

COMPENDIUM *of* SIDE-EVENTS



Events held during the Fifth Meeting of the Ad Hoc Open-Ended
Working Group on Access and Benefit-Sharing (ABSWG-5)
Montreal, 8–12 October 2007

Events held during the Fifth Meeting of the Ad Hoc Open-Ended
Working Group on Article 8(j) and Related Provisions (WG8J-5)
Montreal, 15–19 October 2007

Events held during the Sixth Meeting of the Ad Hoc Open-Ended
Working Group on Access and Benefit-Sharing (ABSWG-6)
Geneva, 21–25 January 2008



Published by the Secretariat of the Convention on Biological Diversity.
ISBN: 92-9225-090-6

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INTRODUCTION

The loss of biological resources has serious consequences for billions of people around the world who depend on nature for their well-being.

It is for this reason that 110 Heads of State and Government, at the 2002 Johannesburg World Summit on Sustainable Development, committed their countries to significantly reduce the rate of biological diversity loss by 2010 (“the 2010 biodiversity target”).

As part of the enhanced implementation of the Convention, major efforts are needed to achieve the 2010 biodiversity target. These efforts include measures to increase worldwide awareness of the Convention on Biological Diversity by reaching out not only to Governments but also to key partners and major groups of stakeholders in the protection of biological diversity, including international organizations, scientific and technical bodies, indigenous and local communities, industry and the private sector.

If we are to achieve the 2010 Biodiversity Target, to significantly reduce the loss of biodiversity, in light of the climate change crisis, we must fully recognize and value the input of all these stakeholders and indigenous and local communities.

As side events organized by agencies and the Convention’s partners and stakeholders represent an invaluable information and a unique mechanism for the exchange of experiences and best practices, I am very pleased to present the second edition of a Compendium of Side Events held during the meetings of the Ad Hoc Open-ended Working Group on Access and Benefit sharing and the Ad Hoc Open-ended Working Group on Article 8 (j) and related provisions.



Ahmed Djoghlaoui
Executive Secretary,
Convention on Biological Diversity



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**Fifth Meeting of the Ad
Hoc Open-Ended Working
Group on Access and
Benefit-Sharing (ABS WG-5)**

Montreal, 8–12 October 2007

Monday, 8 October 2007

1. TOWARDS FAIR AND EQUITABLE BENEFIT-SHARING: KEY ISSUES IN THE ABS NEGOTIATIONS

Third World Network

The panel of speakers included selected delegations from developing countries, NGOs and indigenous peoples' representatives who shared their perspectives on the key issues that need to be addressed in the formulation of a text on the international ABS regime.

2. ADMINISTRATIVE AND JUDICIAL REMEDIES AVAILABLE IN COUNTRIES WITH USERS UNDER THEIR JURISDICTION AND IN INTERNATIONAL AGREEMENTS

IUCN-Canada Office

This event presented a paper on the Remedies issue in ABS. The full paper is available on the CBD website as an information document of this meeting (UNEP/CBD/WG-ABS/5/INF/3). It is the third in a series of technical expert analyses of key legal issues. The first paper researched and addressed the issues of "*Legal Certainty for Users of Genetic Resources under Existing ABS Legislation and Policy*" (UNEP/CBD/WG-ABS/3/INF/10–2 Feb 2005). It was presented to third meeting of the Ad-hoc Working Group on ABS, in 2005. The second analyzed the extent and nature of "*Unauthorised Access and Misappropriation of Genetic Resources and Associated Traditional Knowledge*" (UNEP/CBD/WG-ABS/4/INF/6–22 Dec 2005). It was presented to the fourth meeting of the group, in early 2006.

The author of all three papers, Tomme Young, presented the contents of the current study, focusing on two key objectives: (1) helping non-lawyers understand the legal issue of "administrative and judicial remedies" and (2) identifying the issues and problems that arise when applying this well-established legal system to the ABS issue. Following this presentation, a discussion was held, which was partly a question and answer session (in light of the "teaching" or understanding objective of the side event), and partly a comment and discussion of the possibilities for ABS remedies. The presentation began with a basic discussion of the general legal topic of "remedies," which is not described here.¹ It then moved to a discussion of some of the problems encountered in seeking remedies in the ABS context, as briefly summarized below. A question and answer session followed in which the primary problem — the lack of Article 15.7 legislation or other measures (applying ABS to users of foreign genetic resources, "with the aim of sharing ... the benefits arising from the utilization of genetic resources") was a major focus of discussion.

1. The PowerPoint presentations and notes of this side event will be posted online, however the precise internet location of that posting are not yet known. Interested persons should contact the author of the report by e-mail to Tomme.Young@gmail.com.

SUMMARY AND CONCLUSIONS

The concept of “legal remedies” are not always easily understood by non-lawyers, and may have been forgotten by some lawyers whose work does not focus on the litigation specialties (commercial or tort litigation) or system design specialties (national legislative drafting and legislative vetting.) It is one of the central elements of any functional legal system. It is important to have a systematic and “replicable” system and standards for obtaining remedies, because they are the tool used to create legal certainty for all parties — enabling them to know

- ▶ what their rights are,
- ▶ what legal risks they are taking (*i.e.*, which issues are not yet decided by law)

how their performance or their rights can be proven or documented to enable either (a) obtaining a remedy or (b) defending against a claim for a remedy.

Every ABS transaction, by definition, involves at least two countries.² Consequently, the key question for purposes of ABS remedies is how the general laws apply to ABS laws. In these cases, there are four legal sources to remedy an aggrieved party for violation of an ABS contract: contract law, tort law, national ABS legislation, and civil/human rights. In addition, a fifth category, “penalties,” although not “remedies” is often assumed to be relevant. Consequently, this research also consider the question of penalties, and how they relate to remedies. The availability of remedies depends on where the user and his assets are found: (i) in the provider country, or (ii) outside the provider country. The remedial situation, will be also be affected by the choice of forum (the case is domestic or international), and they type of forum (whether it is brought in the courts, from an administrative body, or through an informal mechanism such as arbitration, or by direct provision in the contract.

