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***239** ACCESS TO BENEFIT-SHARING: RISKS AND OPPORTUNITIES IN THE REGULATION OF BIOPROSPECTING FOR GENETIC RESOURCES

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***2411. INTRODUCTION TO ACCESS AND BENEFIT-SHARING**

a. What is ABS? In general terms, "Access and Benefit-Sharing" (or ABS) refers to institutional arrangements for access to genetic resources, the uses of such resources, and the fair and equitable sharing of benefits derived from such resources.

b. What are genetic resources? Article 3 of the Convention on Biological Diversity (CBD) defines genetic resources as "genetic material of actual or potential value of plant, animal, microbial or other origin containing functional units of heredity."

c. Why is it important? What are the challenges?

i. Recent advances in molecular biology and genome science have created an enormous potential market for unique genetic material from existing organisms and microorganisms in nature. Pharmaceutical, biotechnology and other industrial sectors have an active interest in "bioprospecting" for this material, and the commercial applications from such research can have enormous implications for human well-being.

ii. These commercial applications are in turn being secured through the extension of intellectual property rights (IPRs) over these genetic resources and their derivatives. Some have expressed concern, however, that IPRs involving such resources have been granted without complying with regulations on access and benefit-sharing.

iii. Effective conservation of biodiversity, which has been recognized as a global good in its own right, requires that local communities benefit; the potential value of genetic resources may provide a vehicle for providing such benefits.

iv. But the tremendous potential of these resources has yet to be fully realized, partly because of barriers and uncertainty in the legal and political framework for ABS. Just as recognition of the value of these ***242** resources has increased, so too has the sense that the current governance structure for providing access and use rights over these benefits is inadequate.

v. The ABS debate is therefore of significant interest to policymakers, a broad group of industry sectors (i.e., pharmaceutical, biotechnology; cosmetics; fragrances; horticultural; crop-protection and agribusiness); NGOs interested in conservation and sustainable development; and research scientists.

d. What is happening to address these challenges? In general, the international community is actively examining options to improve the legal framework relative to ABS issues. This activity is ongoing in several international forums, and appears poised for significant developments in the near term. The politics surrounding these issues are polarized, however, leading to an uncertain future about the next steps. The different forums include:

i. a process ongoing in CBD to develop a new international regime specifically focused on this issue;

ii. debates in both WIPO and TRIPs on proposals to change the global intellectual property rights regime to reinforce ABS measures;

iii. a relatively new UN process reviewing the conservation and sustainable use of marine biodiversity beyond

limits of national jurisdiction; and
iv. activity in miscellaneous other settings, including work under the FAO International Treaty on Plant Genetic Resources for Food and Agriculture to elaborate "material transfer agreements" that may embody both access and benefit-sharing provisions.

