UNEP

CBD

CONVENTION ON BIOLOGICAL DIVERSITY

Distr.
GENERAL

UNEP/CBD/WG-ABS/3/INF/6
11 January 2005

ENGLISH ONLY

AD HOC OPEN-ENDED WORKING
GROUP ON ACCESS AND
BENEFIT-SHARING
Third meeting
Bangkok, 14-18 February 2005

RECORD OF DISCUSSION OF THE INTERNATIONAL EXPERT WORKSHOP ON ACCESS TO GENETIC RESOURCES AND BENEFIT-SHARING: GENERATING NEW IDEAS AND THINKING

Note by the Executive Secretary

1. At the request of the Governments of Canada and Mexico, the Executive Secretary has the honour to circulate herewith, for the information of participants in the third meeting of the Open-ended Ad Hoc Working Group on Access and Benefit-sharing, the Record of Discussion of the International Expert Workshop on Access to Genetic Resources and Benefit-sharing, held in Cuernavaca, Mexico, from 24 to 27 October 2004. The Government of Canada has informed the Secretariat of the Convention that the full report of the Workshop (including the Record of Discussion and the experts papers submitted during the workshop) will be distributed at the meeting of the Working Group in Thailand. All the papers submitted at the Workshop are available online at: www.canmexworkshop.com.

2. The Record of Discussion is being circulated in the form and the language in which it was received by the Secretariat of the Convention on Biological Diversity.

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Generating New Thinking and Ideas: Record of Discussion

Opening Remarks

The two co-chairs, Jorge Soberón Mainero of Mexico and Timothy J. Hodges of Canada welcomed participants to the Workshop and thanked the organizers and sponsors of the meeting, which included the governments of Canada and Mexico and their agencies, and the government of Switzerland. They hoped for a wide-ranging and vigorous discussion which would identify areas of agreement and also of disagreement on issues related to access and benefit-sharing (ABS). The intention of the organizers was to prepare a report on the meeting, which would be transmitted to the Secretariat of the Convention on Biological Diversity (CBD) as a contribution to further work on, and negotiations of an ABS International Regime.

Substantive Discussion

I. Identification of Outstanding ABS Issues

Level of National Implementation

Speaker: Valérie Normand
Paper: National Implementation

Speaker: Santiago Carrizosa
Paper: Developing and Implementation ABS Regulation in the Pacific Rim Region: Issues and Challenges

The two papers provided information about the level of activity both globally and in Pacific Rim countries on developing national ABS policies and regulations. While activity is underway in many countries, relatively few have completed the development of a policy framework and/or legislation. Issues for consideration in the paper included: how broad should the scope of legislation be, how should ownership of ex situ collections be defined, how could prior informed consent procedures be improved, the need for effective monitoring systems and conflicting views on patenting of life forms. It was also noted that initial approaches to ABS legislation tended to follow a top-down approach rather than a more community-level approach.

The subsequent discussion focused on two main issues. First of all it was noted that too strong a bias towards CBD related information ran the risk of missing a great deal of information and experience on ABS which was either not directly related to the CBD or which originated prior to active work on ABS in the Convention being undertaken. It was noted for instance that most countries had access laws, but that these were formulated in a multiplicity of regulations and permits (e.g. research permits, collecting statements, export permits, etc) rather than as a framework law on ABS alone. This information is still valid and relevant to work done on an International Regime and ways should be found to collect it. It was also

noted that while there was a multiplicity of laws and regulations governing access, there was much less governing benefits.

The second main point also picked up on the theme of too much bias towards CBD related concepts. It should not be assumed that an International Regime on ABS under the CBD is the best way forward. There were concerns for improving equity, redistributing wealth more widely, and protecting spiritual and cultural values associated with genetic resources.

Selected issues and concerns[1]

- Few countries have completed the development of an ABS policy framework and/or legislation but ABS policy processes are currently underway in many countries.
- Progress in the implementation of the CBD at the national level is difficult to assess since it is the result of the implementation of a set of national policy measures, laws and regulations not merely implemented with the purpose of implementing the Convention.
- There may be too strong a bias towards CBD-related concepts and due attention should be given to considering the role of national and international elements existing outside the scope of CBD when conceptualizing ABS.

National Access Laws (challenges), continuing monitoring and enforcement issues

Speaker: Paz Benavidez
Paper: The Challenges in the Implementation of the Philippine ABS Regulation: Monitoring and Enforcement of Bioprospecting Activities in the Philippines

This paper describes the experience with Executive Order 247 and the current efforts to revise the approach through developing guidelines under the Wildlife Resources Conservation and Protection Act. There are many challenges not the least being developing an effective monitoring and enforcement system which implies finding ways of enforcing agreements outside the Philippines, including coverage of transfers to third parties.

Speaker: Geoff Burton
Paper: National Access Laws: Challenges, Benefit-sharing, Monitoring and Enforcement

The paper outlined that country's approach to introducing national access laws within Australia's federal structure of government, encapsulated in an intergovernmental agreement entitled *the Nationally Consistent Approach for Access to and Utilization of Australia's Native Genetic and Biochemical Resources Act*. The Australian experience was informed by several observations including: the sensitivity of biological research to barriers, the serendipitous nature of research outcomes which argues for encouraging high volumes of research, the need to take the undervalued genetic resources in the global commons into account, and the danger that policy responses lag substantially behind scientific progress.

Speaker: Robert Lettington
Paper: Briefing Note: National Access Laws (challenges)

[1] "Selected issues and concerns" do no reflect consensus or advocate one view over another, but merely are indicative of relative focus in the discussions.

In the Kenyan experience there was a great need for more clarity of objectives for ABS policies, identification of a national authority, the definitions of key terms including 'genetic resources' and a recognition that different sectors require different approaches (e.g., more control might be needed over endemic species compared to non-endemic species).

In the subsequent discussion, some of the concerns expressed by the industry, such as the negative impacts of uncertainty, the lack of transparency and long time delays were underlined. This may have contributed to the pharmaceutical industry increasing its emphasis on combinatorial chemistry. Uncertainty was aggravated by too many different international organizations making policy in the ABS field. On this last point there was also recognition that different forums and international agreements had relevance to various aspects of a potential International Regime on ABS and that they had a constructive role to play.

The issue of competing legal jurisdictions was also raised and it was recognized that key developed country legal jurisdictions were likely to be the basis for contractual arrangements on ABS. This would imply that parties to a contract would be dealing with two different legal systems. While this might be inevitable, it raised the issue of access by source countries to those legal jurisdictions and in particular the barriers that developing countries faced. For instance how would developed country jurisdictions recognize the national laws of provider countries including their customary law practices?

Another issue raised was the sequence of effort. Should the focus be on promoting bio-prospecting activities to develop and extend knowledge of a country's genetic resource base or should effort go into developing a policy framework to govern ABS? It was suggested that these efforts were not mutually exclusive and that one of the goals of a policy framework would be to encourage the development of this type of knowledge.

Finally there was a discussion about the nature and timing of benefits. Some thought that royalty benefits were potentially illusory as well as being very long term. Disputes over the rate of royalty to be charged depended upon a clear answer to the question concerning the base would it be calculated upon. Benefits that focused upon building up local capacities and abilities were potentially easier and faster to obtain.

Selected issues and concerns

- Several international forums and agreements have a constructive role to play in the development of an international regime on ABS. However, there is some concern that overlapping ABS policy-making responsibilities between international institutions may create uncertainty for industry.

- Differences in legal frameworks between countries may have implications for the recognition in user countries of prior informed consent and customary laws in provider countries and the nature and enforceability of contractual arrangements between providers and users.

- Promoting bio-prospecting activities that has as a goal the development and extension of scientific knowledge of a country's biological/genetic resources and developing a

policy framework to govern access and benefit-sharing are not mutually exclusive objectives and can be pursued simultaneously.

- Benefit-sharing in the form of capacity-building which creates short-term local benefits could be a central component of benefit sharing agreements as compared to royalty benefits which are likely to be long term and uncertain.

Access to genetic resources and intellectual property rights: what is biopiracy?

Speaker: Graham Dutfield
Paper: What is Biopiracy?

