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Discussion Paper

Access and Benefit-Sharing for Genetic Resources

Prepared by the ICC Commission on Biosociety and Commission on Intellectual Property

The Conference of the Parties to the Convention on Biological Diversity (CBD) decided at its 7th meeting 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* [access and benefit sharing provisions] *of the Convention and the three objectives of the Convention* (COP 7, Decision 28). This decision was pursuant to direction from the 2002 World Summit on Sustainable Development. The development of this regime promises to have a significant impact on the evolutionary path from the pre-CBD era of relatively unfettered use of genetic resources to the post-CBD era characterized by bilateral and contractual agreements regarding such resources, subject to internationally agreed principles and practices.

The following paper describes the obligations in the CBD and highlights some of the considerations that will need to be kept in perspective as the countries advance this transition both within the CBD process and in related intergovernmental forums. It focuses particularly on complications to this transition that derive from the evolving patterns of use of genetic resources; on identifying those governmental and intergovernmental forums that will play a key role in the orderly transition to post-CBD processes; and on identifying some of the major issue areas that have arisen in those forums that will have to be addressed,

The paper also discusses some implications of the CBD provisions for other multi-lateral agreements, including the International Treaty for Plant Genetic Resources of the UN Food & Agriculture Organization, and the primary international forums responsible for intellectual property rights, the WTO Council on Trade Related Aspects of Intellectual Property Systems, and the World Intellectual Property Organization.

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Obligations in the CBD

The CBD entered into force in December of 1993, with the first meeting of the Conference of the Parties to the CBD in November of 1994. The Convention is far-reaching in its scope and mandates, but nowhere has it spawned a more fundamental change than in the realm of genetic resources[1]. Prior to CBD, many regarded such resources as part of the common heritage of all mankind. The CBD, however, refuted this view and confirmed that states have sovereign rights over their natural resources, and declared specifically with respect to genetic resources that *authority to determine access to genetic resources rests with the national governments and is subject to national legislation* (Article 15).

Importantly, the Convention also obliges Parties to *endeavour to create conditions to facilitate access to genetic resources… and not to impose restrictions that run counter to the objectives of the Convention.* That access *shall be on mutually agreed terms* and *subject to prior informed consent of the* [Party that is the country of origin or Party having acquired the resources in accordance with the Convention]*, unless otherwise determined by that Party.* It further obligates all Parties to the Convention 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… Party providing such resources* (all from Article 15).

Adding yet another layer, the Convention obligates each Party, *subject to its national legislation, to respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities… and promote their wider application with the approval and involvement of the holders of… and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices* (Article 8).

Related to the above changes is the further mandate *recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention,* and obligating Parties to *cooperate … to ensure that such rights are supportive of and do not run counter to its objectives* (Article 16).

Complications in implementing these obligations

The "conceptual model" upon which the obligations were based was one of a linear flow of genetic resources beginning with "bioprospecting" to extract them from their *in-situ* state, following negotiation of mutually agreed terms with the sovereign state and after consultation with the concerned indigenous and local communities. The extracting agent develops a commercial product based upon the extracted resource with some R&D investment, and then shares the proceeds from that product according to the agreed arrangements. It is also evident from CBD discussions that there is a "reference case" that many delegates seem to have in mind

[1] Under the Convention, "genetic resources" has a broad interpretation that includes "any material of plant, animal, microbial or other origin containing functional units of heredity" that is of "actual or potential value" (Article 2).

as they consider the access and benefit sharing (ABS) elements of the CBD. The case that seems to drive much of the thinking is the patented pharmaceutical product based largely upon therapeutic properties extracted from genetic resources, identified through traditional knowledge of these properties, and that yields billions of dollars in profits. Unfortunately, both the conceptual model and this reference case are exceptions to the normal methods of accessing genetic resources and the normal result of the use of those resources. Their persistence in the perspective of many CBD participants sustains misconceptions that have profound implications in meeting obligations under the CBD.