2. ABS UNDER THE CONVENTION ON BIOLOGICAL DIVERSITY

a. The CBD's objectives are to (1) conserve biodiversity, (2) ensure sustainable use, and (3) achieve fair and equitable sharing of benefits derived from genetic resources.
b. The CBD's focus on ABS issues reflects the bargaining leverage of developing countries, where most of the world's biodiversity is located. The treatment of genetic resources under the CBD is premised on the principle of national sovereignty; that is, the state where the genetic material is located has the right to regulate access and set conditions on how benefits should be shared. The CBD specifies that access to such resources requires the prior informed consent (PIC) of the country of origin, and that any access shall be on mutually agreed terms (MAT).
***243** c. Discussion and elaboration of ABS issues has been active topic on CBD agenda since 1998, and has accelerated in recent years, particularly given the general failure of countries to effectively address ABS issues on the national level.
i. In 2001, a CBD working group developed the Bonn Guidelines, subsequently adopted by the sixth conference of the parties (COP-6) in 2002. The Guidelines are intended to assist parties developing legislative, administrative or policy measures on ABS, as well as contract and other arrangements under mutually agreed terms for ABS. They provide a detailed framework for developing ABS regimes at the national level, including an emphasis on obligations of users of genetic resources.
ii. In fall 2002, however, the Johannesburg Plan of Implementation called for action "to negotiate within the framework of the CBD, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources." Developing countries pushed for this mandate because of their perception that the imbalance between providers and users in negotiating ABS agreements, exacerbated by the lack of enforcement or monitoring mechanisms, could be corrected only through a legally binding international regime.
iii. In 2004, the CBD COP mandated the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing "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 of article 15 and article 8(j) of the Convention and the three objectives of the Convention."
iv. Negotiations began at the third meeting of this working group in February 2005. They resumed again in earnest at the fourth meeting in February 2006, resulting in the drafting of a heavily bracketed draft text that was forwarded to the Conference of the Parties for consideration and guidance.
v. COP-8 in Brazil, held during March 2006 (which will conclude after the deadline for submission of this outline) will decide on the future structure of negotiations for the international regime and may provide direction on some of the substantive issues under review.
d. In brief, developing countries are pushing for rapid adoption of a legally binding regime that will require users of genetic resources to ensure fair and equitable benefit-sharing. Developed countries, with some exceptions (Norway), are resisting the push for a legally binding instrument, and instead suggest the need for time to gain experience with the Bonn Guidelines and further develop national ABS regimes before launching a new international system. (This outline will return to the CBD ABS discussions in more detail after reviewing in brief the other key forums where ABS activity is taking place.)

***2443. ABS IN THE INTELLECTUAL PROPERTY RIGHTS SYSTEM**

a. Background on Intellectual Property and Genetic Material: Intellectual property rights are tools to provide incentives for innovation, by giving owners the exclusive right to control the use of a work or product. Genetic material has been part of the intellectual properly landscape since 1980, when the U.S. Patent and Trademark Office granted a patent on a living genetically modified organism, and intellectual property rights involving genetic resources have grown significantly since then along with the growth in genetic sequencing technology.
b. ABS in the WTO and Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs):

i. The TRIPs Agreement was established to ensure minimum IPR standards among WTO members. Aimed largely at harmonizing IPR rules, it requires WTO members to provide minimum standards of protection for wide range of IPRs (such as patents, copyright, trademarks). It requires that patents be granted and honored for any invention; in all fields of technology, provided it is "new, involve[s] an inventive step and [is] capable of industrial application." WTO members may deny patents on grounds of public order, or with respect to plants or animals, but that exception does not extend to microorganisms.

ii. Developing countries seek to amend the TRIPs patent framework as a vehicle to enforce the benefit-sharing requirements of CBD. Various proposals would allow or require national patent authorities to impose ABS-related conditions on patent applicants: e.g., to disclose the origin or source of genetic material used in the patent, provide evidence that the applicant complied with the PIC requirements of the country of origin, and/or provide evidence that the applicant complied with national laws on benefit-sharing.

iii. Some developed countries (including the USG) argue that TRIPS and CBD are not incompatible, and oppose these proposals for mandatory disclosure. They argue that an effective regime for sharing benefits from the use of genetic resources will build in requirements at the *beginning* of the process of accessing resources, not at the point of commercialization. They further argue that developing countries significantly overstate the potential benefits from a complex IPR system for ABS, given that only a small fraction of bioprospecting or traditional knowledge uses ultimately result in commercial application and therefore enter the IPR process. In addition, they highlight significant feasibility obstacles to such a regime.

iv. Industry is concerned that mandatory disclosure provisions would increase uncertainty in the intellectual property regime and accordingly reduce the amount of investment in these resources that is necessary to develop and commercialize them. Industry contends that it is premature to incorporate ***245** ABS provisions into the intellectual property system when the basic elements of the ABS system, many of which have nothing to do with IPRs, are still being developed at the national level and within the CBD.

v. Developing countries nevertheless succeeded in getting this issue added as one of the elements of the "Doha mandate" for the current round of WTO trade negotiations, referred to generically as "the relationship between TRIPs and CBD." This issue is therefore potentially linked to the completion of Doha round, targeted for completion by end of this year. The Hong Kong Ministerial in December 2005 called for intensification of these talks and progress by July 2006. Talks are ongoing, although no prospect of an imminent breakthrough.

c. The World Intellectual Property Organization (WIPO) is also looking at mandatory disclosure issues in its Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). Last fall, WIPO extended the IGC's mandate to include discussions on the mandatory disclosure issue, including in the context of the proposed Substantive Patent Law Treaty. Developing countries have generally sought to shift the debate outside of WIPO because they are concerned that developed countries are using the WIPO discussions as a tool to forestall discussions in the TRIPs Council and CBD.