The paper provides the context for a discussion on 'biopiracy'. There is a perception amongst developing countries and NGOs that the patent system enables corporations to misappropriate genetic resources and associated traditional knowledge or at least to unfairly 'free-ride' on them. The paper seeks to shed some light on the meaning of the term "Biopiracy" and to consider what should be done about it, bearing in mind that an agreement on what is and isn't biopiracy - and how much of it there actually is - is still lacking. While there may be valid reasons for the 'strategic vagueness' of the concept, it is a problem for those working upon legal solutions. There are extreme views on what the term means and the challenge is to find an effective middle ground.

In the subsequent discussion, it was recognized that there is no agreed definition of biopiracy and that each country would define it according to its own views. The key issue was if the international community was going to do something about it. How does the international community take action while acknowledging that some countries have very tough standards and others are more liberal. Should this be undertaken under the CBD or outside of it?

Biopiracy could be defined as when illegal access to biological resources is obtained. It would also be important to differentiate between organized illegal activities and opportunistic illegal activities. A biopiracy framework could address three levels: violation of prior informed consent procedures, violations based on mutual agreements, and third party issues.

When we consider biopiracy we should ask what has been taken. It is not DNA because this moves about freely, nor is it the knowledge of genetic resources. It is the value that lies in traditional knowledge and genetic resources. Biopiracy could be defined as the unauthorized appropriation of values.

The definition of biopiracy is very important. Should the proposed International Regime address it or leave it to national legislation? It was recognized that there were too many polemics on biopiracy and that the paper very usefully deconstructed the concept.

It was suggested that we needed to define the objective of an International Regime and be clear about what we are trying to achieve. Aiming for fairness and equity is very important. The key challenge was to define those principles.

It was noted that biopiracy is not a new phenomenon. What has changed is the perception of biopiracy, which is driven partially by experience rooted in colonial arrangements of an

exploitive nature. A question was raised whether contravening ABS laws necessarily implied biopiracy. More generally, when there is illegal behaviour, is it biopiracy? Potential solutions may be found in concepts underlying copyright law and enforcement.

Finally, it was suggested that the concept of 'strategic vagueness' was a useful one. Reaching an internationally agreed definition was an academic problem. What was important was for countries to define what was legal and illegal according to their own circumstances and then find effective ways of enforcing it.

Selected Issues and Concerns

- There is no agreed upon definition of the concept of "biopiracy". It could be defined and standardized under the IP and/or allow countries to define it at the national level.
- The concept of 'strategic vagueness' is useful as it allows for countries to define what is legal and illegal according to their own circumstances and find effective ways to adopt measures to counter biopiracy.
- In considering measures for countering biopiracy three types of activities need to be considered: violation of prior informed consent procedures, violations based on contracts based on mutually-agreed terms, and third party issues.
- The IR should aim for fairness and equity, as the perception of biopiracy is partially driven by experience rooted in colonial arrangements of an exploitive nature.

II. Vision and Nature of an International Regime: Goals, Challenges, Gaps and Role of CBD and Other Bodies

Vision and Nature of an International Regime

Speaker: François Pythoud
Paper: Vision and Nature of an International Regime on ABS

The paper focuses on the main questions that should be addressed when developing an International Regime on ABS. It refers to CBD Decision VII/19, which identified 21 elements for inclusion in the International Regime under the terms of reference. The paper groups them into 6 categories, which provides a framework the main elements of the International Regime, whose scope would cover both genetic resources and traditional knowledge. It also raises the important question of whether the International Regime should be integrated with other pertinent legally binding and voluntary instruments, or be independent.

Speaker: Tomme Young
Paper: The International Regime from an Implementation Perspective: What Legislation can… (and cannot do) and How this Affects the Vision and Nature of the Regime.

The paper focuses on two basic questions: what is possible from a legal perspective and what is needed to enable "the possible". An important goal in the negotiations of an International Regime should be to develop a roadmap for the solution of legal impediments that currently inhibit implementation. At a minimum this should address the needs of functional ABS law and utilisation of the tools of commercial and market based (contractual) frameworks. The paper notes that while the ABS framework of issues is closely linked to biosafety/GMO frameworks, national and international legislation on these two issues is almost completely separated. Re-linking them might create real commercial incentives for both.

Speaker: Joshua Rosenthal

Paper: Power Point Presentation

The presentation presented information on the approval of new drugs in the United States during the period 1981–2002. Only 6% of all new FDA approved chemicals are derived directly from natural products, while 49% have some relation to natural derivatives. The absolute number of new drugs approved is relatively low and the data shows that the rate of approvals is dropping. From the high point in 1987 (70 new drugs), only 27 new drugs were approved by the FDA in 2002. Information was also provided on the ICBG-NIH project. Despite 10 years of work, $30M of funding, the work of many partners and the review of 500 compounds, no new drugs have been created. This demonstrates that potential pharmaceutical benefits from natural products are not as great as sometimes envisaged and related potential royalty flows could be disappointing. The International Cooperative Biodiversity Group ICBG experience also demonstrates the substantial impact of transaction costs. Finally an International Regime should balance property interests with the need to enhance information flows and increase their public availability.

Speaker: Stephen Smith
Paper: The International Regime as it Applies to Plant Genetic Resources for Food and Agriculture

The paper discusses ABS from the perspective of plant genetic resources for food and agriculture (PGRFA) mentioning the features and limitations imposed by history, biology and laws. It relates to the special needs of this sector to an International Regime on ABS and stresses that continued access to PGRFA is critical to human health, economies sustainability and the environment. An International Regime should promote more effective access to and use of PGRFA. The FAO's International Treaty and the CBD provide complementary paths forward. The needs of both providers and users of genetic resources must be met in order to ensure that the continuum linking farmers to consumers is maintained unbroken. An International Regime with legal certitude will remain non-functional unless additional resources are applied to identify potentially useful exotic germplasm.

Speaker: Peter Einarsson
Paper: Oral presentation

The presentation focused on the situation and rights of people who are directly dependant upon biodiversity for their livelihood (approximately 1/3 of the human population including Indigenous people and farmers). The International Regime must address the fear in these communities that access will be provided widely but the benefits shared only between governments and users. In this regard the Johannesburg Declaration, which focused on benefit-sharing, and both Article 15 and Article 1 of the CBD, are all relevant. There was a

danger that the work being done on an International Regime will focus too narrowly on commercialization. Achieving fair and equitable treatment was a very difficult challenge when the different parties come from such different power positions. The inequality of actors should be recognized and addressed. A relatively narrow focus on disclosure of origin, without effective prior informed consent and monitoring, might serve only to legitimize inequitable exchanges of genetic resources.

Speaker: Robert Lettington
Paper: Vision and Nature of an International Regime: Minimum Requirements and Options from a Practical Developing Country perspective

The paper addresses the core objectives of an International Regime. Too much complexity should be avoided. User country measures and the related questions of enforcement and compliance are the central issues to be addressed by an International Regime. The paper discusses monitoring mechanisms, minimum standards and the need for categorization of the various uses of genetic resources. It also addresses the supporting components of an International Regime including: information clearing, monitoring and capacity building. The main challenges to developing an International Regime are overcoming polarized views of various actors and improving national capacities. Greater attention to capacity building, combined with effective user measures will allow developing countries to comfortably engage in collaborations with developed country actors.

In the initial discussion, which took place after the first three presentations, there was debate about whether we are focussing too much on pharmaceuticals. Many participants discussed the importance of botanicals. Regarding them, was the interest in their genetic resources, or was it more strongly related to the need to purify botanical compounds? The market for botanicals has grown in the past couple of years, but few arrangements are treated as CBD-ABS contracts; botanicals tend to be treated as commodity transactions.

A discussion about the danger of confusing the concept of a legally binding agreement with an enforceable agreement followed. The two concepts were not equivalent. There is also the potential for mixing binding and non-binding elements together in a possible International Regime.

It was noted that this Workshop was focused more on the genetic resources than on traditional knowledge. We were reminded of recent negotiating history on traditional knowledge, particularly as it applied to the negotiation of CBD COP Decision VII/19. Until corrected by negotiators at COP VII, this decision in draft form had treated traditional knowledge incorrectly as something being under the jurisdiction of States. Traditional knowledge is under the exclusive jurisdiction of indigenous peoples. There must be a clear distinction between the treatment of genetic resources and traditional knowledge in an International Regime. It was also noted how intimate was the interplay between traditional knowledge and the identification and use of genetic resources. From the perspective of traditional elders, there is no clear distinction between a resource and the knowledge associated with the resource.