- ▶ *If the user, Genetic Resources (GR) and/or other property of the user are in the provider country*, suggesting that the provider (or source country) has jurisdiction to bring the action, he have clear remedies to the extent of national law. This process can result in a remedy under contractual law, if the contract was unambiguous, valid and enforceable. Where there is no ABS contract, the possibility of remedy is limited. The use of tort law depends on conceptual clarity under ABS (something that generally does not yet exist.) Few countries have clarified their national law with regard to sovereign property and rights over genetic resources, making it difficult to apply national law to ABS. The other potential sources of remedy (civil rights and national criminal law) have not been clarified in connection with ABS.
- ▶ *If the user, the GR and the users’ property has left the provider country*, the availability of remedies is extremely limited. It may be possible to obtain a remedy in the user country under contract law, however, where there is no ABS contract, there is virtually no possibil-

2. Some countries have adopted laws that control domestic utilization of genetic resources by domestic users; however, these transactions are not governed or even mentioned in CBD Article 15, which applies only where a user from one country utilizes GR with origin in another country. Other countries may be involved, where the user’s activities occur in a third country, or where the resources have been transferred to other users.

ity of remedy, unless the user and his assets remain in the provider country. In particular, if there is no ABS contract, it is not possible to seek a remedy for violation of the provider's ABS law (whether written as a separate law of ABS, or interpreted as part of the country's basic laws governing property and other rights), unless the country with jurisdiction over the user adopted specific user-side legislation or other measures. To date, *no country* has adopted such measures.

In addition, there are two central problems that limit use of any judicial or administrative remedies in ABS, whether in user or provider countries:

- ▶ **First**, any contractual action, must be brought by the party claiming the remedy. It will demand that this party should have sufficient funds and knowledge, both of the law and of the activities of the other parties. If the action is outside the provider's country, of course, both the costs and the access to relevant knowledge are much less.
 - ✓ This approach places the initial costs and burdens on the provider and source country. In order to obtain a remedy, the *claimant* must affirmatively bring an action (a costly process, particularly when it must occur in the user's country, rather than the provider's. That action will be dismissed unless the *claimant* is able to show with legally acceptable evidence, that the defendant is utilising genetic resources and has received (informational, commercial or other) benefits arising from that utilisation. In the majority of cases, the user is operating on private property, so that the claimant may not obtain this evidence without a court order. In addition, if the user is not cooperative, the claimant may have to test many substances within the user's facility to determine the species or other origins of the material. These tests and inspections must all meet the standards set by the courts for obtaining, preparing and submitting evidence.
 - ✓ Given that the original objective of ABS was one of equity for less developed countries, the *de facto* delegation of large and costly responsibilities to the providers may be antithetical to the purposes behind ABS.
- ▶ **Second**, and equally important, courts, agencies and arbitrators can only enforce a law or contract, or may only grant a remedy, where the law or contract is sufficiently clear and unambiguous regarding relevant concepts. In ABS, "relevant concepts" include the meaning and identification of "genetic resources," "country of origin," and many other concepts. These are all presently too ambiguous to form a basis for legal action.

CREATING AND ENABLING ABS REMEDIES

As a final point, the event discussed the question of what is needed for the ABS regime to provide or utilize remedies, as a means both of compensating injured parties, but also of promoting compliance and enforcement of ABS. It noted the need to address matters of legal importance, including the following:

- ▶ The courts and remedies can only function where ABS documents and laws are "legally certain" and "unambiguous." It is necessary not only to agree on the meaning of specific

contracts, but to ensure that those agreed meanings can be applied. In other words, when a court is asked “is this a utilization of a genetic resource?” it must be able to look at the specific facts of a specific case and answer yes or no.

- ▶ Similarly, it is important to remember that many users who fail to comply with ABS requirements are not intentional violators. They may not be aware of the requirements, or they may not be using the same definitions of key terms. (they look at their own actions and say, “this is not a utilization of genetic resources” where another party might say the opposite.).

3. THE INTERLAKEN CONFERENCE: FROM THE STATE OF THE WORLD’S ANIMAL GENETIC RESOURCES FOR FOOD AND AGRICULTURE TO THE GLOBAL PLAN OF ACTION FOR ANIMAL GENETIC RESOURCES

Federal Department Of Economic Affairs (FDEA), Swiss Confederation, and Food and Agriculture Organization of the United Nations (FAO)

The lunchtime side-event on Monday, 8 October 2007 was attended by more than 50 people from governments and NGOs, and several groups of indigenous peoples. The event was chaired by Dr. Francis Pythoud, Federal Office of Agriculture, Switzerland, who provided an update on the outcomes of the International Technical Conference on Animal Genetic Resources. The International Technical Conference, which took place in Interlaken, Switzerland, from 3 to 7 September 2007, was attended by delegations from 109 countries and 42 inter-governmental and non-governmental organizations. It was a resounding success. The Conference welcomed *The state of the World’s Animal Genetic Resources for Food and Agriculture* and formally adopted the *Global Plan of Action for Animal Genetic Resources* through the *Interlaken Declaration on Animal Genetic Resources*

Dr. Irene Hoffmann, FAO, presented *The State of the World’s Animal Genetic Resources for Food and Agriculture* and the *Global Plan of Action for Animal Genetic Resources* (GPA).

*The State of the World’s Animal Genetic Resources for Food and Agriculture*³ is the first ever global assessment of the status and trends of animal genetic resources, and the state of institutional and technological capacity to manage these resources. The 169 country reports submitted to FAO were the key sources of information, and strong evidence of the importance and concern felt across the globe about the management of animal genetic resources. All animal genetic resources for food and agriculture are the result of human intervention: they have been consciously selected and improved by pastoralists and farmers since the origins of agriculture, and have co-evolved with economies, cultures, knowledge systems and societies. Unlike most wild biodiversity, domestic animal resources require continuous active human management, sensitive to their unique nature. Only 14 of the more than 30 domesticated mammalian and

3. <http://www.fao.org/docrep/010/a1250e/a1250e00.htm>; <ftp://ftp.fao.org/docrep/fao/010/a1250e/a1250e.pdf>

bird species provide 90 per cent of human food supply from animals. This country-driven process has created a far better understanding of the importance of animal genetic resources to food security and the nature of the threats to these resources. *The State of the World's* report was an important step in achieving the improved management of animal genetic resources, including enhancing the basis for further policy development.

The *Global Plan of Action for Animal Genetic Resources*⁴ consists of the following three parts:

- i. Rationale: The Global Plan of Action aims to provide a framework, agreed by the international community, to support and increase the overall effectiveness of national, regional and global efforts for the sustainable use, development and conservation of animal genetic resources, and to facilitate mobilization of resources, including adequate financial resources, development of institutions, human resources and cooperative frameworks.
- ii. Strategic priorities: There are 23 strategic priorities, clustered into four strategic priority areas:
 - ▶ Area 1: Characterization, inventory and monitoring of trends and associated risks;
 - ▶ Area 2: Sustainable use and development;
 - ▶ Area 3: Conservation; and
 - ▶ Area 4: Policies, institutions and capacity-buildingEach strategic priority includes individual actions which propose steps to achieve the desired outcomes or improvements in current conditions.
- iii. Implementation and Financing: While the main responsibility for implementation rests with national governments, the *Global Plan of Action* also calls upon governments of developed countries to attach due attention, including funding, to the implementation of activities within the strategic priority areas of the *Global Plan of Action* through bilateral, regional and multilateral cooperation.