4. KEY ISSUES TO RESOLVE IN CBD ABS NEGOTIATIONS

a. In general, the discussions within the CBD are taking place against the backdrop of those IPR debates. They are also characterized by a wide diversity of views, including on core objectives and fundamental issues, such as whether there is a need for a new instrument at all, whether the "international regime" for ABS already exists and comprises many different mechanisms in different forums, or whether the international ABS regime should *facilitate* or *restrict* access to these genetic resources. Not surprisingly, therefore, almost all the basic questions remain the subject of debate: the legal nature of the regime, its scope, its modalities, and consequences for noncompliance.

b. Basic process issues have also been contentious, although these are likely to be narrowed at COP 8. They include key questions about how the negotiating process will be structured, such as the scheduled completion date, the number of meetings, the nature or formality of the forum, whether indigenous people should have a special role in the negotiations, what document should be the baseline text for negotiations, etc.

c. The legal nature of the "international regime" remains uncertain: Should it be legally binding, non-binding, a hybrid? Should it bind only "user countries" or include obligations for "provider countries"?

***246** d. In terms of the substantive elements of the regime, the discussion has focused primarily on the perceived need for tools to enforce ABS agreements and measures to insure compliance with Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT).

e. Certificates of Origin: International certificates of origin have been discussed as a potential mechanism to trace

genetic resource flows and identify whether PIC requirements for their use have been satisfied.

i. In theory, the certificates would identify the country of origin (or the source of material where the country of origin cannot be determined). They could also address the legal provenance of the resources and associated knowledge (i.e., evidence of the right to use the resources). Although implementing such a system could be costly and might further reduce incentives to conduct research in genetic resources, it would in theory also provide some benefit to commercial users, including potentially harmonized ABS rules and legal certainty with respect to evidence of the right to use genetic materials.

ii. In practice, however, there is no clear understanding of core issues, such as (1) what information such a certificate would include; (2) how it would operate (e.g., would it accompany the genetic resource from collection all the way through use, or be required only at designated enforcement checkpoints, like borders or patent offices, would it be mandatory or voluntary; if mandatory, how would it be reconciled with trade rules); (3) when it would be issued; (4) who would issue it; (5) how the system would handle the situation where the same resource might be available in multiple countries; (6) what kinds of consequences might exist for noncompliance; (7) what is actually being certified (e.g., the gene, the sample, the collection activity, etc).

f. Disclosure of Origin: As noted above, a closely related -- and highly contentious -- issue concerns the role of intellectual property rights over such resources and the related efforts to amend TRIPs. (The Bonn Guidelines sidestep this question.) Here the debate focuses on whether the CBD regime should address the "disclosure of origin" issue in intellectual property rights applications. There are many open and complex issues that would need to be addressed in any IPR disclosure scheme, whether within TRIPs or within the CBD. They include:

i. What elements would be required to be disclosed: e.g., (1) geographical origin or source of genetic material; (2) evidence of prior informed consent from source country and or local community; (3) evidence of compliance with benefit sharing agreements, etc.

ii. What the legal nature of the disclosure requirement is, and what are the legal consequences for noncompliance: e.g., civil proceedings by opposing ***247** parties; non-processing of a patent application; loss or transfer of patent rights; criminal penalties for false declarations, etc.

