country providing genetic resources”) and
- specifically determine when and how genetic resources could have been “acquired in accordance with this Convention (Art 15.3) particularly when they were collected prior to the convention or for non-ABS purposes (taxonomy, botanical gardens, etc.)

Currently, these issues appear to be interpreted in very different ways by various countries, communities, observers and others.⁶⁰ Development of an agreed or consensus view of these matters will be essential, before the regime can be completed.

Endnotes

- ¹ Johannesburg Plan of Implementation Article 42 calling on countries to:
 - (o) *Negotiate, within the framework of the Convention on Biological Diversity, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources.*
- ² Decision by the COP-7, UNEP/CBD/COP/7/21, VII/19 D p. 299.
- ³ The extreme complexity of the ABS problem has led to a situation in which the negotiations are becoming more specialized and smaller with each meeting, to the point that it begins to resemble a cabal. One person who has participated in ABS discussions from their inception has sometimes referred to the group of negotiators, experts and observers involved in this issue as the “ABS Mafia.”
- ⁴ Article 1 states the Convention’s objectives as follows:

The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.
- ⁵ CBD, Art. 15.2, 15.6, and 15.7. The other provisions of article 15 state that Parties have sovereign rights over their genetic resources, that the system applies to genetic resources from a “country of origin” or from a country that has obtained a legal right to the genetic resource from the country of origin, and imposes contract-like requirements of “prior informed consent” and mutually agreed terms both on access and on benefit-sharing.
- ⁶ Article 15 contains the entire regime-creating language of ABS, and is only 7 clauses, embodying a total of 275 words. In normal legislative practice, this would be approximately enough language to define one major term or specify the scope of the instrument (neither of which is done in Article 15. By comparison, CITES, whose four legislative requirements are relatively simple in concept and were not

generally ambiguous or controversial at the time of adoption, expends over 5000 words on the legislative/permit regime alone.

⁷ This simple view prevailed for years. Only within the last three years have the inconsistencies described in this paper begun to be seriously discussed in international forums.

⁸ Articles 16 and 18, 19, 15.6, and 17, respectively.

⁹ The ABS concept is also tied to five key definitions contained in the Convention, (“biological resources,” “biological material,” “country of origin,” “country providing resources” and “genetic resources”) found in Article 2, as well as five other ABS-related phrases found in small clauses within Articles 16-21 (some would add Article 8).

¹⁰ The CBD Secretariat maintains a database of national ABS legislation maintained online at <http://www.biodiv.org/doc/lists/nfp-abs.pdf>. National laws therein include a variety of different levels of regulation, leading to varying counts of how many are “regulatory systems” and how many are “mentions.”

¹¹ The Bonn Guidelines were developed through a series of meetings – the Second Expert Panel on ABS, the first meeting of the Ad-hoc Open-ended Working Group on ABS and COP VI, the Bonn Guidelines were, originally adopted as an addendum to CBD Decisions 6-24 (UNEP/CBD/COP/6/24), and in 2002 were reproduced in a booklet published by the CBD Secretariat.

¹² Although it is the first to be finalized and adopted, the ITPGRFA is not the only process ongoing in other forums relevant to ABS. See, e.g., the discussions in the WIPO Standing Committee on Law of the Patents (SCP), and in the TRIPS Council of the WTO, and the work of the various international bodies focusing on traditional and indigenous knowledge, including the CBD’s Article 8j Working Group. These processes have generally attempted to utilize (i.e., to wait for clarification of) the CBD definitions and concepts. Another international process, focused on marine genetic resources, is the deliberations of the UN Intergovernmental Consultative Process on Oceans and the Law of the Sea (UNICPOLOS). In this process, however, the meaning and application of CBD terminology has not been used, so that much of the “marine genetic resources” discussion has focused on applying limits on the taking of samples – a “sustainable use” matter – rather than on ABS and the CBD’s third objective. See report of the 8th Meeting, at <http://www.iisd.ca/vol25/enb2543e.html>. Consequently, this process has not made any progress that could be used to identify special ABS coverage for marine genetic resources. See also CBD, Art. 3.