Many Commercial Resources Are Already Outside the Country of Origin: The conceptual model of a linear process beginning *in-situ* simply does not apply to most of the resources that are or will be utilized in commercial applications. Genetic resources have been extracted from *in-situ* conditions and utilized for commercial purposes, including breeding to select for particularly genetic traits, for centuries. They have also been extracted for taxonomic and other research by both academic and public research institutes around the globe and many of these have established *ex-situ* collections ranging from zoos and aquariums to herbaria such as the various botanical gardens and the Consultative Group on International Agricultural Research (the "CG system"). Such centers, in turn, have a very long history of providing genetic resources for academic and commercial R&D around the globe.

Much of the resources that are being used in commercial and non-commercial R&D today and that will likely be used in the near future were extracted prior to CBD entry-into-force and therefore are deemed legally in-use despite the fact that there typically was no PIC or mutually agreed terms of benefit sharing. While many of the repositories of such resources have maintained detailed scientific records of their specimens, there has been no obligation for such records, not all such records go back to the point of original *in-situ* conditions (those in particular centers of origin, for example) and not all researchers and users have maintained them.

Beyond this class of historically accessed genetic resources, there is a class of unknown size that has been extracted post-CBD. Some of these have been extracted pursuant to formal agreements with sovereign states (e.g. Costa Rica's much noted early agreement with the major pharmaceutical company, Merck, regarding access to genetic resources); but some may have been extracted according to conventional (pre-CBD) practices in countries, particularly those where national legislation has not yet been approved or implemented or in some cases where national legislation may provide for less demanding terms for certain types of extractions (typically those made by academic researchers). Finally, there are, indeed, resources in in-situ conditions, which may in the future be extracted in conformity with adopted and implemented national ABS regimes; but these examples conforming to the "conceptual model" are only a small proportion of the resources likely to find their way to use.

Changing Patterns of Resource Use: The "reference case" of a blockbuster biotech pharmaceutical drug is also becoming more distant from reality, as science and product development patterns evolve. It is certainly true that much of the interest in drug discovery that drove ABS into CBD discussions in the 1980's was just that: "drug discovery" enabled by access to naturally occurring genetic resources – the "green gold" of rainforest biodiversity and the like.

However, reliance upon naturally occurring genetic resources within the pharmaceutical industry is giving way to science and technology that enable "drug design" at the molecular level. Many of the major global pharmaceutical manufacturers are increasingly focused on high-throughput process screening of synthetic compounds. While a number of niche players remain seeking-out and exploiting natural products, development costs are enormous (>$800 MM and 10-12 years) and competition from synthetics-based processes formidable. A large number of pharmaceutical companies, including many of the major pharmaceutical companies have reduced or terminated natural product research in recent years.

The reality is that the dominant commercial interests in naturally occurring genetic resources today are not the pharmaceutical interests, but the more mundane industries of agrochemicals, plant breeding, flavours and fragrances, industrial enzymes and herbals. These are typically characterized by far more specialized applications with more limited potential market returns. Importantly, some of these (e.g. herbal remedies that are so popular in many cultures) are exploited for large-scale commercial value with little or no value-adding R&D, and therefore are never destined to be the subject matter of patents. In this respect they not only do not fit the "reference case," but to the extent that many of the ABS proposals focus on patented products and the patent application stage, such high-volume uses of genetic resources may actually be bypassed entirely in benefit sharing efforts.

Dangers Of "Getting It Wrong": Any ABS regime, be-it national, regional or global, has two simultaneous effects: on the one hand it determines the ability of countries to secure PIC and benefit-sharing from future use of their genetic resources; and on the other hand it determines the cost of accessing such resources and influences the risk and therefore the potential value associated with use of those resources. The problem with the current state is that the change from the assumptions that initially drove CBD negotiation on ABS is all in the direction that diminishes demand for and value of *in-situ* genetic resources. The danger is that ABS regimes may be designed with the expectation of an enormous global pharmaceutical industry with an irrepressible appetite for *in-situ* genetic resources in order to feed commercial development of blockbuster drugs. This notion suggests that such resources are necessary, that they can be expected to yield enormous profits and that, therefore, the market for such resources is, in essence, a "sellers market." In such a scenario any bureaucratic burden, direct costs of access, claims against future patentability or the like are negligible and, in the end, will be willingly absorbed in order to keep open channels to access the resources. Nothing could be further from the truth.