In the *Interlaken Declaration on Animal Genetic Resources*⁵ Governments affirmed the crucial need to maintain and use the full diversity of animal genetic resources. They committed themselves to facilitating access to these resources, and ensuring the fair and equitable sharing of the benefits arising from their use. The Interlaken Declaration recognizes that there are currently major gaps and weaknesses in national and international capacities to manage animal genetic resources that need to urgently be addressed. To overcome these, it states, substantial financial resources, and long-term support for national and international animal genetic resources programmes, must be found.

The successful outcome of the International Technical Conference is a further milestone in the work of FAO and its Commission on Genetic Resources for Food and Agriculture. The

4. http://www.fao.org/ag/againfo/programmes/en/genetics/ITC_docs/html

5. http://www.fao.org/ag/againfo/programmes/en/genetics/ITC_doc.html

Interlaken instruments join *The State of the World's Plant Genetic Resources for Food and Agriculture* and the *Global Plan of Action on Plant Genetic Resources for Food and Agriculture*, and lay the basis for a coherent overall approach to all sectors of genetic resources for food and agriculture.

The outcomes of Interlaken provide a first internationally agreed basis for the characterization, inventory, monitoring, conservation, development and sustainable use of animal genetic resources, which are increasingly at risk, and for sharing the benefits and responsibilities fairly and equitably. Animal genetic resources are of particular importance in a number of fragile and marginal environments, where they provide the mainstay of livelihoods. Climatic change both increases the risk of the loss of these resources, and increases their importance in adapting to climatic change, as well as in meeting the food security needs of a growing world population, and in achieving the Millennium Development Goals, particularly Goals 1 (*eradication of extreme poverty and hunger*) and 7 (*ensure environmental stability*). The task before the international community now is to translate the outcomes of Interlaken into concrete and sustainable action.

Each presentation was followed by plenary discussions. Questions referred to ABS in research projects on animal genetic resources, the involvement of industry in the process, and the future policy processes within FAO and international fora. Participants who had also attended the Interlaken Conference stressed the importance of the *Global Plan of Action* as a tool for national policy development and for attracting donor funding. NGOs pointed out the importance of the ecosystem approach, particularly for pastoral systems, for the successful implementation of the Plan.

Tuesday, 9 October 2007

4. STRENGTHENING ABS EFFORTS IN DEVELOPING COUNTRIES: INCORPORATING CAPACITY BUILDING AND TECHNOLOGY TRANSFER INTO PIC AND MAT

The American Bioindustry Alliance (ABIA) and the Biotechnology Industry Organization (BIO)

Mrs. Susan K. Finston, Executive Director of the ABIA, Side-Event Moderator; Ms. Lila Feisee, Managing Director for Intellectual Property, BIO, "*BIO Members Commitment to Up Front Benefits through Model Material Transfer Agreement (MTA) Terms*", Side-Event Panelist; Dr. Robert M. Friedman, VP for Public Policy, and J. Craig Venter Institute, "*Capacity Building & Technology Transfer Benefits from the UCSD/Venter Institute CAMERA Project*", Side-Event Panelist; Dr. Manisha A. Desai, Patent Counsel, Eli Lilly and Company, "*Generating Meaningful ABS Benefits through Increased Legal Certainty for Stakeholders*", Side-Event Panelist.

The fifth meeting of the Convention on Biological Diversity's (CBD) Ad Hoc Open-ended Working Group on Access and Benefit-sharing was held in Montreal from 8 to 12 October 2007. During the meeting, the ABIA and BIO (the Biotechnology Industry Organization) co-sponsored a side-event ("*Strengthening ABS in Developing Countries: Capacity Building and Technology Transfer*"). By focusing on practical approaches that provide front-loaded benefits to CBD Members and other stake-holders in the ABS process, the very well-attended side-event's presentations and lively discussion highlighted the importance of capacity building and technology transfer in creating an enabling environment for the generation of benefits under an ABS International Regime on Access and Benefit-sharing.

INTRODUCTION

Despite the best efforts of researchers and companies, ABS experts have documented that successful commercialization of Genetic Resources (GR) and/or Traditional Knowledge (TK) products is the rare exception rather than the rule. Based on this real-world experience, experts recommend front-loaded ABS alternatives, such as, for example, training, capacity-building, and inclusion in joint research projects, that bring proven benefits at an early stage to all stakeholders in the ABS process. The joint side-event focused on the following front-loaded measures: Model Codes of Conduct, Model MTA Terms, and the University of California/ J. Craig Venter Institute "CAMERA" Programme. Speakers at the side-event also discussed the "chilling effect" of mandatory patent disclosure, especially when juxtaposed with front-loaded approaches like the Traditional Knowledge Digital Library (TKDL), which produces more practical benefits. Due to time constraints, the joint side-event did not discuss other important available measures that provide front-loaded ABS benefits. ABIA/BIO plan to address these other measures at their joint side-event at ABS WG-6 and beyond.

PROGRAM

A. The Value of Front-Loaded Benefits

Mrs. Finston provided an overview on the value of front-loaded ABS elements for inclusion in ongoing discussions on potential elements for an ABS International Regime. She also noted that international ABS experts increasingly caution against reliance upon the patent system as a mechanism for enforcing ABS benefits at the point of commercial success because, even after the issuance of a patent (which is itself based on substantial time and research effort), biodiversity product development is a slow, uncertain process. Few life science products in the research and development (R&D) cycle reach the commercial stage, let alone provide a return on investment. It is estimated that only one in 10,000 patents may result in a successful commercial product.

For example, as is widely known, Merck/INBIO Agreements in Costa Rica did not result in new Merck products. These and subsequent R&D agreements, however, did enable INBIO and other Costa Rican research institutions to strengthen their science base and thus become a

recognized pre-eminent biodiversity research center in Latin America.⁶ Similarly, in the case of P57 (Hoodia), which was patented by CSIR (South Africa) in 1997 (and earlier), no innovative product has yet reached the market through the CSIR/Phytopharm/Unilever Agreement.