iii. How would the regime apply to so-called derivative materials? What kind of link between the genetic resource and the patented product would trigger such a requirement: e.g., if the invention makes immediate use of the genetic resource; if access to the genetic resource is necessary to make the invention or replicate it; if the genetic resource were used in the research that led to the invention and were essential to deriving the invention; if the genetic resource were used in the research but were incidental in deriving the invention; if the genetic resource were used to facilitate development of the invention; etc.

g. Role of Traditional Knowledge: The CBD mandate includes so-called "article 8(j) issues," which refers to the interests of indigenous and local communities regarding traditional knowledge, practices or innovations in connection with genetic resources. These interests are not easily recognized or protected under the existing intellectual property regime, and the ABS process has come under pressure to ensure that these communities are included in the benefit-sharing arrangements being developed.

h. Recognition of different types of benefit-sharing: It remains to be seen whether the instrument will reflect the full scope of benefits that provider countries might receive from providing access to genetic rights, or whether there is instead a narrow focus on financial benefits in the form of royalty payments or access fees.

i. Capacity-building for national systems: How will the mechanism supplement and enhance (rather than supplant or undermine) national ABS systems?

j. Scope of application/Variability of Rules: Should the mechanism set different rules for ABS depending upon the end use of the genetic material: e.g., limited applicability for academic and scientific research, compared to research for commercial application; different applicability for use of genetic material for food and agricultural uses, given the extensive existing resources of *ex situ* genetic resources for those uses, etc. The regime for sharing genetic material is more developed in some areas (e.g., plant genetic resources for food and agriculture) than in other areas, and a tailored regime that takes account of the different needs of different sectors may be valuable.

k. Role of guidelines: How will the regime build on existing guidelines, such as the Bonn Guidelines as well as those developed by industry sectors, such as the Biotechnology Industry Organization's Guidelines for Bioprospecting?

l. For each of these elements, there are fundamental debates about the degree to which their implementation would *enhance* a functioning ABS system, or *undermine it* with unworkable requirements that ultimately would discourage the sustainable use of genetic resources.

***2485. RISKS AND OPPORTUNITIES IN AN INTERNATIONAL ABS REGIME**

a. The main risk, then, is that the regime will impose excessive and unworkable burdens or increase the already considerable legal uncertainties associated with the development of these resources. If that happens, it could effectively stall further progress in this promising field. In the worst-case scenario; such a result could lead to a permanent loss of access to and use of this material due the loss of habitat and extinction of biodiversity. That result is in nobody's interest, but it is one that is quite possible.

b. The main opportunity is that a well-designed ABS regime could minimize existing obstacles to genetic research in a way that would maximize the sustainable use of these resources, while at the same time ensuring their conservation and the equitable sharing of benefits associated with their development.

i. Some kind of new international ABS instrument now appears all but certain to emerge within the next two to four years.

ii. A well-designed ABS regime could resolve current obstacles at the national level to bioprospecting. These current obstacles include regulatory uncertainty (e.g., lack of clarity on permit application process, failure to identify a point of contact with authority to grant PIC) and political resistance flowing from the impression that the current international system is imbalanced and that developing countries are unlikely to receive adequate benefits in return for access to genetic material.

c. The prospects for success are uncertain. The debate has become so polarized in recent years that any genuine progress, even in areas of mutual interest, will be difficult.

6. AN EMERGING RELATED ISSUE: MARINE GENETIC RESOURCES BEYOND THE LIMITS OF NATIONAL JURISDICTION

a. Introduction to marine genetic resources:

i. The deep ocean is a major reservoir of global biodiversity, particularly in “hotspots” around seamounts, deepwater corals, methane seeps, and hydrothermal vents.

ii. Bioprospecting for genetic material in the deep ocean has increased notably in recent years as deep-water exploration technology becomes more accessible. The pharmaceutical, biotechnology, and cosmetics sectors are all active in the field.