¹³ See, e.g., Burhenne et al. 1994. Some commenters, although recognizing these problems, assumed that they would not prevent implementation. This assumption was not unreasonable. See Glowka, 1998. It is common for national lawmakers to find and adopt specific legal solutions to international implementation problems and for those initial solutions to be later adopted by other countries so that they become eventually the international solution. Unfortunately, in the case of ABS, no country has yet addressed the legal problems described in this section. Thus, there is no national legislation that could be generalized to become a general approach to ABS implementation. Instead of addressing these problems, however, many commentators simply felt that they could be ignored, suggesting that by using the private contract mechanism for granting access to genetic resources the Parties could avoid the need to clarify the various imprecise and ambiguous elements that are essential to ABS functionality.

¹⁴ The following sections of this paper will look at some of the underlying causes – the reasons that countries have not been able to adopt legislation.

¹⁵ A few developed countries have begun processes to develop such systems, but so far, Australia is the only developed country to have formally adopted provider-side ABS legislation.

- ¹⁶ Most countries that have adopted ABS laws have noted that these systems are not functional or are, at least, seriously flawed in terms of their implementation.
- ¹⁷ "User measures" is the common way to refer to the obligations under CBD Art. 15.7, quoted in full above. Moat relevantly, it requires that "each Contracting Party shall take legislative, administrative or policy measures, ...with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources" A few countries have adopted laws calling for patent-related disclosure of the origin of genetic resources used in the patented innovation. However, most of these are voluntary measures whose primary result is to give the user country some information which it will keep in a public database that might be accessed by the provider country. Even where such provisions are mandatory, the user's failure to comply will not affect the validity of the patent or create any obligation (or incentive) to share benefits.
- ¹⁸ There are many possible reasons for Parties' poor Article 15 performance to date. National legislative draftsmen generally find it impossible to create legislation that implements ABS due to the ambiguities and uncertainties regarding the practical meaning of Article 15. These points, and the factors that have formerly (apparently mistakenly) been claimed as the reason for inaction, are considered in more detail in Cabrera and Lopez, 2007 at 1.2 and 2.1.3, and Tvedt and Young, 2007 at Chapter 2.
- ¹⁹ This issue is discussed in more detail in Tvedt and Young 2007.
- ²⁰ See note 27.
- ²¹ One approach to creating internally consistent definitions of these three concepts and the relationship between them is found in Tvedt and Young, 2007, at chapter 4. It should be noted, however, that many other options are possible. The parties need to simply choose one option and use it as a basis for creating the rest of the regime system.
- ²² There have been so many inquiries into this question that a full list would be extremely long. Two recent discussion which are easy for the author to cite are Cabrera and Lopez 2007 at 1.2, and Tvedt and Young, 2007, at 2.7.
- ²³ One example of this approach is found in the African Union Model Legislation for the Protection of the Right of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources (formally endorsed by all African Union States, but at this writing, not adopted in whole or in part by any) which applies its benefit-sharing provisions to all "biological resources."
- ²⁴ It is possible to design an ABS regime using this approach. In fact, this is generally the orientation assumed by the ITPGRFA. Within the CBD negotiations, however, it is not a universally recognized view.
- ²⁵ Most analyses of the implementation of globally recognized legal concepts focus on the number of different legal systems (comparing systems based on whether they are structured under principles of "common law," "civil law," "planned economies" and/or "religious law" and noting that (although categorized under one of these classifications) each country appears to provide a different mix of these principles. In fact, however, for purposes of determining whether a particular "international regime" can be legally effective, or provide legal certainty (the primary question relevant to the ABS regime) the more important question about each country is whether it is a "strict rule-of-law" system or a "flexible legal implementation" system. The concepts of international commerce tend to expect that all countries will function under the strict rule of law (that is, applying laws and legal principles in a rigorous way, based on precedent or other specific rules which assume that each court's decisions (and thus the actions of any person whose transaction or activity might end in a court) are basically "replicable." In fact, however, nearly all developing countries apply the law in a more flexible

way, based on the wisdom and understanding of the particular official (agency, court or appeal to superior officials) to read and understand the policies and laws and use them to come to a decision which that official believes is just and fair. For officials applying law in this way, the fact that a strict interpretation of two policy statements results in conflict and inconsistency would not present any serious obstacle to coming to a legally accepted decision. In countries that operate using a stricter (replicability-based approach to the rule of law, however, such inconsistency could make the entire system un-implementable ("void for vagueness.") Consequently, they could not adopt a law or series of laws under which genetic resources have many different interpretations. For ABS, this poses a serious problem, since the primary use countries in North America and western Europe, as well as most "common law" countries and some other OECD-participating non-member countries (such as Brazil) operate under strict "rule of law" legal systems, and are thus currently unable to adopt ABS legislation.