The state of affairs today is better understood to be one of vastly diminished demand for genetic resources, with major elements of the remaining demand largely focused upon *ex-situ* sources that are not covered by the CBD and that have been available for years, decades and even centuries in some cases, and with little or no ability to reach back and determine with any legal specificity the origin of those resources. Complicating this further is the equally important reality that the commercial endeavors still heavily dependant upon natural genetic resources tend to be less value-adding and therefore less able to absorb significant costs associated with accessing or using such resources.

This caution extends even to resources destined for more value-adding R&D that becomes

dependent upon patentability of any ultimate products to secure a return that makes that R&D investment worthwhile. Industries such as industrial enzymes, for example depend upon secure rights to commercialize their products. To the extent efforts to enforce ABS obligations end up clouding patents or otherwise compromising rights to utilize particular genetic resources, the likely outcome is simply to abandon any attempt to utilize those resources or other such resources likely to generate similar claims. The obvious result in such extreme circumstances would simply be the absence of any benefits.

This state is different from that envisioned at the time CBD was being negotiated, but it can still yield equitable benefit sharing arrangements called for by the CBD. However, it must be understood that the key to arriving at appropriate ABS processes is to understand that the current state of affairs is far more delicate than much of the rhetoric of the negotiating halls would imply. Appropriate and equitable regimes will have to be the product of a delicate balance between the interests of those with an ongoing commercial stake in natural genetic resources and the countries that steward these resources in *in-situ* conditions. Arriving at such balance will require a common understanding of the realities for countries, public and private research institutions, and commercial enterprise with potential interest in genetic resources. This will also have to recognize current ABS initiatives as, essentially, trials to help determine what provisions and approaches are most effective in stimulating orderly access and returning real benefits. Countries need to take an objective and open look at the effectiveness of such initial efforts; and make measured judgments based upon an honest reading of their outcomes. What the process cannot afford at this early stage, is to unwittingly lock-in ABS processes that are at odds with today's commercial realities and that would consequently stifle any access and preclude any benefits, shared or not.

Response of governments and intergovernmental organizations

It has been only a decade since the obligations in the CBD entered into force. A total of 187 countries and the European Union are now Parties to the CBD[2], but relatively few of those governments have yet adopted legislation to come into full conformance with CBD access and benefit sharing expectations, including:

- Establishment of centralized responsibilities for granting prior informed consent (PIC);
- Definition of their internal processes establishing appropriate benefit-sharing arrangements; and
- Identifying and enabling appropriate indigenous and local communities (and determining when and how they should be consulted).

Early Country Initiatives: A handful of countries have pioneered the establishment of Access & Benefit Sharing regimes and associated contractual arrangements. One of the earliest of these was the 1991 agreement between the government of **Costa Rica** and Merck. Under this agreement, the National Biodiversity Institute provides the company with plant, animal and soil samples in exchange for short-term exclusive rights to study the samples. The Institute was

[2] The United States, Andorra, Brunei Darussalam, the Holy See, Iraq, Somalia and Timore-Leste are remaining non-Parties.

provided funding for laboratory equipment, Merck has proprietary rights to any innovative products derived from those resources, and the Government receives royalties from commercialization of associated products (significantly, resources accessed under this agreement have yet to yield any commercial products). This arrangement has become a model in other more specific initiatives. For example, an access and benefit sharing agreement similar to the Costa Rica agreement was that between the Kani Tribes and Tropical Botanic Gardens Research Institute, in Kerala, South India, for access to the anti-fatigue herb Aarogyapacha (*Trichopus zeylanicus)*, and its development and commercialization as the well–known "Jeevani".

Such pioneering country initiatives are now beginning to accrue enough experience to enable critical analysis of strengths and weaknesses, and within the past several years a number of such analyses have begun to appear in various academic and policy journals. In time, such analyses should enable more refined judgments on the merits of specific proposals in light of evolving circumstances as country experience grows and more intergovernmental attention is given to aiding countries.

