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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 sentences[6] 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 information[8]), 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 work***[12]

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 developing[15] 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 occur[27], 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, an 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 affect 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 is 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 data[48]);*
  - *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 is 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 overseeable "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 o 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 detain 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 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.

26 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 Dedeurwaerdare, 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 Nº 181, as amended (taking into account amendments up to SLI 2006 Nº 131, Parts 8A, 9, 10, and 17). And see, Queensland Biodiscovery Act, Act Nº 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 secretes 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 interin 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 . Hendrikx, 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."

[59] See note 13, above.

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

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