²⁵ Discussed in more detail in Tvedt and Young, 2007, at 4.1 et passim.

²⁷ Specifically, given that factual data cannot be protected by patent and may be a trade secret, how can it be shared with the source country while still protecting it as a trade secret? Obviously, if one waits until patenting or publication by the user, then the user will no longer need to be concerned about maintaining secrecy; however, at this point, the source country's "share" is meaningless, since the information is essentially public and available to all.

²⁸ See Holm-Müller et al., 2005; Latorre, 2005; Frison and Dedeurwaerdere, 2006. At minimum, results of recent "user surveys" indicate that most users do not know or particularly care what the ABS provisions require, assuming that they are exempt, so long as they acquire GR through secondary sources (collections, collectors and middlemen) outside the source country.

²⁹ A representative of the pharmaceutical industry specifically stated that in future, to avoid ABS complications he would always acquire his genetic material from other collectors, both those who have recently collected the materials and botanic gardens whose collections include foreign-collected materials and their progeny. Presentation of T. Henkel, "A Perspective from Pharmaceutical Industry," Presentation to High-level Experts Meeting - Addressing the Access and Benefit-Sharing (ABS) Challenges in the Context of the Convention on Biological Diversity (Tokyo, 8-9 February 2007) and other remarks in that meeting

³⁰ At that point, since no country has adopted user measures, the user's use of the resources will be legal under the user-country law. It is normally not possible to control or track the physical ability to obtain samples, unless either (i) the users voluntarily provide the relevant information and agree to these controls, or (ii) both source and user countries (and other countries in which the biological material has been taken) are willing and able to oversee all potential utilization activities involving genetic resources derived from any biological material. It is still unclear whether either of these actions is required under the CBD.

³¹ Normally, to gain access to private property, one needs legal authorization – approval from a judge or agency, subject to a law which governs reasons for entry and limits the action that may be taken.

³² For lawyers, this concept is sometimes called the "Rule Against Perpetuities." No matter what it is called, it is normally a very complex concept, and differs from country to country.

³³ In the discussions, it appears that some negotiators equate "derivative" with "extract." Others assume that, including "derivative" would make the obligation of the user permanent. The strictest version, would be as follows: a "secondary user" buys a commercial product which was developed by a "GR-user" under an ABS contract. In that transaction, the GR-user would pay a share of the purchase price to the original provider. However, if the commercial product is a "derivative",

the secondary user would have to pay benefit-sharing on his new product, essentially creating a double payment.