Several other initiatives have emerged in the post-CBD era that merit review and analysis in the context of the current ABS activity. These include pioneering country regulations such as those of The Philippines and others such as the bold regional initiative of the Andean Community. Unfortunately, experience with these initiatives has shown them to be problematic, with a sense emerging within industry that, while these have provided clearer lines of responsibility and greater clarity of process, those processes are burdensome and these have actually tended to discourage access. Such programs are blazing a trail, but these programs need to be evaluated with hard data from the involved countries to determine with greater clarity just how effective they have been in enhancing both access and benefit sharing.

The Bonn Guidelines – A Cornerstone: The examples borne of real experience such as Costa Rica's and the Andean Community remain limited, however. As more and more countries have struggled to respond to the CBD's new obligations and opportunities, it has become apparent that countries, national research institutes and other R&D centers, commercial enterprises and other stakeholders are all being drawn into relatively uncharted territory. Recognition of that prompted the CBD in 1999 to begin work on guidance to aid countries in establishing legislative, administrative and policy measures on ABS, and to aid countries and other stakeholders in negotiation of ABS-related contractual arrangements. The result of this effort was adopted in 2002 as the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization.

The Bonn Guidelines are voluntary. They recognize the breadth of potential circumstances and interests drawn into ABS obligations, and present an array of considerations that are relevant in each stage of the ABS process, along with examples of approaches that may be relevant for inclusion in legislation or in specific contractual arrangements. This represents an essential first step in imparting some order to the process of adapting to ABS obligations, and is a necessary precursor to the type of systematic evaluation of the impact of various options that should ultimately help countries to define the most appropriate approaches, given their particular circumstances and goals. In this sense, the Bonn Guidelines represent a key foundation upon

which countries can now begin to systematically build their individual frameworks and through which they can gain real experience in managing access and benefit sharing arrangements. This is, indeed, a necessary first step and should enable more real-world experience to be developed and shared among countries in developing ABS regimes.

Other Intergovernmental Activity: The CBD obligations spawned proposals in several other intergovernmental forums, particularly elements relating to genetic resources utilized in agriculture, and those relating to intellectual property rights. The former includes both the International Union for the Protection of New Varieties of Plants (UPOV) and the newly negotiated International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR), of the UN Food and Agriculture Organization. The latter is particularly significant as it has commissioned development of a standard Materials Transfer Agreement (MTA) as a vehicle through which to address ABS issues and thereby bringing use of genetic resources associated with some major food crops into conformance with expectations of the CBD. Work to develop this MTA was began in the Fall of 2004.

Of particular concern to industry is the protection of intellectual property rights associated with innovations that make use of genetic resources, where those innovations depend upon extensive R&D investment. This has become a major issue in discussion of access and benefit sharing. As such, it is drawing into these discussions the major institutions that steward intellectual property rights within the global family: the WTO's Council on Trade Related Aspects of Intellectual Property Rights (TRIPS); and the Committee on the Reform of the Patent Cooperation Treaty and the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, both of the World Intellectual Property Organization (WIPO). The latter Committee was created to consider the ABS issues along with other issues, but proposals relating to ABS matters have been offered in all three of these forums. Similarly, IPR proposals have been presented in conjunction with CBD ABS consideration.[3]

Key emerging issues

Workable Country ABS Regimes: The key to realizing the CBD promise of facilitated access and equitable benefit sharing remains the country's national regime. The transition from more open, often unregulated resource use to use under the authority of the sovereign state is not complete until the state adopts and implements a regime defining its interests and clarifying its expectations of other participants in ABS processes. These regimes must establish the authority to enter into the contractual relationship that is at the heart of the access and benefit-sharing paradigm. These regimes must clearly define the authorities in which responsibility for negotiating mutually agreed terms is vested, and must address not only commercial enterprises engaged in bio-prospecting, but also academic and other research institutions that may extract resources of potential value. Similarly, such regimes must also clarify expectations regarding the role of indigenous and local communities, including the process for identifying communities

[3] See ICC paper on TRIPS and the Biodiversity Convention: What Conflict? for a more complete discussion of IPR issues.
http://www.iccwbo.org/home/statements_rules/statements/1999/trips_and_bio_convention.asp

that should be consulted regarding resource extraction and use, and legal protections for agents relying upon such consultations.