There was also a discussion about basic approaches to an International Regime. What is the basic objective? Will it be made up of hard law and soft law? Should the regime draw in other institutions by reference or attempt to give them direction? How will the International

Regime relate to the objectives of the Johannesburg Declaration? Should it be negotiated in one comprehensive and complete form or should the negotiations and implementation be staged or progressive?

Finally, participants discussed the importance of political will. Data on progress towards creating ABS policies at the national level might suggest that there is insufficient political will. Others thought that there was significant political momentum behind ABS but that a lack of capacity at the national level and a lack of clarity in the concepts impeded progress. There was potential for the negotiation of an International Regime on ABS to act as an enabler at the national level.

The second part of the discussion focused upon trying to delineate the different elements of an effective International Regime, based on simple and clear goals. There were two general approaches: a *holistic* approach with a wide range of objectives and coverage of all stakeholders or a *staged* approach, which addressed specific issues.

Many thought that the second option was more practical but others thought that a philosophical discussion focusing on the core objectives of the CBD (Article 1) was an essential precondition to developing an effective International Regime. While there was a presumption that the CBD should maximize commercial benefits, the CBD's core objectives focus on conservation and sustainability. This tension needed to be resolved.

Further discussion noted that tension between objectives as they relate to ABS, public interest and public gain, was not necessarily an impediment. It meant that a balance between different objectives needed to be defined. "Strategic incoherence" could be a positive thing because it left parties the flexibility to implement ABS measures which met national and local needs.

A CBD declaration was suggested based on the principle that no commercial gains should be derived from illegal bioprospecting activities in other countries. It could be left to individual governments to work out how to implement this, according to their own circumstances.

There was also discussion about harmonization and minimum standards. There was disagreement about whether these objectives were feasible in the short term because of the accelerating pace with which scientific developments are taking place.

There were different opinions about the concept of certificates of origin. Some thought that they would be an essential element of an International Regime. Others thought that the concept of certificates had not yet been properly developed. Before negotiating on certificates we had to know what they were, have the ability to model them and determine what potential costs and benefits they would provide.

An International Regime should provide developing countries with access to knowledge, which would enable them to add value to their own resources. It should also ensure compliance by user countries to national ABS legislation in provider countries. This could be formulated as substantive compliance with national laws through transparent conduct.

Selected issues and concerns

- A lack of capacity, political will and conceptual clarity has impeded progress in ABS implementation but the decision to negotiate an international regime has provided new momentum to address the issues.

- Two general approaches were proposed for the nature of an effective IR: a *holistic* approach comprising a wide range of objectives and coverage of all stakeholders versus a *staged* approach which addressed specific issues and was proposed as more practical.
- Distinction should be made between "enforceable" and "legally binding". A view is that we have a problem of non-enforceability rather than one of non-legally-binding since the CBD already contains ABS-related provisions and is legally binding.

- There is a need for a clear distinction between the treatment of genetic resources and traditional knowledge (i.e. prior informed consent procedures and benefit-sharing arrangements)in the IR.

- There is a need to resolve whether the core objectives of the IR should place the focus of benefit-sharing on commercial benefits or on conservation and sustainability or both.

- An IR should provide developing countries with access to science and knowledge in order to add commercial value to their own biological/genetic resources, and which would ensure compliance by user countries to national ABS legislation in provider countries.
- "Strategic incoherence" may have a positive impact on national ABS policy development and public welfare since it allows Parties the flexibility to implement ABS measures which specific national interests and local needs.
- There was no consensus on whether potential IR goals of harmonization and minimum standards were feasible in the short term because of the accelerating pace with which scientific developments are taking place.
- If certificates are to be considered as part of an IR there is the need to define their nature and purpose, to model their impacts, and to determine their associated costs and benefits.

III. Specific Issues for Consideration in the Elaboration of the IR

Interface with Existing IP System and Limits and Opportunities for Existing IP Rights

Speaker: Martin Girsberger

Paper: Disclosure of the Source of Genetic Resources and Traditional Knowledge in Patent Applications.

This paper analyses the following issues and contains proposals for a way forward with regard to the declaration of the source of genetic resources and traditional knowledge in patent applications. The issues considered include: what terminology should be used to cover genetic resources and traditional knowledge; how should the concept of "source" be defined; what should trigger a disclosure requirement; what is the legal basis of the disclosure requirement; should voluntary or mandatory disclosure be required at the national level; and what sanctions could be considered for failure to disclose or wrongful disclosure. The paper draws a number of conclusions based on the recent Swiss proposal submitted to the WIPO working group on Reform of the PCT.

Speaker: Kim Connolly-Stone
Paper: The Interface with Existing Intellectual Property Systems: Limits and Opportunities for Existing Intellectual Property Rights

The paper considers relevant aspects of the CBD and the WTO on Trade Related Aspects of Intellectual Property Rights (TRIPS) with a view to determining what flexibility exits under TRIPS to take national measures in support of ABS objectives, including prior informed consent (PIC), mutually agreed terms and benefit-sharing. Particular attention is given to the various proposals in favour of disclosure of origin or source of genetic resources and associated traditional knowledge, and evidence of PIC or benefit-sharing, in applications for patents and plant variety rights (PVRs).

It concludes that the IP system can support ABS through disclosure, in addition to ABS systems of disclosure and other areas of law. Parties should take advantage of the flexibility available under TRIPS to provide policy space to implement ABS policies. The IP system could also require mandatory disclosure of source of genetic resources and associated traditional knowledge in applications for patents and PVRs and collect information about whether PIC and benefit-sharing has occurred, but this should not become a substantive requirement for patentability. If disclosure of PIC and benefit-sharing is required, however, an amendment to TRIPS would be needed. Some difficult areas to address included: defining the trigger for disclosure, prescribing suitable documentation, minimizing compliance costs, achieving progress in TRIPS Council and combating the effect of free trade agreements which required parties to opt out of TRIPS flexibility provisions.

Speaker: William Kingston
Paper: Four Reforms for Wider Benefit-Sharing

The paper focuses on advocating reforms of intellectual property rights to contribute to protection of genetic resources and traditional knowledge as well as to benefit-sharing. The present system of intellectual property rights is effectively a unitary system based on the United States approach, more diversity is needed. The present system has developed in ways which reinforce the market powers of capability and persuasion which advanced-country firms possess in strength. Other countries need intellectual property rights which compensate for their weakness in these types of market power. The four reforms are: returning to states the power to limit the absolute monopoly which trade marks deliver, direct protection of

innovation, compulsory arbitration of disputes, and introducing a financial dimension into the measurement of all grants of intellectual property rights.

Speaker: Ruth Okediji
Paper: Access and Benefit-sharing and the Interface with Existing IP Systems: Limits and Opportunities - Comments prepared for the Experts International Workshop on Access and Benefit-Sharing, Cuernavaca, Mexico, October 24-27, 2004.

The paper comments on a number of issues where the interface between intellectual property rights and ABS offer possibilities for developing the framework of an International Regime on ABS. Concerns about the incompatibility of intellectual property and traditional knowledge that revolve around the concept of value should be reconsidered in the light of the protection of non-economic values already existing within the intellectual property system. There is also considerable overlap between copyright, patents and trademarks or trade secrets. A single product could have many overlapping rights. Traditional knowledge could benefit immensely from this. The possibility of patenting some forms of traditional knowledge may compel a legal framework that can straddle both a *sui generis* system of protection at the national level and the international intellectual property system.

Furthermore, the possibility of an International Regime outside the intellectual property system raises the question of appropriate legal baselines. One baseline is a property rule regime, which has been the dominant choice for international intellectual property treaties. A second baseline is a liability rule regime which allows use to occur through implicit license and the appropriate compensation is determined subsequently. Features of both regimes could coexist in the same system. While most existing proposals for a *sui generis* ABS International Regime are based upon the property rule, the possibility of a liability regime could be a serious alternative, particularly for traditional knowledge. It would also address the problem of high transaction costs. Finally the paper notes that availability of alternative legal sources for intellectual property rights create an "opt-in" system where creators essentially choose the type of protection model suitable for their interests.