Hence, given these tremendous odds against commercial success, front-loaded benefits guarantee or make available early-stage returns to the providers of GRs, CBD Members and local communities and/or indigenous peoples. Capacity building and technology transfer remain critical to the successful implementation of these front loaded efforts, and CBD Members need to ensure workable, sustainable enabling environments for the transfer of technology.

B. BIO's BioProspecting Guidelines and Model Material Transfer Agreement (MMTA)

1. BioProspecting Guidelines for BIO Members

Ms. Feisee underscored BIO members' strong support for the goals of the CBD to promote access and benefit-sharing of countries' biological resources for sustainable development. She reported that BIO had undertaken the initiative to develop "*Guidelines for BIO Members Engaging in BioProspecting*," (the BIO Guidelines) to assist its members to adhere to the Bonn Guidelines.

More specifically, Ms. Feisee explained that the BIO Guidelines were developed to educate BIO members about the issues that can arise in accordance with bioprospecting activities, and to provide BIO member companies seeking to better understand bioprospecting. To this end, the BIO Guidelines identify "best practices" that can be considered by BIO member companies (and, hopefully, by others, too) who elect to engage in bioprospecting activities.

Ms. Feisee further commented that while BIO members generally work with materials obtained from *ex-situ* sources (e.g., genebanks, depositories, internal sources), the BIO Guidelines provision of general principles and "best practices" to follow when a BIO member decides to engage in bioprospecting activities. The BIO Guidelines attempt to avoid difficulties that the private sector has encountered when applying the CBD and the Bonn Guidelines to proposals for, to obtain access to, *in situ* resources. Among these difficulties has been the uncertainty over the meaning of the definitions included in the Bonn Guidelines, i.e., the scope of "genetic resources," and type of information appears to be required for obtaining permission to access biomaterials. For example, the BIO Guidelines only apply to biomaterials of non-human animal, plant or microbial origin that contain functional units of heredity and, that, are subject to the requirements of prior informed consent (PIC). This is clearly consistent with the CBD. Clarity on this point is very important to BIO's members because fundamental biotechnology discoveries are biological and generally gene-based in nature.

6. At the ABIA Curitiba COP-8 Side-Event, Mr. Jorge Alberto Cabrera Medaglia, Legal Adviser to the Instituto Nacional de Biodiversidad (INBIO), and Adviser to the Costa Rican Ministry of the Environment, on technology-transfer related benefits to Costa Rica through ABS Agreements over the past 15 years. See <http://www.abialiance.com/html/news.html> for a summary of his presentation and tabular data on benefits to Costa Rica from front-loaded ABS Agreements which provided legal certainty, i.e., IP Rights (IPRs), to Merck and other companies.

2. *BIO's MMTA for ABS*

In addition to advice in respect of bioprospecting activities, BIO members also expressed an interest in having an MMTA that they could employ for the transfer of genetic resources found *ex situ* and *in situ* for specific authorized use(s). BIO's MMTA comports with the long-standing position of both the ABIA and BIO that mutually agreed terms (MATs) or contracts provide the most effective means of fulfilling the objectives of the CBD, because they allow the contracting parties the most flexibility in structuring the successful conditions for transfer, allocating benefits arising from the transfer, and administering the transfer. As a result, the MMTA provides a structure that facilitates compliance with the CBD and allows the contracting parties the necessary flexibility to customize the benefits, both front-loaded and at later stages, for each particular situation through mutual agreement. Thus, and importantly, BIO's MMTA is not a standard (one-size-fits-all) contract such as the Standard Material Transfer Agreement (SMTA) developed under the International Treaty on Plant Genetic Resources.

The SMTA was developed for a very specific type of low-cost, limited purpose and administratively simple transfer. By contrast, BIO's MMTA can be a "stand-alone" agreement for use in the transfer a small number of samples of a single GR from an *ex situ* collection, or BIO's MMTA can be employed as part of a bioprospecting agreement, or BIO's MMTA can be supplemented to cover the transfer of associated technological information such as TK. At the same time, development of BIO's MMTA can be used in capacity-building efforts to assist resource providers in understanding the full range of front-loaded options available to them.

Please visit <http://bio.org/ip/international/200507guide.asp> to review the BIO Guidelines and BIO's recommended MMTA.

C. Capacity Building and Tech Transfer Benefits from CAMERA

Dr. Robert Friedman of the J. Craig Venter Institute provided an overview of the University of California/ J.Craig Venter Institute CAMERA Program. Dr. Friedman noted that microbes are the most abundant, most diverse, and least understood organisms on the planet. CAMERA is a large-scale database that seeks to help scientists understand the vast biological diversity among microbes and the vital role that these organisms play in ecosystem function.

Many researchers and research institutions around the world are undertaking marine microbial sampling to better understand how ocean ecosystems function, including the vital role they play in absorbing carbon from the atmosphere. CAMERA allows scientists to place the resulting research in the public domain, with full attribution of the origin of the microbial marine samples, which is often a condition of the mutual agreements with those countries in which the sampling occurred. CAMERA not only makes the huge amount of genetic data from microbial ecosystems available to scientists worldwide, but also includes the software and computational capacity to analyze these data, all at no charge to users. Software tools and training for "entry level" scientists are included, along with the cutting-edge tools and large-scale analyses previously accessible to the expert few. CAMERA is a joint project of the

California Institute for Telecommunications and Information Technology of the University of California at San Diego, and the J. Craig Venter Institute. Funding was provided by the Gordon and Betty Moore Foundation, which recognized the importance of enhancing the capabilities of research scientists worldwide.

D. Unintended Consequences of Mandatory Patent Disclosure Contrasted With Positive Alternatives

Dr. Desai presented examples of unintended adverse consequences of mandatory patent disclosure (pursuant to national patent laws) and underscored positive alternatives.

Manisha A. Desai, Ph.D., of ABIA member company, Eli Lilly and Company, presented examples of unintended consequences of patent disclosure in national patent laws and underscored positive alternatives. She cited her ongoing analysis of various patents relating to GR or associated TK for which allegations of biopiracy have been made. She showed that many of these patents already included information about the source or origin of the GR in question, but that disclosure did nothing to prevent allegations of inappropriate behaviour or to avoid the necessity of protracted litigation and/or other dispute resolution across borders. In addition, her analysis showed that claims of biopiracy have been asserted where there are multiple sources for the GR, and where this was clearly stated by the patent applicant in accordance with national laws, creating uncertainty and bad feelings between providers and user of the resources.