- ³⁴ As noted in footnote 45 and accompanying text, the most recent study has assumed, that genetic resources will be governed by national law governing land. This assumption is probably incorrect.
- ³⁵ There is no example in property law, including intellectual property law, in which an identical intangible resource can be owned by many countries or persons, each of whom has an unfettered right to sell or transfer it. This issue is discussed in a forthcoming book: Bhatti, S., S.Carrizosa, P.McGuire, T.Young. 2007. Contracting for ABS: The Legal and Scientific Implications of Bioprospecting Contracts.
- ³⁶ At least one country, Australia, has legislated in a way that indicates that any person that owns or possesses as specimen of biological origin also owns the rights to genetic resources it contains. See AUSTRALIA, Environment Protection and Conservation Regulations, 2000, Statutory Rules 2000 N^o 181, as amended (taking into account amendments up to SLI 2006 N^o 131, Parts 8A, 9, 10, and 17). And see, Queensland Biodiscovery Act, Act N^o 19, 24 Aug 2004; and other documents available on the CBD's ABS Measures database. <http://www.cbd.int/abs/measures.shtml> This provision, however, appears to be inconsistent with the Australian law on patents, which apparently recognizes the right to patent naturally occurring genes, without getting permission from the owners of rights in that material. Consequently, although having espoused an approach, it cannot be said that Australia has, as yet, integrated that approach into its property law.
- ³⁷ This category normally includes land and permanently constructed improvements (buildings, roads, fences, weirs, bridges, etc.)
- ³⁸ Often including special ownership rules for some types of property (motor vehicles) which are different from other personalty and movable items.
- ³⁹ In many countries, for example, water is part of a complex "common property" regime, under which water rights may or may not be linked to rights in land.
- ⁴⁰ This term is generally used to describe government-owned property held by virtue of its sovereign duties to its people, as distinct from other kinds of property which the government controls under other theories.
- ⁴¹ Patrimonial concepts vary greatly, but generally focus on establishing a single governmental ownership concept for dealing with the property which is held on behalf of the entire citizenry. It is similar to the concept of "public trust."
- ⁴² Intellectual property is a "legislatively created" concept, under which one who creates or invents something is given special rights to control its use or commercialization.
- ⁴³ There are many other kinds of intangible properties including shares in a company, intangible rights in land (easements, profits, appurtenances, etc.), trade secrets and other properties which are not tied to a particular tangible item but are clearly and specifically held by a definite person or entity.
- ⁴⁴ The sovereign right of countries over their natural resources has been generally recognized for many decades. Mgbeoji, 2001. Prior to 1992, however, no legal instrument suggested that there was any kind of commercial right of any person or country to exert dominion, ownership or other legal rights in the genetic information or other characteristics of any naturally occurring species or variety of plant, animal or other biota.
- ⁴⁵ 2007. "Report on the Legal Status of Genetic Resources in National Law, including Property Law where Applicable, in a Selection of Countries." UNEP/CBD/WG-ABS/5/5.
- ⁴⁶ As noted above, in order to effectively impose such a new obligation, it would seem necessary for the system to provide some sort of quid pro quo and/or create incentives or other motivations for users and countries with significant numbers of users under their jurisdiction.

- ⁴⁷ The following description is taken from an interim draft of a future book: Bhatti, S., S.Carrizosa, P.McGuire, T.Young. 2007. Contracting for ABS: The Legal and Scientific Implications of Bioprospecting Contracts. None of the other authors bears any responsibility for this description, which may or may not appear in that book.
- ⁴⁸ See Mgbeoji, I., 2006.
- ⁴⁹ Although the technology needed to isolate natural genes is generally available (i.e., there was no innovation in the isolation process), and no other "inventive step" is involved, these patents have been upheld in at least two countries (Australia and the US).
- ⁵⁰ In theory, it also defeats the purpose of IPR protections, which are intended to enable innovation, rather than to prevent access to raw materials and natural examples.
- ⁵¹ Consider the possibility that one user could patent coltan, charging a royalty to all industries using it in telephone or developing new uses for it in computer and other technologies. The result would be an impediment to future technological innovation, and would also negatively impact the markets and prices for copper and coltan, affecting the value of those resources.
- ⁵² For a private contract to be fully "binding," it must be "enforceable", in cases of disagreement between its parties. This creates a problem for ABS, where many basic components of the contractual system are un-agreed indistinct or vague, since courts and government agencies normally will not even attempt to enforce contracts that are ambiguous. This is not a choice on their part – it is mandatory. It is impossible to apply the rules of law to achieve reproducible results, when primary facts cannot be pinned down. A more complete discussion of the obstacles to enforcement of ABS is contained in Young, 2007.
- ⁵³ Unless the person has practical knowledge that the use is ongoing, he will not know that he should investigate the private actions of the user. It may be (marginally) possible to obtain this knowledge in cases where the user has obtained an ABS permission or contract, but will be virtually impossible as to other users. .
- ⁵⁴ See Young, 2005 addressing the problems of "legal certainty" in detail; Tvedt and Young 2007, at Chapter 3, addressing the lack of "user-side measures" and Young, 2007, regarding the problems of enforcement if ABS operates under "command and control" approach.
- ⁵⁵ A discussion of the manner in which incentive and motivation can be integrated into the international regime is found in Tvedt and Young, 2007, at 3.5 and 6.2.
- ⁵⁶ Such evidence might be in the form of a "certificate of benefit-sharing" or other certificate. Until the incentive system is created, however, it will be impossible to design a certificate, and the system for obtaining such a certificate, verifying its authenticity (when the certificate is used), and maintaining confidentiality regarding its contents. Hence, recent international discussions of the creation of an "Internationally Agreed Certificate of Source, Origin or Legal Provenance", although of great interest, may not have been timely. It will be useful to revisit this issue when the regime is more nearly completed.
- ⁵⁷ Most contemporaneous accounts stated that the three objectives of the Convention are three inter-dependant "pillars" on which the CBD is founded . Hendriks, et al., 1993.
- ⁵⁸ Although thought by some to be the only practical instrument on ABS, the ITPGRFA currently appears to utilize an approach which is significantly different in function and framework from Article 15. Among the most obvious inconsistencies between the two is the fact that the ITPGRFA has assumed a definition of genetic resources which presumes that the term means the same as "biological resources" or even "biological diversity. As noted above, this choice has not been adopted by the CBD, suggesting that there may be a significant