During the first part of the discussion, which took place after the first two presentation, it was pointed out that disclosure alone does not create a compensatory right. The Yellowstone Park experience was relevant as the Park did not have a compensatory interest despite disclosure. In addition, it was asserted that disclosure should apply within and without the patent system if it captures different forms of innovation. Norway is also considering the addition, in its national legislation, of a requirement of proof that benefit-sharing was achieved.

It was noted that the pharmaceutical industry supported disclosure but it should be kept in mind that because of long lead times, most potential benefits would have already come and gone by the time a product was approved for market. There should be a focus on contractual arrangements which provide for benefit-sharing at earlier stages.

Finally the concept of "essentiality" was raised. In the case where an innovation might be based on many different compounds, only one of which was deemed essential, it was confirmed that the Swiss approach could encompass disclosure of the essential element only.

There was also a recognition that TRIPS amendments would be difficult and time consuming to obtain. There was debate about whether purely voluntary disclosure of ABS related

information required a TRIPS amendment and the conclusion was that it did not. However, some thought that a voluntary system would not have much effect and that mandatory disclosure was needed which would in turn require a TRIPS amendment. On the other hand if a few important user countries required disclosure this would be influential.

It was proposed that a certificate of origin could be designed as proof that PIC had been obtained. This might reduce the administrative burden on patent offices. In addition, one way to encourage continued flexibility in the IP system was to include the need for flexibility in an ABS International Regime. This might help address the problem of TRIPS flexibility provisions being dropped in FTAs. It was also noted that disclosure requirements would act as incentives for provider countries to better grant access to genetic resources to user countries.

In the final discussion it was suggested that an additional reform could be to use aid funds in cases where intellectual property rights might be bought out to further a development goal. It was suggested however that this might just encourage further challenges by intellectual property holders.

It was noted that trademarks were useful instruments that could be used to provide protection particularly for traditional knowledge and that American indigenous groups were using them. However, there was less applicability to genetic resources because products so derived typically were not marketed according to their source.

There was finally discussion about the danger of an ABS International Regime being contained within an IP/TRIPS paradigm that might impose unnecessary constraints on achieving CDB/ABS objectives. It was noted that the existing intellectual property system was not fostering innovation but rather protecting investment. There was another view that criticism of TRIPS and the current intellectual property system ran the risk of "throwing the baby out with the bath water". While there is a need for better balance between public and private interests, criticism of trademarks undervalued the benefits of the attention to quality standards, which a trademark implied.

Participants also debated about the intellectual property system and its role in an ABS regime. Some thought that the intellectual property system was very elastic and could perform different roles depending upon national objectives. Others thought that trying to find a sufficient level of flexibility within TRIPS for ABS needs should not box in the International Regime. It should be possible to develop the International Regime for its own specific goals. For instance, benefit-sharing and the protection of traditional knowledge should not expire with the end of a patent term.

There was concern that too much emphasis on disclosure through the patent system would give providers a false sense of security. A patent in itself did not imply benefits. For instance a patented drug was worthless unless approved by the drug authorities. Patents do not cover many forms of innovation. Innovation can rely for instance upon trade secrets for protection, which can last indefinitely.

There were some doubts about the true value of the disclosure of origin. Without knowing its true value, it will be hard to calibrate the negotiating price to pay for it. There was also concern about mandatory disclosure requiring a TRIPS amendment, which most thought would be very difficult to obtain.

It was noted that there is a need for harmonization on triggers for disclosure. The fears of plant breeders were also raised because their products originate from hundreds of different sources, which would be very difficult to identify and properly disclose.

It was suggested that a music industry model might be compatible with a liability regime whereby users of genetic resources and traditional knowledge paid a fee to a collection agency in the same way that radio stations paid for music.

It was thought that the key to benefit-sharing was a system of incentives for users of genetic material and traditional knowledge. There was the example of the Orphan Drug Act in the United States, which broke existing intellectual property laws by allowing the National Health Office to ensure, for a defined period, that no licenses be granted to competitors of anyone that had developed eligible drugs meeting the national need to combat obscure illnesses. The results were good.

There was discussion about incentives for industry to comply with an International Regime. It was noted that compliance measures had to be balanced with incentives. It was noted that developing a transparent, easily enforceable system, which provided certainty to users, would be enough incentive for industry. Referring to the example of plant variety protection systems, it was noted that the intellectual property system alone could not deliver enough incentives to promote wide-ranging research. This had to be delivered by the public sector. Consequently when commercialization occurs, benefits should be invested back into research. It was suggested that the International Regime had to have a balance between incentives (the carrot) and the intellectual property system (the stick). There were two ways of using the patent system for disclosure. There was pure disclosure at the administrative level only and disclosure, which became a substantive requirement for patent. The second approach could put unrealistic burdens upon patent authorities.

Selected issues and concerns

- There is the risk of putting unnecessary constraints on achieving CBD objectives if IR is unduly constrained by rights under WTO-TRIPS. Relation between disclosure and benefit sharing should be closely looked at.
- Two approaches for disclosure: as an administrative measure or as a substantive condition for patentability.
- Voluntary disclosure in patent applications would not need a TRIPS amendment. Countries adopting disclosure requirements in their national IP laws would help move forward this debate.
- Disclosure requirements in patent applications could provide incentives for provider countries to facilitate access. A transparent, easily enforceable system, which provided certainty to users, could be an incentive for industry to comply with an IR. A certificate of origin as proof of PIC may reduce administrative burden of IP offices. There may be a need for harmonization on triggers for disclosure.
- Too much emphasis on disclosure could give providers of genetic resources a false sense of security.

Limits to rights over genetic resources: the issues of derivatives. Defining the line between tangible and intangible property rights

Speaker: Fernando Casas

Paper: Genetic Resources Property Rights. The Derivatives Issue. Tangible and Intangible Property Rights (text in Spanish)

The paper examines the potential ABS International Regime, benefit-sharing, property rights on genetic resources and their derivatives, in the light of Andean experience. The concept of derivatives is defined as well as the size of the market opportunity. The main actors include: the nation State, business, indigenous peoples and the scientific community. Particular issues addressed include: the limits to rights, the role of the State, genetic resources and derivatives, provider rights, user rights, non-material or intangible property and traditional knowledge.

In the subsequent discussion it was recognized by many that this was a very complex issue and one that could not be avoided in the elaboration of an International Regime. It was underlined that genetic resources are not just about genes. They include a much wider range of material (molecules, enzymes, etc), which were the basis of derivative products with a very large market value. Derivatives are also strongly connected to traditional knowledge.

It was noted that defining the term "derivatives" was very difficult. There was a continuum starting with original material, progeny, unmodified derivatives (ie genes) and modifications. The US NIH attempted 10 years ago to define how far along this continuum providers could claim control before ownership be transferred to the user. Other speakers also recognized the difficulty of finding a clear dividing line.

It was noted that in the academic world there was a great deal of exchange and modification of genetic material and that it would be extremely difficult to develop an administrative structure that captured and reported upon this natural scientific activity.

It was noted that derivatives was not a definitional problem but a political and conceptual problem. It was unlikely that the international community could reach an agreement on its meaning. Neither the CBD nor the FAO International Treaty was able to do it, despite a strong effort. We have an expanding world of private rights, which are rolling back the public domain. The issue for the International Regime is do we wish to encourage this development, brake it or attempt to reverse it.

It was suggested that we should concentrate on conceptually mapping the concept and then find a different word to cover it.

A participant warned that derivatives should not include coverage of research tools in areas of biotechnology because this would have a huge chilling effect on research.

A participant noted that we are living in a transitional society where life forms are increasingly becoming private property. Asymmetry in property regimes between countries is growing. Addressing derivatives in an International Regime is essential.

Selected issues and concerns

- The derivative issue is not a mere definitional problem but a political, economic and conceptual problem so it is unlikely that the international community could reach an agreement on its meaning.
- Defining the term "derivatives" has proven to be very complex and one that could not be avoided in the elaboration of an IR. Concept could be conceptually mapped and recaptured under a different term or terms.
- In the academic world there was a great deal of exchange and modification of genetic material and that it would be extremely difficult to develop an administrative structure that captured and reported upon derivatives used in scientific activity. A concern was raised that if protection for derivatives extended to research tools this would have a huge chilling effect on biotechnology research.
- As life forms are increasingly becoming private property under intellectual property rights, the issue of derivatives should be addressed within the IR.