Dr. Desai also cited positive alternatives to mandatory patent disclosure that provide meaningful assistance to world-wide patent offices in their examination of patent applications — including TK databases or digital libraries (TKDLs) adopted by a growing number of CBD members. These types of databases provide for efficient prior art searches, and can assist in preventing the granting of patents for claimed inventions lacking novelty and/or an inventive step. Dr. Desai further pointed out that these types of databases may also provide incentives for commercialization by providing transparency about the origin of GRs, the related TK and any indigenous groups from whom PIC may be obtained as appropriate pursuant to national laws.

Referring to points made by Mrs. Finston, Ms. Feisee and Dr. Friedman, she added that capacity building efforts, as well as model material transfer agreement (MTA) terms and model Codes of Conduct can also be useful for protecting interests in GRs and associated TK.

CONCLUDING REMARKS

ABIA member companies and BIO member companies believe that the CBD ABS Working Group negotiations should include a greater focus on the benefits of model Codes of Conduct and on model mutual agreements like Material Transfer Agreements (MTAs) that can provide both front-loaded and longer term benefit-sharing, and — (monetary and/or non-monetary) as well as other front-loaded systems such as capacity building, scientific exchange and other forms of technology transfer.

Research Institutes like the J. Craig Venter Institute are already very active with a large number of developing countries and are demonstrating the concrete benefits obtainable from joint research projects on marine micro-organisms.

ABIA member companies and BIO member companies continue to be concerned about the misplaced patent-centric approaches to ABS that have already “chilled” bioprospecting and other commercial and non-commercial research efforts and, believe, that there are attractive, alternative approaches such as the establishment and use of TK data bases (TKDBs) as an additional source of subject matter in the prior art. Such TKDBs have already been implemented by India, China, Venezuela and several others. Use of a TKDB in China has already provided proven incentives for research and investment in the commercialization of Traditional Chinese Medicine (TCM).

While user measures and enforcement tools will, of course, remain a part of any eventual ABS International Regime, both the ABIA and BIO believe that it is critical that emphasis be placed on positive incentives that bring benefits, rather than on negative policies that fail to bring stakeholders together for mutual benefit and, as a result, discourage sustainable use of biodiversity resources.

5. THE PROBLEM WITH THEFT: CANDID CONVERSATION ABOUT BIOPIRACY

The Third World Network, the African Centre for Biosafety and the Edmonds Institute

More than 80 participants attended the TWN/ACB/EI side event on the 9th October 2007, entitled: “THE PROBLEM WITH THEFT: CANDID CONVERSATION ABOUT BIOPIRACY”.

While intense resistance continues from some quarters to developing the international ABS regime, misappropriation is also continuing. The panel presented recent research from South Africa that calls for further investigations, and alerted delegates to developments at the WHO on avian flu viruses.

The African Centre for Biosafety launched a booklet titled “Bioprospecting, Biopiracy and Indigenous Knowledge: Two case studies from the Eastern Cape Province, South Africa.”

Two presentations based on this publication were made by the ACB, one by Mariam Mayet and the other, by Michelle Koyama.

Ms. Mayet introduced the booklet against the backdrop that over 70% of South Africans rely on traditional medicine for their basic health care needs and where local communities have a long history of using a wide range of medicinal plants in the treatment of an array of diseases. She outlined the shortcomings of South Africa’s legal framework on access and

benefit-sharing and the protection of indigenous knowledge, and concomitantly, the concerns regarding the unlawful acquisition of indigenous knowledge by both the public and private sectors. She discussed one of the case studies in the booklet, which focuses on bioprospecting conducted by a publicly funded South African research institution involving the use of indigenous knowledge for non-commercial gain. She raised important questions regarding the interface between non-commercial bioprospecting and biopiracy, highlighting the need for all forms of bioprospecting involving indigenous knowledge to require the prior informed consent on the communities involved as well as provisions for communities to opt for the sharing of non-commercial benefits if they so wished.

Ms. Michelle Koyama discussed the second case study, which deals with the use and subsequent patenting of traditional uses regarding two species of locally indigenous and endemic plant species, namely, *pelargonium sidoides* and *pelargonium reniforme* by a German company, Schwabe Pharmaceuticals, without the knowledge or the consent of the local communities and holders of the knowledge. She sketched the historical background, tracing briefly the transfer of knowledge of the use of the *pelargoniums* from a traditional healer in South Africa up to the recent registration of patents on the use of the plants in the treatment for AIDs and AIDs related diseases such as TB, as well as other various infections and symptoms of diseases.

The side event opened up rich and fruitful discussions regarding the problems with on-going biopiracy in the developing world and the overburdened responsibility that governments in developing countries have to bear in addressing the complexities of the issues involved. The side event revealed that whilst some developed nations are intent on avoiding the environmental debt they owe to the developing world as a result of biopiracy — as evidenced by the blocking tactics of some countries in the ABS negotiations — indigenous peoples in developing countries continue to suffer politically, economically, environmentally, yet ironically, they continue to remain the custodians over the world's biodiversity and indigenous knowledge. The need for the research community to acknowledge the rights of indigenous peoples and local communities was stressed. A number of participants called for better understanding of ABS regulation by researchers, and that compliance with ABS regulation will not hamper genuine research.

The other issue that was presented at the side event was the on-going negotiations at the World Health Organization on the rules for sharing of avian influenza viruses and the benefits derived from research on such viruses, including vaccines and diagnostic tools. This was presented by Chee Yoke Ling of Third World Network, who highlighted that this is a concrete international ABS case that has far-reaching implications for the CBD ABS negotiations, and developing countries in particular need to coordinate their national positions in the two negotiation tracks. An important WHO intergovernmental meeting will take place on 20-23 November in Geneva, to consider the terms and conditions for flu virus sharing and for the fair and equitable sharing of benefits from virus research.

Thailand first alerted countries to the flaws in the WHO Global Influenza Surveillance Network (GISN) at the annual World Health Assembly in 2006. Indonesia, China, Viet Nam, Thailand have been the main donors of the virus samples as those countries have bird flu outbreaks that are closely monitored, especially for fear that the H5N1 strain may mutate and cross over to humans, triggering a pandemic.

However, it has come to light that contrary to a 2005 WHO guideline (which requires consent of originating countries for other uses, and has since been removed from the WHO website), WHO designated centres and laboratories (all these are national labs and research centres in the US, Australia, UK and Japan) have themselves been seeking patent claims over gene sequences and derivatives. At the same time, Northern commercial vaccines developers have of course been accessing the isolated virus strains to vaccine, diagnostic tools etc. and patenting different parts and processes. The result is unaffordable products for developing countries, including those countries that donated the viruses in the first place. There is also a limited supply of vaccines as manufacturers are limited, and developed countries are already signing advance purchase agreements to secure their own national stockpiles. So if a pandemic does occur there will be a disaster in developing countries, most of who would be left to rely on limited WHO stockpiles that are essentially from donations — again sufficiency of supplies is an issue for countries that need vaccines and diagnostics most urgently.