difference between the two instruments at the most basic level. The ITPGRFA states that it is “in harmony with the CBD” (ITPGRFA, Art. 1.1), however that statement has not yet been mirrored in any statement adopted by the CBD COP. Possibly this omission is significant, given that the “harmony” between international instruments is normally determined by the manner in which they are implemented. If a country can and does implement both instruments in a harmonious way, then the instruments are “in harmony,” at least in that country. If, however, two international instruments are facially inconsistent, but a later instrument states its intention of being “in harmony” with the older instrument, it is usually felt that the newer instrument will have to be interpreted (or rewritten) in a way that causes it to harmonize with the other instrument. Singer/Sutherland, *Statutory Interpretation*, under “harmony.”

³⁹ See note 13, above.

⁴⁰ An introductory discussion of these definitional issues is found in Tvedt and Young at Chapter 2.

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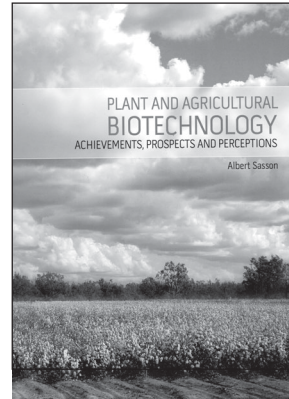
New Arrival

Plant and Agricultural Biotechnology: Achievements, Prospects and Perceptions by Albert Sasson

COCyTE, N.L. (Ciencia Y Tecnología De Nuevo León, México) UNU/Institute of Advanced Studies and BioEuroLatina, Mexico. Pp.444, 2006.

Over the last few decades, there has been significant development of biotechnology through a very wide spectrum of human activities, from medicine and health care to agricultural and food production, and through biofuel production, environment protection, bioremediation and biomining. The present book mainly provides an overview of conventional agricultural biotechnology, genetically engineered crops extension, commercialization, benefits and prospects, innovations in advanced crop biotechnology along with the successful case studies of many developing countries. It also addresses the future of agricultural bio-industry in both technologically advanced and developing countries.

The book broadly consists of thirteen comprehensive sections or (chapters) though without any numbering followed by conclusions and prospects of agricultural biotechnology for the betterment of the human kind. The first chapter highlights the status of conventional agricultural biotechnology as the most widely adopted biotechnology in developing countries, where agriculture plays dominant role. Some of the interesting success stories of plant-tissue culture and clonal multiplication of crops in Malaysia, Cote d'Ivoire, Indonesia, Central Africa and Latin America, Thailand, Colombia and Ecuador have been presented. This technique is very effective even in rudimentary conditions and provides a regular source of income to the marginal farmers. In Argentina, an autotrophic and hydroponic system (SAH) has been developed for the *in vitro* production of potato plantlets. However,



within a month's time from only 200 plantlets produced *in vitro*, 10,000 potato plantlets could be obtained. Similarly, for rapid expansion of cassava production, a technique was developed at the National Research Council Canada Plant Biotechnology Institute, that enabled the production of mosaic disease-free plants from *in vitro* cultured shoot apical meristems. Later, both these techniques have been successfully replicated to other countries as well for e.g. Bolivia, Chile, Colombia, Ecuador, Peru, Venezuela, Colombia, Africa and India.