As of October, 2004, only 12 national regimes and the Andean Community and Central American regional agreements were listed on the database of such regimes maintained by the CBD. Some other regimes have been adopted but not yet listed. For example, the Biological Diversity Act 2002 came into force in India in April of 2004, with an innovative three-tier system for the purposes of implementing ABS provisions that will merit close scrutiny as experience is gained. Unfortunately, though, this sparce list of regimes remains indicative of the limited experience countries have accrued to date in implementing ABS provisions.

As discussed, this limited experience inherently limits the ability of countries and intergovernmental processes to make refined judgments regarding the most effective provisions to ensure both the encouragement of access and use of resources and the equitable sharing of benefits. Countries remain challenged to respond to the CBD, nevertheless. The Bonn Guidelines are therefore an important tool to aid countries in thinking through the task of framing national regimes. In addition, the WIPO Intergovernmental Committee is developing Intellectual Property Guidelines for Access and Benefit Sharing Contracts as another tool for countries – this one geared specifically to those resource uses that may contribute to R&D and ultimately to the perfecting of intellectual property rights dependent in part on such resources.

Standard Material Transfer Agreement (Standard MTA): Material transfer agreements (MTAs) are contracts that evolved in the commercial and academic arenas to govern transactions for the transfer of genetic materials. In practice, MTAs vary from transaction to transaction but contain common elements. To ensure that MTAs for "expedited access" to genetic resources within the "Multilateral System" established by the FAO International Treaty on Plant Genetic Resources contain an appropriate level of benefit-sharing, the Parties agreed to create a Standard MTA that promises to be an important contribution to the evolution of the larger ABS structure. While it applies only to certain categories of genetic materials and for access for certain uses, it may serve as a model with broader applicability in international circles. The Expert Group commissioned to develop the Standard MTA has been directed specifically to include provisions specifying benefit-sharing arrangements. The Standard MTA is also to apply to any subsequent transfer of the genetic resources for food and agriculture.

Disclosure of Origin/Source and/or PIC: Intellectual property rights associated with use of genetic resources are looming as a major issue, with a combination of circumstances focusing disproportionate attention on IPRs versus other aspects of the access and benefit sharing. The continued prominence of the "reference case" of patented blockbuster pharmaceutical has led some key players in this process to focus narrowly on the patenting step as a leverage point in the ABS process. In particular, a number of proposals have emerged to use the patent process as leverage to enforce national ABS regimes. These include proposals[4] to amend the TRIPS Agreement *to include an obligation to disclose the origin of genetic resources and associated traditional knowledge and to provide evidence of PIC and fair and equitable benefit sharing* as a condition of patentability.

[4] See 24 June, 2003 submission to the TRIPS Council, from Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, India, Peru, Thailand, and Venezuela.

The problems with such proposals are twofold. First, they would introduce into the patent process a precedent for its use as an enforcement tool rather than a tool to encourage and provide access to innovation. Second, because of the complications discussed earlier, such a requirement would be virtually impossible to meet for much of the genetic resources already in *ex-situ* conditions, where the country of origin may not be known or where such country may be one that did not have provisions for securing PIC. Some recent proposals have recognized such questions and sought to moderate disclosure obligations. Recently adopted Norwegian regulations, for example, would require disclosure of the country of origin where known, and would not link this disclosure to patentability (enforcing by other regulations). Such requirements still have the potential to cloud legal rights, however, and face the same practical challenges noted above, relating to the resources already in *ex-situ* conditions.

Switzerland has proposed in both the TRIPS Council and in WIPO that consideration be given to obligations to disclose the source of genetic resources used in products for which patents are being sought, again, without linkage to patentability. A declaration of the source from which the material was received would be a much more manageable obligation in most circumstances. This practical advantage finds support in some circles, but here again the attempt is to utilize the patenting process to drive implementation, a precedent that is strongly resisted in other circles. Such narrow focus on genetic resources used in patented innovations – even in its *source* disclosure manifestation -- also suffers from the reality that most of the resources extracted from *in-situ* conditions would be effectively bypassed by a system focused on patents.