Other third parties (e.g. U.S. research institutions outside the GISN) have also been accessing the viruses put into the system and seeking patents or publishing scientific articles.

Attempts were made to adopt a WHO resolution that would have fairer access and benefit-sharing terms between provider countries and the WHO designated centres and laboratories, but the weak draft that emerged from work in 2006 led Indonesia to announce in early 2007 that it was withholding further sharing of virus samples until the GISN is reformed.

In May 2007 when the WHO met there were intense negotiations with Indonesia invoking the CBD. Some developed countries and to some extent the WHO Secretariat in Geneva, have been in opposition arguing that for the purpose of global public health, there should be free sharing. Nevertheless, an Indonesian proposal supported by more than 20 countries led to the adoption of a resolution entitled “Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits”.

It recognizes, *inter alia*: (a) the sovereign right of States over their biological resources, and the importance of collective action to mitigate public health risks; (b) that intellectual property rights do not and should not prevent Member States from taking measures to protect public health; (c) the importance of international sharing, with WHO Collaborating Centres, of clinical specimens and viruses as a contribution to assessment of the pandemic risk, development of pandemic vaccines, updating of diagnostic reagents and test kits, and surveillance for resistance to antiviral medicines.

It stresses “the need for effective and transparent international mechanisms aimed at ensuring fair and equitable sharing of benefits, including access to, and distribution of, affordable diagnostics and treatments, including vaccines, to those in need, especially in developing countries, in a timely manner”.

The resolution called for an inter-disciplinary working group (this took place in Singapore at the end of July) “to revise the terms of reference of the WHO Collaborating Centres, H5 Reference Laboratories and national influenza centres; devise oversight mechanisms; formulate draft standard terms and conditions for sharing viruses between originating countries, WHO Collaborating Centres and between the WHO Collaborating Centres and third parties; and to review all relevant documents for sharing influenza viruses and sequence data ...”

The Singapore meeting ended unsatisfactorily with many uncertainties. Developing countries were predominantly represented by their health officials, and it seemed evident that there was little or no national consultations with the CBD ABS negotiators.

The resolution also called for an expert paper on the patent issues related to avian flu viruses, and this has been prepared by the World Intellectual Property Organisation (WIPO).

Participants at the side event appreciated receiving this information which was unknown to most of them. Discussions emphasized that decisions at the WHO should not undermine the development of the international regime on ABS and that national coherence was crucial to ensure fair and equitable benefit-sharing to safeguard public health in developing countries.

Ms. Beth Burrows of the Edmonds Institute, who chaired the side-event pointed out that there are many other issues and cases of biopiracy that are going on, and that what the panel presented was but a tiny glimpse at the theft that continues to take place from countries and from indigenous peoples, local communities and even ordinary citizens, as shown in the case of U.S. citizen Mr. John Moore, whose challenge against the patents on his cell lines first grabbed international attention.

6. BEYOND ACCESS: WHAT YOU NEED TO KNOW ABOUT THE USER SIDE OF ABS

Fridtjof Nansen Institute

Presentation of the results of a legal study on the obligations of users and user countries under the CBD, and the legal obstacles that still prevent the utilization of user-country law as a tool for ABS Implementation. (See also *Launch Of The Abs Series, No. 1, 2 And 3—Expert Analyses Of Critical Abs Issues*, IUCN — Tuesday, 9 October 2007, Evening).

7. USING TECHNOLOGY TO MAXIMIZE UTILITY OF GENETIC RESOURCES UNDER STANDARD MATERIALS TRANSFER AGREEMENTS

Creative Commons

Materials Transfer Agreements (MTAs) can and should benefit from the low-cost, advanced communication opportunities of modern electronic networks as part and parcel of the standardization process. Key considerations during the process of standardization on chosen and excluded options should be documented in a clearly understandable manual to support potential users. This should also include clear identification of cases in which use of the standard MTA is advisable and cases in which it should not be used. This side event demonstrated the Science Commons MTA suite developed for genetic resources “not” typically covered by the CBD. The Science Commons suite is designed from its roots to exploit the opportunities of the network world and exposes the key terms of MTAs in formats easily accessible to all parties to materials transfer, including the offeror, the research scientist, and the computational search frameworks. This side event also featured StrainInfo.net, a key element of the materials transfer process — the ability to discover materials on the network and to have the requests for transfers fulfilled. Attendees had the opportunity to test the Science Commons MTA suite themselves and interact with the key personnel from both Science Commons and StrainInfo.net.

8. LAUNCH OF THE ABS SERIES, NO. 1, 2 AND 3 — EXPERT ANALYSES OF CRITICAL ABS ISSUES

IUCN — The World Conservation Union — Environmental Law Centre

In one of IUCN’s three Side Events organized during the Fifth Meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing (WG-ABS-5) in Montreal, Canada, the IUCN Environmental Law Centre launched the first three books of the ‘*ABS Series*’ — a five-volume sub-series of the ELP’s Environmental Policy and Law Papers (EPLP 67). The Series provides intensively researched expert analysis by internationally respected authors and contributors on key issues of access to genetic resources and benefit-sharing under the CBD. The books no. 1, 2 and 3 address the “access” and the “user side” of ABS as well as questions around tracking and monitoring the international flows of genetic resources. The event benefited greatly from the presence of several of the authors and editors who presented concise and thought-provoking introductions to the content and main results of the books.

Mr. Daniel Klein, Legal Officer at the IUCN Environmental Law Centre (ELC), welcomed and briefly introduced the Event and the presenters to the audience.

First, Ms. Tomme Young, editor of the ABS Series, presented an overview over the series and the project under which it is being developed: The ABS Series represents the centerpiece of *The*

ABS Project, which has been carried out by IUCN ELC, since 2003, with the financial support of the German Federal Ministry for Development Cooperation (BMZ). Through a combination of leveraging and network-building, *The ABS Project* was able to produce a large volume of publications, activities and other results.

Ms. Young also gave an introduction to the first book of the Series — “*Addressing the Problems of Access: Protecting Sources, While Giving Users Certainty*”, by Jorge Cabrera Medaglia and Christian López Silva (EPLP 67/1) as the authors could, unfortunately, not be present. The book focuses on the aspect of access to genetic resources. Recognizing that all existing ABS legislation addresses only the “provider side” of the ABS issue, it brings together a comprehensive analysis of that body of legislation, and considers the aspects that are still non-functional or have not yet been properly addressed.