For the commercial production of plantations banana was one of the first crops to be multiplied *in vitro*. Further, clonal multiplication of coffee, oil-palm and date-palm are the success story of conventional agricultural biotechnology.

After a brief explanation and definition of genetically engineered plants and crops in the second chapter, the extension of genetically engineered crops have been thoroughly discussed in third chapter of the present book. Around fifty crop species viz. maize, soybean, wheat, potato, tomato, papaya, melon, sugar-cane and cotton have been genetically transformed are insect resistant, disease and virus resistant. These crops are designed to tolerate climatic stresses such as cold, heat and drought. It has been also estimated that the net economic benefits to producers from transgenic crops are enormous. According to the global study by Australian economists on transgenic grains, oilseeds, fruit and vegetables, projected a global potential gain of US\$ 210 billion by 2015. Further, it is estimated that application of biotechnology in rice would be more beneficial to many Asian countries to produce around 770 million tons of rice required to feed an additional 650 million rice consumers. Likewise, some commercial crops like maize, wheat, soybeans, banana, sugarcane and coffee are the best examples of the extension of genetically engineered plants.

The fourth chapter entitled *Innovation Prospects for Advanced Crop Biotechnology* discusses its status in developing countries viz. China, India, Brazil, Chile and Argentina as they are in constant pressure to increase their production as well as productivity. The developing countries are continuously facing challenges to protect environmental and biological diversity and subsequently diversify agro-products to meet the requirements of the consumers. It is suggested that, in this scenario, the advanced agricultural biotechnology can contribute to meet these challenges. The chapter also discusses in detail the different initiatives

under taken for the development of biotechnology in several developing countries viz. China, India, Brazil, Chile, Costa Rica and Argentina.

The future of agricultural bio-industry in both technologically advanced and developing countries has been analyzed in the next chapter. However, the two most challenging agricultural problems which developing countries face today are to provide sufficient food to billions of human beings, while preserving their biodiversity. The rapid increase in population and their demands for food have not been adequately taken care by the industries and services sector. It is therefore crucial to increase agricultural production through biotechnological research which has the potential to tackle the major problems of the developing world related to poverty, food, hunger, health and environment. The book identifies certain solutions to the challenges for agriculture and emphasized on agricultural R&D innovation to enhance productivity and improve natural resource management, increase household skills and know-how and lower food prices for consumers. The introduction of transgenic cotton and soybeans varieties in Africa and US are the illustrative example of the positive impact on trade of transgenic crops, apart from establishing commercial relationships between the exporting and the importing country. Farmers as well as the companies are benefiting from growing and selling transgenic crops like cotton, soybeans, oilseed rape and maize, primarily from the higher price of seeds. In India, ITC, an Indian conglomerate directing the farmers to use hybrid seeds, fertilizers and maintain wider space between plants to increase the soybean yields.

Overall economic impact and benefits of transgenic crops are analyzed in great detail in the chapter entitled '*Benefits of Transgenic Crops.*' The chapter documented that in US due to extensive adoption of biotechnology derived varieties there are stances of higher yields, higher farm incomes and reduced pesticide use. For the benefit of the consumers, Japanese researchers have identified the ways to genetically modify the presence of enzyme (lacrymatory factor synthase) in onions that causes irritant effects to eyes. Monsanto and Cargill have formed a joint venture to modify the protein composition of soybeans and maize grown for animal feed. Weed management is an important incentive for farmers which can also contribute to higher yields. In the chapter, author also stressed that improvement in the nutritional quality of food is as important as to increase the higher productivity. Very rich examples of

bioengineering crops have been mentioned that are capable to reduce many micronutrient deficiencies.