***249** iii. But these ecosystems are vulnerable, primarily from unsustainable fishing practices. Many of these ecosystems lie in areas beyond national jurisdiction, however, and there is no clear international framework governing activities aimed at these resources.

iv. The conservation and sustainable use of these resources has therefore attracted growing international attention. In addition, developing countries have also taken the position that such resources are “the common heritage of mankind” -- which in this context does not mean free to all but rather owned collectively by all -- and that benefits derived from them must be shared accordingly.

b. A new UN process is established:

i. The UN General Assembly adopted a resolution in 2004 to establish a working group to examine these issues. Its mandate was to (a) survey activities of international organizations on the conservation and sustainable use of marine biodiversity beyond areas of national jurisdiction; (b) examine the broad range of issues (scientific and legal) relating to the conservation and use of such biodiversity; (c) identify key issues where more study is needed; and (d) to consider options to promote international cooperation for conservation and use of such resources.

ii. The meeting in February was the first meeting of this working group. The group did not adopt any decisions or make significant progress in resolving open issues, but it did set the stage for further, more focused work.

c. Legal Context

i. The international legal framework applicable to these substances is ambiguous. It currently consists of a patchwork of instruments, none of which directly address the treatment of marine biodiversity or bioprospecting for marine genetic resources. These include UNCLOS, the CBD, various intellectual property rights agreements, and regional fisheries agreements.

ii. Each agreement is relevant to some degree, but there is no comprehensive mechanism that governs activities directed at or genetic resources beyond the limits of national jurisdiction.

iii. UNCLOS is the starting point for evaluating any rules applicable to activities relating to these resources. But UNCLOS does not specify which regime is applicable to genetic resources located beyond national jurisdiction. A debate has therefore emerged about the status of these resources under the Convention, focused primarily on whether they are analogous to seabed mineral resources, which are declared the "common ***250** heritage of mankind," or instead should be treated as living marine resources on the high seas, generally free to be collected and sampled by all.

iv. A number of other instruments exist that may be relevant to bioprospecting activities, including mechanisms under which countries agree to exercise their jurisdiction to control activities in the high seas to protect the marine environment or set sustainable harvest limits for fish These include measures to establish so-called "marine protected areas."

v. There are also various codes of conduct under development that would apply to marine scientific research in the deep seabed. Reliance on such voluntary codes is likely to increase in the absence of any clear binding regulatory or management framework. One such approach is being developed by a scientific initiative known as "InterRidge," which would apply to organizations and individuals performing MSR on hydrothermal vents (both within and beyond areas of national jurisdiction). In addition, codes of conduct for access and benefit-sharing that have been developed for land-based bioprospecting may also be relevant.

d. Summary of Meeting

i. It was widely agreed that illegal, unregulated and unreported (so-called "IUU") fishing, together with the destruction wrought on fragile ecosystems on the ocean floor by bottom trawling, poses the greatest immediate threat to these unique marine ecosystems and their associated biodiversity. Many countries, supported vocally by the NGO community, called for near-term action to address this most immediate threat to these ecosystems, and urged the UN General Assembly to adopt a resolution calling for a moratorium on unregulated high-seas bottom trawling.

ii. On other issues, positions vary among developing and developed countries. Developing countries are concerned, as they are in the terrestrial context, with controlling access to and sharing of benefits arising from these genetic resources, which they view as the "common heritage of mankind." These countries advocate the need to consider a new regime to implement benefit-sharing. Developed countries in turn believe that the ISA lacks jurisdiction over marine genetic resources.

iii. Some countries have suggested that the legal debate should be sidestepped for the time being in favor of pragmatic approaches to provide more immediate protection of these resources.

***251** e. Next Steps on Marine Genetic Resources Beyond National Jurisdiction:

i. It is likely that further meetings will be convened and that additional international action (including a new binding agreement, as proposed by the EU) will be pursued.

ii. Near-term action with respect to high-seas bioprospecting will be focused on concrete steps such as establishing guidelines or a code of conduct to govern such activities.

iii. These developments will primarily affect commercial interests such as the pharmaceutical, cosmetics, and biotechnology sectors.

iv. If the EU's call for a new implementation agreement takes hold, then it will be difficult to confine the scope to marine protected areas.

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