A related concern is that this exaggerated focus on the patent process as an ABS tool may actually inhibit progress on ABS. The reason is that it invites the ABS process to become a forum for a broader range of potentially divisive issues. This is already evident in efforts by some countries to migrate concerns relating to genetic resource IPRs from primary intergovernmental institutions responsible for IPRs, WIPO and the WTO TRIPS Council, into the CBD. This not only threatens to undermine global forums charged with IPR responsibility, but threatens to mire access and benefit sharing in intractable debate.

Certificate of Origin/Source/Legal Provenance: Another suggestion receiving attention within CBD is that of developing a certificate of origin/source/legal provenance that would be required for certain movements or transactions involving genetic resources. Such a certificate could ideally document the compliance of parties to the transaction with ABS regimes of the respective countries, much as do the certificates required for international transfer of plants or animals under the UN Convention on International Trade in Endangered Species (CITES). Unlike the CITES certificates, however, the idea of genetic resource certificates would not necessarily be restricted to international movement of the material. Instead, notions are being explored that would require such certification at certain strategic points in the potential track of such resources from extraction to the point of commercial use.

The practicality of such a system clearly needs to be evaluated. In theory, it could have the potential to draw the broader range of uses of genetic resources into PIC and benefit sharing regimes (including uses that do not depend upon patents or other intellectual property protections). The challenge of handling materials already in *ex-situ* conditions would be no less

for this option, however, even if means can be devised to enable such a certificate to link with resources throughout the complex web of relationships that in which they may be involved (e.g. academic and non-academic researchers, multiple commercial parties, etc.). One additional question relating to such certificates is how they might relate to (or be integrated with) the notion of an MTA that would track ownership of resources.

Traditional Knowledge and Indigenous & Local Communities: It is clear that the CBD imparts expectations regarding consulting with concerned indigenous and local communities in any bio-prospecting and in negotiation of mutually agreed terms regarding genetic resources. However, the CBD recognizes the sovereign right of the states over such resources. In this context, national regimes must not only articulate national standards for meeting ABS interests of the sovereign state, but must also provide guidance and a degree of legal certainty regarding appropriate consultation with indigenous and local communities. Experience has demonstrated the potential for such consultation to be pursued in good faith, only to have new groups emerge after-the-fact and challenge the authority of the groups initially consulted. Such eventualities can cloud title to the resources and the failure of states to provide legal certainty in such matters therefore increases risk. In such cases, the increased risk must be accounted for and will result either in lower benefit offering or if the uncertainty is too great, will discourage any attempts to access resources in the first place.

Related to the question of consultation is the very difficult matter of how to identify and appropriately safeguard the interests of the holders of traditional knowledge (TK) that may play a role in identifying or accessing genetic resources. This issue poses extraordinary legal challenges. Unlike the question of country of origin, there may well be elements of TK that correspond to considerations of the patent system and therefore raise the question of applicability of the existing patent system to protection of TK. Some have suggested need for recognition of new rights as necessary for such protections. In either case, the questions posed for the intellectual property regime are challenging.[5]

Codes of Conduct Among Commercial, Public and Non-Profit Institutions: Voluntary codes of conduct have been adopted by many companies involved with use of genetic resources, and by a number of groups of stakeholders. This is emerging in the minds of many as an integral element of the transition to meet the broad mandates of the CBD. A prime example is MOSAICC (Micro-Organisms Sustainable use and Access regulation International Code of Conduct), a voluntary code of conduct to support the implementation of the CBD at the microbial level. The MOSAICC was developed by a consortium of 12 intergovernmental, non-governmental and private sector partners covering a broad spectrum of interests in microbial resources. Such codes have been evolving as experience has been gained in working with the CBD and its country-level implementation, and promise to become more widespread as the challenges of the CBD become more evident and as more countries frame national regimes.

[5] See ICC paper on Protecting Traditional Knowledge for a more complete discussion. http://www.iccwbo.org/home/statements_rules/statements/2001/protecting_traditional_knowledge.asp