The book also presents the potential hazards of genetically modified crops as well as the evaluation and management of risks associated with transgenic crop cultivation. In this chapter, author has beautifully explained in detail the journey of migration of monarch butterfly from US and Canada to Mexico and their exposure to the nature. However, it was stated that the biggest threat to the monarch's survival are man-made deforestation, development of highways and suburbs. The concept of 'bio-invasions' has been also considered as the major threat to biological diversity and the impoverishments of human communities. The incorporation of the precautionary principle in principle 15 of the Rio Declaration and in the preamble to the CBD as a basis for decision making and risk assessment with respect to the transboundary transfer of GMOs or living modified organisms (LMOs) have been analyzed in the next chapter that may have adverse effects on the conservation and sustainable use of biological diversity. The author throws light on the flaws in the precautionary principle as the principle itself provides no guidance on its application in situations where an action could lead to uncertain benefits and harms simultaneously. It has also been suggested in that case, prior to its application, there is need to formulate hierarchical criteria on how to rank various threats based upon their characteristics and the degree of certainty attached to them. Human mortality and threats to the environment can be associated with the public health criterion in this context. Apart from this, immediacy, uncertainty, expectation value, adaptation and irreversibility criterion have been put forth for consideration.

The author also cautioned about the risk assessment associated with genetic crop cultivation, as some degree of hazard is always associated with every technology. However, risk also comprises an outrage component which covers everything about risk apart from its possible effect on people. It is therefore important to be aware of the factors associated with the risk which are the contributing factors of an outrage. Findings of quite a few studies on the consumption of genetically modified food and its effects on human health and environment have been presented with a mixed picture. Biosafety regulations to deal with the health and environmental rDNA-derived products and in particular transgenic crops are a significant step in this direction. Though many international agencies like UNEP/GEF,

OECD, EC, FAO and ISNAR are actively involved in the harmonization of biosafety regulations in different regions. ICGEB Biosafety Unit was established to provide services relating to GMOs and their release into the environment, apart from information dissemination and the establishment of a biosafety clearing house, scientific training in risk assessment for the release of GMOs in the environment. Various policy measures and initiatives undertaken in both developing and developed countries with regard to the cultivation of transgenic crops and biosafety regulations have been discussed at length to present their holistic approach on the various issues involved in it.

The author raised a very important question in the chapter '*International Regulations and Trade Disputes*,' is the Cartagena protocol on biosafety a hindrance for advanced agricultural biotechnology? The role of Codex Alimentarius Commission (CODEX) has also been discussed which are responsible for adopting international standards for the trade of foodstuffs derived from transgenic organisms. It also adopts standards that may be used by its 162 participating governments to develop national regulations. It was stated that two WTO Agreements are relevant for CODEX standards, viz. the SPS Agreement applies to those national laws designed to protect life and health from risks arising from, among other things, additives, contaminants, toxins, diseases and pests. The other TBT Agreement applies to all national technical regulations and standards governing product characteristics, labeling and packaging. However, the focus on food safety in international trade and in trade agreements has made trade issue alike for many developing as well as developed countries. In addition to risk assessment involved in releasing transgenic crops in the environment, the concept of biovigilance has been put forth to keep a check on their patterns of behavior. Accordingly, all the plots cultivated with transgenic species should be mapped with respect to their characteristics.

The issues of '*Traceability, Labelling and Transparency*' of products derived from GMOs, as well as the coexistence of the latter with conventional and organic agriculture has been thoroughly discussed in the next chapter. It states that traceability implies the monitoring of products through the whole chain of production and distribution and its potential effects on human health and the environment. In this context, labelling is the key factor that indicates the presence of transgenic organisms on the food labels. The French Agricultural Research Institute (INRA) and the University of Grenoble, from the

perspective of traceability, labelling and transparency proposed three options on the acceptance of transgenic organisms. Firstly, the complete phase out of production of GMOs, secondly the total submission in the scientific views and recognize these GMOs harmless and safe for human health and environment. And, lastly, they emphasized on the establishment of two separate production chains, one transgenic and the conventional one, for the consumers to decide on their own. The French researchers opted for the third option.