Then, Mr. Morten Walløe Tvedt of the Fridtjof Nansen Institute (FNI) presented the main findings of the second book of the ABS Series: “*Beyond Access: Exploring Implementation of the Fair and Equitable Sharing Commitment in the CBD*”, by Morten Walløe Tvedt and Tomme Young (EPLP 67/2), in collaboration with FNI addresses the “user side” and the main questions surrounding the benefit-sharing obligation of Article 15.7 CBD. It provides the first intensive analysis of national legislation addressing the user side of the ABS issue and examines the problem of “user measures” and the significant additional work that is needed by user countries as well as the negotiations of the international regime on ABS if the ABS regime is to become functional.

Finally, *Manuel Ruiz* from the Sociedad Peruana del Derecho Ambiental (SPDA) summarized the five contributions (Chapters) of the third book of the ABS Series: “*A Moving Target: Genetic Resources and Options for Tracking and Monitoring their International Flows*”, edited by Manuel Ruiz and Isabel Lapeña (EPLP 67/3, in collaboration with SPDA) examines the question of how genetic resources can be tracked and monitored, an element or mechanism that has been indicated would be essential for ensuring that ABS rules and requirements are complied with. It focuses on a number of different perspectives on this issue, considering legal, practical, economic and scientific approaches and issues.

The launching and distribution of the first three volumes was well received, noticeable from the 700 copies picked up by delegates during the launch and the following days. It is hoped that the current negotiations of an international regime on ABS as well as efforts in ABS implementation on national and regional levels will benefit from the analysis, findings and suggested approaches presented. The first two books (EPLP 67/1 and EPLP 67/2) are available online at: <http://www.iucn.org/themes/law/info04.html>. The third book, which was released as advance copy, will soon be available in its final typeset version, equally at the indicated ELP publication website.

Books No. 4 and 5 of the ABS Series (entitled *Contracting for ABS: The Legal and Scientific Implications of Bioprospecting Contracts* and *Covering ABS: Addressing the Need for*

Sectoral, Geographical, Legal and International Integration in the ABS Regime) are in the phase of finalization and expected to be available in January 2008, at the sixth meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing (WG-ABS-6), in Geneva, Switzerland.

Wednesday, 10 October 2007

9. COMMUNITY CERTIFICATES OF ORIGIN

Asociacion Quechua Aymara Para Comunidades Sustentables “Andes”

The event this workshop discussed the concept and practicability of “Community Certificates of Origin” and presented experiences from Peru and other regions on the development of this concept and its relation to the protection of the collective biocultural heritage of Indigenous Peoples.

10. ACCESS AND BENEFIT SHARING: REAL PROBLEMS AND FALSE SOLUTIONS

Global Forest Coalition

While governments fiddle with false solutions like minor adaptations in patent law, biopiracy is growing unabated. All over the world new cases of shameless biopiracy have been reported over the past years. Addressing these problems requires a fundamental review of existing intellectual property rights regimes, including the Trade Related Intellectual Property Rights agreement of the World Trade Organization. Some of the most valid proposals to adapt these regimes have been dismissed by industry and their governmental allies as “unrealistic”, but it is far more unrealistic to presume that minor adaptations in existing intellectual property rights systems would lead to fair and equitable access and benefit-sharing. The side event exposed some of the real stories of biopiracy and highlighted proposals to adapt legal systems governing biodiversity, traditional knowledge and intellectual rights to the realities of Indigenous Peoples and other holders of traditional knowledge.

11. THE IMPORTANCE OF GENDER IN ABS

IUCN—The World Conservation Union and the CBD Secretariat

A presentation was made on the promotion of gender equity and equality as one of the key elements towards sustainable development and poverty alleviation. An analysis was made of the importance of mainstreaming gender criteria in the ABS process and practical ways of addressing gender issues were presented. The key speakers at the event were Ms. Lorena Aguilar, Sr. Gender Advisor IUCN, Ms. Marie Aminata Khan, CBD Gender Focal Point.

Women have, for centuries, played a key role in the conservation and management of biological resources. Women's knowledge of biodiversity and its value for meeting the food, health, clothing and housing needs of their families, is crucial for meeting the sustenance and development needs of a large sector of the world's population. Their role takes on even greater importance where their knowledge and skills, in the management of resources, is fundamental for meeting the basic necessities of countless millions of the world's poorest.

Recognition by the international community of the importance of women for conservation and sustainable use of biodiversity, including their leading role in farming and forest conservation, as well as in the maintenance and development of traditional medicine, is widespread. International instruments are replete with references to women's key role in these areas, as in combating poverty.

International law and policy has established clear obligations upon states to protect against discrimination of women, and calls for adoption of measures to promote equity and secure equality. International instruments also make numerous commitments to promoting equity and fair and equitable sharing of benefits derived from use of biological diversity.

Women bear a large share of the burden for conservation and sustainable use of biological diversity and for sustaining families and communities, in particular the poor. Despite this, their contribution is frequently undervalued and their opportunities to influence policy and law, as well as to participate in the design and implementation of development projects, are often minimal. Opportunities for women to participate in benefit-sharing arising from use of biological diversity and from their knowledge of its uses are in many cases dependent upon decisions taken in their absence.

Lack of clear legislative and policy guidance places undue reliance on programme managers, contract negotiators, community leaders and national authorities to mainstream gender to the design of projects, law and policy, as well as in distribution of benefits. Likewise, the lack of national policy means that negotiators in international forums have, for the most part, no guidance on what position to take on gender issues.

12. THE ABS FOR AFRICA INITIATIVE: ACHIEVEMENTS AND UPCOMING ACTIVITIES

Deutsche Gesellschaft Für Technische Zusammenarbeit (GTZ), Dutch Directorate for International Cooperation and the Secretariat of the Convention on Biological Diversity

Organized by the Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ) GmbH, the Dutch Directorate for International Cooperation (DGIS) and the Secretariat of the Convention on Biological Diversity. .

Participants from six workshops held to date under the ABS for Africa Initiative reported on the different events they attended. The events, which addressed various aspects of ABS, have

either taken form of multi-stakeholder workshops focusing on a specific region, or addressing specific topics such as the certificate of origin or bio-trade and ABS. Over 60 participants attended the side event which reviewed the history of the ABS for Africa Initiative. .