New Forms of Sui Generis Protection Relevant for the International Regime (Genetic Resources and-or Traditional Knowledge)

Speaker: Graham Dutfield
Paper: New Forms of Sui Generis Protection

The paper focuses upon a *sui generis* system of protection applicable to traditional knowledge. It stresses that such a system must respect the holistic and collective nature of traditional knowledge. It can only be developed with the close collaboration of traditional knowledge holders and their communities. It suggests that a CBD-related system should probably limit its scope to coverage of traditional knowledge associated with biological resources or with the environment more generally. Such limited scope would make consensus easier to achieve but can also be dangerous. On the one hand, a harmonized system cannot easily accommodate diversity, which might render the system useless. On the other hand, a system tailored to a few ethnic groups might alienate other indigenous peoples. The paper provides a check list of key points for negotiating and policy making in this area.

Speaker: Jock Langford

Paper: Sui Generis Protection of Genetic Resources and Associated Traditional Knowledge

This paper considers the issue of *sui generis* protection of genetic resources and associated traditional knowledge from three perspectives: (1) *sui generis* protection of genetic resources under national access and benefit-sharing law, (2) *sui generis* intellectual property protection of genetic resources and traditional knowledge, and (3) *sui generis* protection of genetic resources and traditional knowledge outside the scope of intellectual property rights. In the first case there seem to be development of two systems, one focused upon creating national level *sui generis* property rights based upon the principles of prior informed consent (PIC) and mutually agreed terms (MAT) and a second regime based on indigenous and local community PIC for accessing traditional knowledge and associated genetic resources. Regarding (2), the paper identifies areas of intellectual property law that are more readily adaptable to protecting genetic resources. These could include application of the IP concepts of:

appellations of origin, data protection for confidential business information which could be applied to traditional knowledge and possibly some forms of taxonomic data, and, certification systems including the possibility of a CBD certification mark. Regarding (3), Article 8(j) of the CBD affords an opportunity to develop *sui generis* systems of protection recognized under national law that resemble the customary laws and traditional protocols of indigenous communities.

In the subsequent discussion, it was suggested that intellectual property systems could be used to protect traditional knowledge and that there is a need to find a mechanism that, where appropriate, provides for the use of traditional knowledge for commercial purposes. There was discussion about the importance of using aspects of customary law as the basis of new forms of national legal protection of traditional knowledge. It was also noted that customary law systems, particularly in Africa already included components of colonial European law so that there was not a very clear distinction between customary and western law. Others doubted that intellectual property systems could protect traditional knowledge and customary law effectively because the IP system was designed based on western legal philosophies and to achieve western industrial and cultural goals.

It was noted that the protection of traditional knowledge was directly connected to the territorial rights of indigenous peoples and one could not be protected without the other. Misappropriation of traditional knowledge was less of a problem than the pernicious effects of economic development on indigenous and local communities, their lands and societies.

It was noted that there is a great need for capacity building at the local level to empower traditional knowledge holders and create informed participation by indigenous peoples in the development of an International Regime. One way of doing this was to include aboriginal representatives in delegations to international negotiations in this area. It was noted that the UN system's unwillingness to recognize indigenous participation and voting was a barrier. Solutions required full recognition of the right to self government by indigenous communities.

Selected issues and concerns

- IPR system could be used as a complement tool for protecting traditional knowledge, in particular trade marks and trade secrets , but other mechanisms should be in place.
- Another view is that intellectual property systems cannot effectively protect traditional knowledge and customary law because the IP system was designed based on western legal philosophies and seeks to achieve western industrial and cultural goals as compared to the values and objectives of indigenous and local communities.
- Some highlighted the importance of using aspects of customary law as the basis of new forms of national legal protection of traditional knowledge.
- It was noted that there is a strong connection between TK and land rights of indigenous peoples which needs to be reflected in the elaboration of TK protection.
- Participation of indigenous peoples in the international debate on ABS is essential.
- There is a need to foster capacities for TK holders so that they can play an effective role in the elaboration of the IR.

Indigenous Peoples: Community—level PIC for Accessing Traditional Knowledge and genetic resources, feasibility and Good Practices

Speaker: Brendan Tobin

Paper: Customary Law as the basis for Prior Informed Consent of local and indigenous communities

This paper seeks to highlight the importance of customary law and practices for the realisation of the three objectives of the Convention on Biological Diversity and to help define the modalities for ensuring the effective recognition, respect and enforcement of customary law in any International Regime on ABS. Such regime will have to link together a variety of legal systems and ensure that their consistency and relevancy is recognized. Issues addressed here include: PIC of indigenous peoples and local communities, searching mechanisms for the protection of TK, building bridges between indigenous customary law and practice and national and international legal regimes. The paper also addresses the challenge for ongoing processes to elaborate a system for defining ownership and "responsibility" under law in a culturally sensitive and appropriate fashion, without leading to an erosion of confidence and security for communities.

Speaker: Peigi Wilson
Paper: Indigenous and local communities: Community-level prior informed consent for accessing traditional knowledge and genetic resources

This paper considers various questions regarding ABS and related TK in an effort to reflect common issues of concern raised by various First Nations peoples in Canada. The paper refers to a philosophical difference between the modern perspective which focus is individualistic, and that presupposes human dominance over nature, as opposed to the traditional paradigm based on sustainability, spirituality and seeking human harmony with nature. In the view of the author, the real challenge in the elaboration of an International Regime on ABS will be to ensure that the regime meets the demands of both the modern and traditional paradigms.

Speaker: Paul Kuruk

This presentation explored the concept of prior informed consent as the cornerstone of an International Regime established under the CBD. PIC rules lie in national and regional instruments. There is a need to reflect on the implications of incorporating community-level PIC rules into an International Regime. The African Model Law is an example of legislation that regulates the interface between the collection of biological resources and the recognition of the associated traditional knowledge of indigenous groups. It is critical that PIC rules incorporated in an International Regime be consistent with the customary law of countries. The assumption underlying the need for compliance with customary law is that it presupposes that customary law is an effective legal system. There is still work to do to

ensure that elements of customary law are part of the legal international system and that national customary law is recognized by all countries.

In the subsequent discussion, consistency between western law and customary law when elaborating PIC rules was a key area of discussion. When creating an International Regime on ABS, it is crucial that all countries recognize the existence of customary rules in some countries and that those rules should not be override by any other legal system. Unlike western law, customary law tends to be more uncertain, is oriented towards the resolution of conflicts for the sake of the harmony in the group. It was suggested that views about certainty and uncertainty should be tempered when talking about customary law. It was also brought to discussion that rules for PIC in some communities are not clear to the members of the communities and that rules for PIC incorporated in an International Regime may seek information that is still unknown by the communities. The discussion about certainty and uncertainty of the legal system and the rules regulating access to GR and TK must be clear so that compliance does not become burdensome on users only.

Protocols of customary law at the community level should outline the rules of engagement of the parties. This bottom-up approach may be a solution to ensure PIC is given by a community. It was suggested that a competent authority that would ensure the compliance with PIC rules should be identified. The identification of a national authority would facilitate the implementation of PIC rules and contribute to the clarification of the rules that need to be observed. The authority could play a role in compiling information about sources of TK, custodians of TK, rights over this knowledge etc. However, it was mentioned that a national authority may have the mandate to give access to land based on PIC but if the community does not recognize this authority, access may be refused. There is a clear need to involve the communities in the decision-making process. It was brought to discussion that the general tendency is to associate PIC to indigenous communities. However, it was specified that PIC does not apply only to indigenous groups but also to all groups that have traditional knowledge in various areas such as fisheries and agriculture. The variety of people that use traditional knowledge in their daily activities makes it more difficult to elaborate a system that will engage them all in the elaboration of PIC rules.