Though the issue of coexistence between the three types of agriculture based on conventional crops and intensive farming, organic farming and transgenic crops has been raised at the Council of European agriculture ministers in 2002. Organic farming which has a strong growth rate across the European Union's member countries might be threatened by contamination by genetically engineered crops, when they are gradually adopted and grown. The chapter highlights that, later the European Commission considered that the modalities of coexistence between transgenic crops and conventional ones should be decided upon by the member states. For that, a three year programme called Sustainable Introduction of GMOs into European Agriculture (SIGMEA) was launched to create awareness about the co-existence.

The chapter also reveals the comprehensive measures undertaken by France to ensure crop existence in the case of maize. According to a research study, modelling and trials have shown that a minimum distance of hundred metres was necessary between a transgenic and a conventional agricultural plot in order to keep the level of transgenic material under 1 per cent in the conventional crop. Further, in case of two plots adjacent to each other, flowering in the plots should occur at a four-day interval. Though EC has adopted the pro-GMO attitude, whereas it seems that new members of the European Union are not more enthusiastic about GMOs than their predecessors, although countries like Hungary, Poland and Romania are found to be in favor of cultivating transgenic crops. On the other hand, researchers and experts also argue that GM crops can also bring benefits to small farmers and contribute to a more environment-friendly agriculture.

The issue of social acceptance of biotechnology derived products through the debate on patenting genetically engineered organisms has been examined in the chapter entitled '*Intellectual Property Protection: Impact on the Acceptance of Transgenic Crops.*' An overview of *sui generis* legislation in the shape of the Plant Varieties Protection and Farmer's

Right (PVFR) Act, 2001 was enacted by Indian Parliament to provide protection of new crop varieties has been mentioned. It has also been recognized that patenting and intellectual property protection are important ways to ensure a fair return to industry for its investments in R&D of new knowledge and technologies as they are vital ways to foster continued national innovation.

Besides, the issue of patents, it highlights that WIPO also addressed the issue of the growing gap between developing and developed countries with respect to intellectual property laws and its effect on access and rights to genetic resources. Further, it also aims to make an inventory of traditional knowledge in order to prevent its illegitimate appropriation by a third party. The concept of bioprospecting means the exploration of biological diversity for commercially valuable genetic and biochemical resources has been clarified. It also presents the 'access and benefit sharing' system that aims to promote scientific and technological breakthroughs from plant and animal sources while recognizing the contributions and rights of those who cultivate and preserve these resources. Furthermore, it provides a useful source of information regarding an Indian herbal medicine, Jeevani and the traditional knowledge of local Kani tribe. Jeevani is claimed to have anti-fatigue, anti-stress properties and other benefits. This case study shows that fair benefit sharing arrangements can play a key role in the enhancement of social and economic development among local communities.

Controversy related to the agricultural biotechnology from the different groups of stakeholders like consumer associations, organic farmers, environmentalists on the one hand opposed to the alterations of the foodstuffs and environment contamination. On the other hand, researchers, farmers, regulatory agencies and private industries are mainly concerned with the post harvest conditions and increase in yield and productivity and nutritional value. Apart from this, the debate on transgenic crops also deals with justice and democracy. Role of media coverage of biotechnology is a key factor in the social acceptance of these technologies through transparent information. It creates the general awareness about the potential benefits as well as the risks associated with their commercialization in the agricultural and food sectors. It was emphasized that there is a genuine need to bring science and society closer together to build a "knowledge democracy" in which the community is well informed about the technology and its application for the betterment of the humankind.

The final chapter summarizes the conclusions and prospects from the viewpoint of large consensus that research in developing countries should be linked to the problems and requirements of the local communities in their struggle against hunger, food security and undernutrition. The book rightly concluded with L. Fresco's remarks that "clearly the question is not what is technically possible, but where and how life sciences and biotechnology can contribute to meeting the challenges of sustainable agriculture and development in the 21st century."

On the whole the book gives an indepth account of achievements and prospects of agricultural biotechnology, highlighting different aspects of its benefits and risks with many examples from developing countries. The volume is loaded with comprehensive analysis of the wide range of agricultural techniques and its impact on both developed and developing countries. It is a great source of information for the students, scientists and researchers, civil societies and the stakeholders about the implications and prospects of agricultural biotechnology.

— Beena Pandey