Finally, the codification of TK was also at the heart of the discussions. What are the best ways to share TK and clarify the rules for PIC in different countries? Some are of the views that codification is not the best way to go, while others think that codification could work but would need to be flexible. I was also noted that not all the TK that is in the public domain was placed there by the communities. Rules within communities sometimes limit the sharing of knowledge between their members. When it comes to redress and legal procedures, it was mentioned that the current legal systems may not be adapted to protecting TK and may lead to encouraging the disclosure of TK. Western legal systems aimed at defending owner's rights may therefore have perverse effects on the protection of TK.

Selected issues and concerns

- Current legal systems may not be adapted to protecting TK and may lead to encouraging the disclosure of TK.

- When establishing procedures for PIC, respect of customary law should be ensured and possibilities to override it avoided.
- Protocols of customary law at the community level should govern the rules of engagement of the parties.
- Clear compliance rules for accessing to GR and TK at the community-level should place obligations on both providers (indigenous and local communities) and those accessing genetic resources and associated traditional knowledfge.
- Identification of a National Competent Authority for ensuring PIC by indigenous communities could facilitate the whole process and give more certainty to all parties.
- Community-level PIC does not apply only to indigenous communities but also to other TK holders such as local communities.
- In the context of the elaboration of the international regime, many cited the need for an international ABS workshop on issues related to community-level PIC and the protection of traditional knowledge.

Measures to Ensure Compliance with CBD and Access Legislation

Speaker: Kelly Bannister

Paper: Mechanism for compliance with ABS by the Academic Research Community (Canada)

This paper explains how the scientific community often stands in an interface between the providers and users. University scientists are key intermediaries between several different actors. Ethnobiology takes place at the complex interface of ethics and law, governed by institutional research policies that must incorporate evolving sets of ethical and legal standards at the international, national, and local levels. Some Canadian universities and professional associations have developed codes of ethics for conducting genetic research. The paper briefly explores the merits and challenges of existing policies and codes of ethics in Canada. Existing institutional research policies are worth examining as a potential mechanism for incorporating new access and benefit-sharing policy and facilitating compliance with ABS by the academic research community. The existing research policies aim at being consistent with ethics policies for research involving humans and intellectual property ownership policies.

Speaker: Maureen Wolfson
Paper: Scientists as users and providers: A South African Perspective

This paper provides a South African perspective of benefit-sharing. The author describes the composition of the Biodiversity Act of South Africa, signed end of May 2004. The purpose of the Act is three-fold: 1) regulates bioprospecting, 2) regulates the export of indigenous biological resources, and 3) provides a fair and equitable sharing by stakeholders of benefits arising from bioprospecting involving indigenous biological resources. Under the Act, permits are required for bioprospecting projects and export of any indigenous biological resources to be used for bioprospecting and any other kind of research. PIC must be obtained from stakeholders providing access before a permit is issued. When not done for export purposes, research is excluded from the law. Despite the policy vacuum which existed in South Africa (SA) before passing the Act, a number of research organizations have developed policies on ABS. The provincial authorities in the nine different provinces of SA are in different stages of

developing policies. However, within government and other institutions, expertise on ABS is deficient which makes it difficult for the government and institutions to develop adequate policies.

Speaker: Joshua Rosenthal
Paper: Measures to Ensure Compliance with CBD and Access Legislation

This presentation focuses on the experience of the International Cooperative Biodiversity Group (ICBG - United States). The ICBG model is presented as a way to encourage companies to follow codes of conduct when conducting research. Codes of conduct are based on ABS principles and IPR protection that must be respected for a research permit to be granted. The ICBG main objective is to change the behavior and attract companies by presenting a range of positive incentives resulting of their good behavior when conducting research. Among other companies will have access to academic expertise, access to unique resources, share burden of field and transaction costs, etc.

The subsequent discussion started off by a comparison between the activities of botanical gardens and universities. The difference between short versus long-terms projects, access for research or commercial purposes, dependence on funding from private sector illustrate how universities and botanical gardens approach to ABS may differ. However, there is a need for those institutions to work together. It was also discussed that codes of conduct must come with a set of positive incentives for compliance.

One intervention was made questioning the involvement and satisfaction of indigenous peoples in the creation of codes of conduct. In SA, the involvement of the communities in this process tends to increase over years but there is a recognized need for further involvement and input from indigenous communities. From a Canadian perspective, it was recognized that there is space for a greater involvement of indigenous peoples in the creation of the codes of conduct. The experience of the involvement of indigenous peoples in the elaboration of the codes of conduct of the International Society of Ethnobiology was positive from the scientific side but: Was it satisfactory for the indigenous communities? This question remains.

The discussion also reiterated the importance of the work done by scientists in the conservation of biodiversity. There is a need to keep exploring the earth and, as we just scratched the surface, scientists are key in this exercise. The issue of access is therefore at the heart of this process. Access is about talking to people that live on the lands where the resources lie. If no dialogue is established between the users and the providers, no access will be granted and no benefit will be shared.

Acknowledging that structures already exist to encourage scientists to follow codes of conduct when conducting research, there is still efforts to be made to raise awareness among students. Students are often the channels through which genetic material is transferred from a country to another. It is generally recognized that a framework is needed for a better understanding of the underlying rights and duties of ABS both at the research and administrative levels. Students and scientists are willing to comply with the rules but the framework regulating those rules must be simple and flexible enough.

On a practical note, it was mentioned that capacity-building and resources are needed for ensuring that PIC is given in a timely fashion so that research projects are not put on hold for indeterminate periods. It is easier to bypass the law than trying to comply with a system that does not work. Scientists and providers of PIC both share the burden of complying with PIC requirements.

Finally, it was mentioned that public opinion also plays a role in the elaboration of codes of conduct as the general public is becoming highly interested in supporting cautious approaches to research dealing with genetic materials.

Selected issues and concerns

- Scientific community practices governing access to and use/exchange of genetic resources vary among research institutions (e.g. botanical gardens versus universities) and fields of study. Awareness of ABS may be a key factor in these differences.
- Codes of conduct have a useful role in ensuring compliance with ABS principles, policies and laws. Some structures already exist to encourage scientists to follow codes of conduct when conducting research. It was suggested that codes of conduct must come with a set of positive incentives for compliance.

- Access is key in order to derive benefits and through their work, scientists contribute both to scientific advancement and to the creation of value from biodiversity. .

- Scientists and students are willing to comply but request regulatory procedures that are simple and flexible. However, further awareness of ABS issues is needed among these groups.

- It is desirable for indigenous communities to be involved in the development of codes of conduct for accessing traditional knowledge and related genetic resources.

IV. Instruments/tools/measures which could assist in achieving the International Regime including Mechanisms for Monitoring and/or Verification

Product and Process Certification Including Certificate of Legal Provenance/ Source/Origin

Speaker: José Carlos Fernandez
Paper: Elements for the Design of a Certificate of Legal Provenance

This paper makes the case for a certificate of legal provenance as a key instrument to help source countries identify violations to access conditions taking place in other countries with users under their jurisdiction. Such a system could be based upon a number or code attached to all documentation involving a particular genetic resource that could be checked against a central clearing house of certificates available for verification purposes and which would contain the specific conditions for accessing the genetic resource. The paper elaborates on various aspects of such a system identifying nine key elements and discusses the merits and limitations of the certificate system.

Speaker: Leonard Hirsch

Paper: The Smithsonian Institution: The Life of Natural History Museum Specimens

This paper explains how basic research, collections, and organizations work, and why ABS regulations should be modified to facilitate taxonomic, systematic and ecological research. It describes how burdensome regulatory systems impose costs that far exceed the benefits, and transfer those costs to provider and/or organizations least able to bear them. The paper advocates a mechanism for material exchange that is clear, expeditious and cheap. Material transfer agreements should recognize that museum collections are multi-purpose and differentiate between research and commercialization activities in a dual track system that facilitates basic science and provides for heightened scrutiny and obligations for applied and commercially oriented research. The paper suggests that there could be a Taxonomists Rights principle established by the CBD similar to the Farmers Rights principle in the FAO International Treaty.

Speaker: Brendan Tobin
Paper: Certificates of Origin, Legal Provenance and Source: Mutually Exclusive or Complementary Elements of a Comprehensive Certification Scheme

The paper presents a framework for a system of certification. It focuses primarily on addressing the issues of the subject matter to be certified and what is being certified. A proposal is also made for utilizing certificates as a tool for promoting a more flexible access and benefit-sharing procedure which incorporates elements of both liability and property regimes discussed by Ruth Okediji in her conference paper entitled "Access and Benefit-sharing and the Interface with Existing IP Systems: Limits and Opportunities - Comments prepared for the Experts International Workshop on Access and Benefit-Sharing, Cuernavaca, Mexico, October 24-27, 2004, Section III above). The paper lists eight categories of information that could be included in such a certificate. It addresses what should be certified which could include source, origin and or legal provenance and suggests that comprehensive system of certification could accommodate all. It addresses issues of feasibility and cost and key questions for future consideration which include: what should trigger issuing a certificate, who could issue it, how would multiple source situations, how could the information be stored, what penalties, and what would be the system's basic objective. Finally the paper notes that the results of a UNU-IAS research into this topic will be presented to the Working Group on ABS in February, 2005.

In the subsequent discussion, many practical aspects of the potential certificate were raised. It was suggested that a system could not control all transactions involving genetic resources. It was noted for example that less than 1 in 1000 Mexican permits for collection of biological material are destined for biotechnology end uses. A feasible system could be based upon the type of use. There was discussion about a "trigger" point i.e. at what point in the research-to-full-commercialization continuum, would the holder of a genetic resource be obliged to return to the provider country to discuss benefit-sharing arrangements appropriate to a commercial situation. There was also the basic question of what would a possible certificate certify. Would it be the origin, source country, the movement of the sample, the movement of the knowledge related to the sample, the legal provenance of a genetic resource or some combination of these factors.

In another intervention, it was questioned how a potential certificate would work if it was the information about a genetic resource that was being exchanged rather than the actual sample itself. Another issue raised was how to differentiate between difference species in the same sample which might not leave the provider country jurisdiction but not be investigated and identified for years afterwards. It was suggested that this could be worked out by providing a sample number and then an additional level of numbering system differentiated by species as these were identified.

There was debate about the feasibility of keeping track of many hundreds of thousands of transfers of biological specimens. The task was compared to the international banking system's ability to track millions of financial transactions. It was noted that if the banking system could look after their transactions it should be technically feasible to track a smaller number of biological specimens even if the absolute numbers were still large and the time span for the records might extend out for hundreds of years. It was noted that banking system is able to pass on the cost of tracking financial transactions to the users themselves and that this might be more difficult for an ABS regime, which wished to facilitate research.

It was noted that the certificate of origin could not easily apply to traditional knowledge until a way of identifying the issuer of a traditional knowledge certificate was developed. It was noted that aspects of the copyright system could be applied to traditional knowledge. It was also noted that researchers derived a reputational and professional benefit from using traditional knowledge in their academic and professional activities. This was a significant benefit even if not part of the conventional definition of commercialization.

The issue of compliance was raised. What would happen if the user did not comply with the terms of a properly identified ABS agreement? The need for a transparent system was underlined.

There was recognition that a certificate of origin was a tool for and not a solution to a functional and comprehensive International Regime. It could be a significant component of such a system if it could be designed so that the costs did not outweigh the benefits. There was recognition that such a system should not impede taxonomical and research activities. It was underlined that the foundation of an International Regime was made up of national legislation on ABS.

Selected issues and concerns

- There is a need for a transparent system to administer the flow of genetic resources within the IR.

- The certificate is a tool, but not the only solution for a comprehensive and functional IR. It could be a significant component of such a system if it could be designed so that the costs did not outweigh the benefits.

- Measures in case of non compliance, the reduction of transaction costs and the facilitation of research – particularly taxonomic one- are key issues to bear in mind when designing an effective certificate of origin.

- One challenge posed by the certificate of origin is that it may need to cover both the biological sample and the information associated with the sample.

- Another challenge is to include TK in the coverage of the certificate and determine which entity would be entitled to issue the certificate.

- Concerns were raised about the practicality of a certificate system given the fast and important flow of biological specimens. A certificate system should not impede taxonomical and research activities.

Company Conduct, standards and certification

Speaker: George Greene
Paper: ABS Management Tool Project: Summary Project Description

The presentation outlines a project to develop and field-test an ABS management tool. Its purpose was to develop collaborative and mutually beneficial relationships between ABS providers and users. It aims to develop a set of substantive practice standards and management process framework and, at a later stage, consider approaches to assurance (ie from internal review to verification to certification). The potential structure of the tool is described as well as aspects of both a PIC and a community and indigenous participation practice standard. Once the tool is developed the study coordinators intend to field test the framework with three pilot studies.

Speaker: Lene Lange
Paper: Tropical Biodiversity, An Industrial Perspective

The presentation outlines the Novozyme's development of an internal code of conduct governing ABS. Novozyme is a major European chemical company which uses enzymes (of natural source) for various consumer and industrial products. The guiding principles of the company's benefit-sharing policy include no use of natural products without PIC and disclosure of origin in all research and patents. The presentation described its collaborative relationship with Thailand. Despite its overall positive experience with its own corporate policy, there are several pitfalls. These included: mismatched expectations on the level of royalties potentially available in a low margin industry, the desire of middlemen rather than providers to get the benefits, the practical difficulty of obtaining PIC in many countries, obstacles to scientist-to-scientist collaboration, and poor awareness and implementation of ABS policies in academia. Novozyme will not work in countries nor accept material from ex situ collections which have not followed CBD principles on ABS.

In the subsequent discussion, the need for a potential International Regime to address the availability of *ex situ* culture collections was raised and also the need to develop more *in situ* culture collections. Also an ABS regime should facilitate scientist-to-scientist collaboration. In partial answer to a question whether there were industry-wide codes of conduct, it was noted that US PhRMA members (including both biological and agricultural companies) were intending to release a code of conduct in this area very soon.

It was noted that commercial users of genetic resources should not just take provider country assurances that national ABS policies were being properly followed. These users should look behind the national legislation.

There were questions about the linkages between the ABS management tool and potential linkages to other management tools such as ISO and other systems. There were also questions about the criteria to be employed in selecting pilot project sites and related funding. It was noted that the management tool, once developed, could be a good capacity building instrument.

It was noted that companies wishing to follow best practices had to consult fully with indigenous peoples. It was noted that indigenous peoples had to facilitate consultation so that it was feasible to undertake. It was recognized that in the absence of an agreed framework on ABS related to traditional knowledge at, at least the national level, well-meaning companies might avoid using it rather than risk misappropriation. There was a reference to the consultative process developed by oil companies for exploration activities in remote areas and the suggestion that a similar process could be used by PhRMA members.

Five key elements of this discussion were identified: protection of resources might have to come first; there was good potential for a win-win collaborative relationship between industry and providers; and an International Regime should have clear objectives and goals; there were many outstanding concerns (eg the link between benefit-sharing and conservation, how to control and also facilitate research etc); the need for follow up work on a variety of topics (eg certificates of origin, effective codes of conduct, meaningful dialogue with indigenous communities, the measurement of benefits and the use of other instruments such as trust funds).

Selected issues and concerns

- How would an IR deal with *ex situ* collections?
- An ABS regime should facilitate collaboration among scientists.
- There is good potential for win-win collaborative relationships between industry and providers.
- More work needs to be done to understand the linkages between benefit-sharing and conservation of biological resources.
- Consultation with indigenous peoples is imperative for companies wishing to develop best practices.

Government User Measures

Speaker: Birthe Ivars
Paper: Government User Measures-Incentives for Compliance

This paper provides examples of user country measures taken in Norwegian patent legislation and outside the patent system. It exemplifies the recently amended national patent law in Norway. Among other things, the paper presents the penalties in cases of infringement of the duty to disclose information, as well as the duties to provide information according to the patent law. It concludes by addressing traditional knowledge in the legislative process on ABS in Norway.

Speaker: Brendan Tobin

The participant addresses the following question: How to ensure the enforcement of rights embodied in an International Regime on ABS? There is a need to ensure that States will support the protection of the rights of their citizens and will take action to have those rights respected. Rights of indigenous peoples are not always defended by States and the linkage of the issues under discussion here to broader policy issues would increase the commitment of States to defend the rights of indigenous groups. Many reasons such as the costs of procedures, legal assistance, and travel expenses make it difficult for citizens to have a real access to justice. The existence of a special ombudsman office was proposed as a way to respond to claims, help case building, and take action on behalf of groups of citizens. There is a need to reflect more on two specific questions: the enforcement of ABS laws in foreign jurisdictions and the possibility to take action in foreign countries.

Speaker: Christian López-Silva
Paper: User Measures in Provider Countries: Use of Simplified Procedures and Its Trade Implications

The author talks about how most of the attention has been focussing on developing regimes to control access, and less attention to promote compliance by users. The paper explores the possibility of putting in place a measure that would consist in introducing at the national level and in the International Regime a provision that provides for the availability of simplified procedures for nationals of jurisdictions where user measures have been adopted. The identification of such user measures could be done through a database administered by the CBD Secretariat and built upon the information provided by National Competent Authorities. The adoption of these simplified procedures would, according to the author, have the effect ofencouraging non-parties to join the CBD and increase compliance with ABS requirements. Many challenges relating to the consistency of the measures taken with the WTO national treatment and most favoured nation principles still need to be addressed. However, the basic principles regulating the relationship between WTO rules and MEAs, CTE analysis and case law may be interpreted as allowing for the development of such measures.

In the subsequent discussion, a general agreement was reached that many challenges prevent citizens to have a real access to justice to defend their rights. The case of the Basmati Rice, was given as an example that the costs, the difference between legal systems (customary vs

western law), the recognition and enforcement of judgements are some of the challenges that arise when going to court for justice and that developing countries do not have the resources to overcome these barriers and have access to justice. Many interventions were made to the effect that more funds are needed to help citizens from developing countries to take action before the courts. Reference was made to the WTO fund for litigation and proceedings that was set up to help developing countries in accessing justice.

The issue of redress and transboundary application of the law was also highly discussed. It was highlighted that penalties may drastically vary from a country to another. The fact that for similar cases different sanctions from civil to criminal law may be applied, contributes to uncertainty. There is a need for a better understanding of The Hague Convention and the transboundary application of law when elaborating an International Regime on ABS. Many subsequent interventions were made regarding the existence of national measures that are not widely shared and the difficulty to have a comprehensive understanding of the measures.

While some people suggested that it is a function of the providers to ensure that the right regime is in place for redress and enforcement, others said that measures included in the law of user countries also needed to be revised. One remaining question is about the value added of an International ABS Regime with regards to enforcement of national laws in foreign countries. Current measures included in national law need to be re-assessed to really address this issue. One of the options would lie in the use of administrative remedies. More work should be done to elaborate ways of ensuring redress, such as the removal of licenses, instead of taking action before the courts. Existing structures may offer solutions to stop the abuse of rights that do not necessarily need to be settled before the courts of justice.

Finally, some additions were made to the presentation on the Norwegian patent legislation. It was mentioned that the control is outside the patent system. Wrongful information purposely provided by an applicant may lead to imprisonment or fine. The detection of a violation and the sanction depend on the patent examiners and the police authorities and on whether they have the resources to enforce the law. As it stands right now, the legislation does not include any requirement regarding the disclosure of traditional knowledge.

Selected issues and concerns

- Many challenges prevent citizens from having effective access to justice in order to defend their rights as they relate to either TK or genetic resources.

- Redress and transboundary application of the law are issues that need to be addressed.

- Legal systems of user countries could be revised to ensure the existence of measures for effective redress.

Benefit-sharing as a goal of the IR (opportunities, kinds of benefits, successful experiences and why, lessons learned, transaction costs, limits to benefit-sharing)

Speaker: Mohamad bin Osman

Paper: Access to Genetic Resources and Benefit -Sharing

This paper explores the relationship between ABS, the FAO ITPGRFA treaty, and the CBD. There is a need for reality check, to acknowledge that the efforts of the negotiations are oriented toward economic benefits. However, to reach economic benefits, countries will have to find solutions to a wide range of ABS related issues such as the need to add values to biological resources, to recognize that corporate investment is crucial for encouraging the research, to take into consideration that transaction costs for accessing GR are escalating, and ensure that the cost/benefits ratio is positive. Many other bottlenecks such as the lack of resources for developing technological capacity are still to be removed. According to the author, importance should be placed on an ABS regime that provides a strong framework for benefit-sharing and provisions for monitoring. The author presents a few examples of projects on BS realized in Malaysia. In the view of the author, there is a need to look at as many models as possible to learn more about ABS.

Speaker: Preston Scott
Paper: Benefit-Sharing as a Goal of the International Regime: Lessons Learned form Genetic Resources Research at Yellowstone National Park

The paper presents the experience at Yellowstone National Park and how it has gone from a pilot project to a whole nationwide project. The objectives of the project are three-fold: conserve biodiversity, promote research and generate benefits for biodiversity conservation. These objectives should be met with a minimum of changes in regulations or law. Minimal changes in law would maintain legal certainty thereof facilitating the involvement of industry and attribution of private-sector funding.

The paper also reflects on two kinds of interface: 1) interface between a new IR and the national governments (sovereignty), and 2) the interface between access approaches and the mechanics of benefit-sharing which have been mainly contractual so far. These two levels are not mutually exclusive. The papers also states that when elaborating an International Regime on ABS, the diversity and flexibility of existing approaches should be taken into consideration. Both on the international and national levels, we should look at existing structures to address ABS and not create a totally new mechanism. According to the author, there is already an IR on ABS and it is called the CBD. The difficulty to articulate what ABS is about, may come from deeper implementation problems. The current issue countries are facing is how to improve it and make it work better in a timely fashion. The States have the first responsibility for managing GR and the IR would only be filling a gap.

Speaker: Geoff Burton

The participant reflects on the responsibilities of users and providers, the importance to look at an international code of ethics for the biotechnology world. Many aspects such as implementation mechanisms, time constraints, credibility of the CBD and the negotiation process, the importance of non-commercial research, existence of non legal compliance

mechanisms such as codes of conduct, certification systems etc, are still pending. More work is needed to confront this reality and address these issues adequately. The authors also states that the industry is not reluctant to benefit-sharing but needs to know the rules and needs certainty. There is a need to establish a practical dialogue with industry regarding benefit-sharing.

The interface between an International Regime on ABS and the existing ABS regulations and policies was at the heart of the subsequent discussion. There is a need to make sure that an International Regime will be consistent with what is being established within States. The consistency between the two levels of jurisdictions would create an incentive for compliance and would encourage local communities and scientists to participate and comply with ABS policies. One of the remaining questions is to whether an IR will facilitate ABS goals in countries that do not have ABS policies or regulations.

Selected issues and concerns

- There is a need to ensure consistency between national measures and measures within the IR.
- The protection and preservation of genetic resources is an investment in the future, in particular, the development of future biotechnology applications.
- ABS is a window of collaboration between the industry and the providers of GR to ensure that benefits are first created and then shared equitably.
- Any IR should: be an enabling institution, oriented towards capacity-building. It should support the creation and sharing of benefits, address adequately the concepts of national sovereignty versus international regulation, address regulatory and contractual approaches, ensure balance between access rights and rights of providers, and balance between conservation and benefit-sharing. An IR should be simple and tangible.
- There are still remaining concerns over the creation of an IR. These include: to ensure effective participation of stakeholders, facilitate corporate governance, evaluate the limitations of codes of conduct, international enforcement and the the compatibility between legal systems and the implications of countries with no current ABS laws and policies. .
- Future work should consider the role/feasibility of certificates of origin, the use and effectiveness of codes of conduct, ensure dialogue with industry, the measurement of "benefits", evaluate the capacity of existing mechanisms to support the achievement of ABS objectives and consider the merits of the creation of international funds for conservation.

V. Final Remarks on the Workshop

Co-chairs*:* Jorge Soberón (CONABIO, Mexico) and Timothy J. Hodges (Environment Canada)
The two co-chairs thanked the participants for a stimulating discussion and recognized and thanked all the staff who had made the arrangements for the workshop. The co-chairs will be providing their thoughts on the results of the Experts Workshop and the areas needing further

work over the next few weeks. This will form the basis of a report to the next meeting of the CBD Open-ended Working Group on ABS, scheduled for February 2005.

All the papers submitted at the Workshop are available online at:
www.canmexworkshop.com