Following opening remarks from Léontine Crisson (The Netherlands Ministry of Agriculture, Nature and Food Quality) and Anne-Katrin Pfeiffer (German Federal Ministry for Economic Cooperation and Development), Dr. Andreas Drews (Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ) GmbH) outlined the objectives, instruments, milestones and results achieved so far under the Dutch-German ABS Capacity-Development Initiative for Africa.

Dr. Kassahun (Ethiopian Institute of Biodiversity Conservation) reported on the pilot workshop held for Southern and Eastern Africa in Addis Ababa, Ethiopia, in October 2005. He explained that participants discussed bio-prospecting cases and national ABS legislation, and highlighted that recommendations on future work under the Initiative were elaborated on the basis of capacity-building needs identified by participants. Dr. Andreas Drews explained that the Initiative was called into life following this pilot workshop. .

Outlining the kick-off workshop held in Cape Town, South Africa, in November 2006, Kabir Bavikatte (Natural Justice, South Africa) presented the vision for ABS in Africa in the year 2010, as developed by workshop participants. He highlighted that the vision reflects all stakeholders' interests and is intended to guide the Initiative's work. He said the field trip to the San-Culture and Education Center !Kwa ttu, where participants discussed the case of bio-prospecting Hoodia with stakeholders, had been instrumental in elaborating this multi-faceted vision. .

Prof. Johnson Ekpere (Nigeria) subsequently outlined a workshop that focused on the certificate of origin. At this workshop, held in Addis Ababa in March 2007, participants reviewed the report put forward by the technical expert group that had met to discuss the same subject in Lima, Peru, in January 2007. Prof. Ekpere stressed that participants developed a common African viewpoint on the subject matter. .

Pierre du Plessis (CRIA, Namibia) reported on a workshop entitled "ABS, Biotrade & Commercial Research", convened in Windhuk, Namibia in June 2007. He noted that discussions highlighted the difficulty of distinguishing between bio-trade and ABS, and drew attention to the field trip, which illustrated the Namibian pipeline approach of bio-prospecting Marula.

Bon N'Konzi (Republic of Central Africa) reported on the multi-stakeholder workshop held for central African countries in Douala, Cameroun, in September 2007. He said that the workshop, which was organised in partnership with the Commission des Forêts d'Afrique Centrale (COMIFAC) examined the status of relevant ABS legislation and implementation in the region, and prepared a common position for WGABS-5. N'Konzi stressed that the field trip to village communities harvesting *prunus africana*, and discussions with these and other stakeholders of this bio-prospecting case had been of great value to the workshop deliberations. .

Following this presentation, Suhel al-Janabi (GTZ) introduced the African delegations briefing and capacity-development meeting that had taken place immediately prior to WGABS-5. He underscored that this bilingual workshop for African delegates was organised in partnership with the African Union, the Government of Quebec and the Institut de l'énergie et de l'environnement de la Francophonie (IEPF). The meeting had provided participants with a background on the ABS process and a technical briefing on all substantial agenda items of WGABS-5. .

Finally, Dr. Andreas Drews announced further steps planned under the Initiative, including multi-stakeholder workshops for Western Africa and the Maghreb to be held in November 2007, and an Africa wide workshop in December 2007. He drew attention to a delegations briefing that will take place prior to WGABS-6 in Geneva, Switzerland. .

For further information on the Initiative, please visit www.abs-africa.info.

- ▶ Léontine Crisson (Ministry of Agriculture, Nature and Food Quality, the Netherlands) welcomes participants to the side event
- ▶ Anne-Katrin Pfeiffer (Federal Ministry for Economic Cooperation and Development, Germany) draws attention to funding opportunities for ABS capacity-development activities under the GEF
- ▶ Dr. Andreas Drews (Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ) GmbH) highlights results achieved so far under the Initiative
- ▶ Dr. Kassahun (Institute of Biodiversity Conservation, Ethiopia) reports on the pilot workshop
- ▶ Kabir Bavikatte (Natural Justice, South Africa) presents the vision for ABS in Africa in the year 2010
- ▶ Prof. Johnson Ekpere (Nigeria) explains that participants of the “certificate of origin”-workshop considered the recommendations put forward by the technical expert group
- ▶ Pierre du Plessis (CRIAA, Namibia) explains the risk involved in commercialising genetic resources
- ▶ Bon N’Konzi (Central Africa) reviews the workshop held for central African countries
- ▶ Suhel al-Janabi (GTZ) reports on the first African delegations briefing

Thursday, 11 October 2007

13. EXPLORING ISSUES RAISED BY SYNTHETIC BIOLOGY

Action Group on Erosion, Technology and Concentration

A patent for the first completely human-made species has been applied for — what are the implications for the environment, for intellectual property, etc.?

14. IMPLEMENTING THE UNITED NATIONS DECLARATION ON THE RIGHTS OF INDIGENOUS PEOPLES RIGHTS IN ACCESS AND BENEFIT SHARING

International Indigenous Forum on Biodiversity

Indigenous peoples discussed the recent adoption of the United Nations Declaration on the Rights of Indigenous Peoples and the relevant provisions relevant to access and benefit-sharing and made suggestions on how these minimum standards should be implemented in an international regime on access and benefit-sharing and national ABS legislation.

15. THE INTERNATIONAL REGIME—IMPLICATIONS FOR PHARMACEUTICAL RESEARCH AND DEVELOPMENT

EFPIA

Presenters : Ms. Brendan Barnes, EFPIA, Ms. Manisha A. Desai, Eli Lilly and Company, Mr. David Rosenberg, GlaxoSmithKline

The very idea of access and benefit-sharing implies a transaction. Many transactions are commercial in nature, so this means not only that the International Regime (IR) has implications for business, to which business must respond, but also that the architects of the regime should try to understand how business operates.

This is the key to facilitating access and sustainable use, but to assume that sustainable use is the priority for all parties would be wrong. For many delegates to the Working Group, the primary purpose of the regime is to prevent abuse. It is often unclear what is being abused. This is a crucial judgment for the Parties. For the IR to address the goal of preventing abuse requires a completely different approach than that which would be implied by a primary objective of facilitating sustainable use.

In the seminar, EFPIA noted that it considers that reports of biopiracy are highly exaggerated and urged Parties to submit concrete examples so that a substantive discussion could take place, rather than an exchange of rhetoric.

Which industries make use of biodiversity or its products? There are many — among them, pharmaceuticals, food and drink, herbal medicines, seeds, horticulture, biotech, fragrances and cosmetics. The question — which sectors — itself raises further questions of definition and scope that the International Regime will have to address. The nature of use differs profoundly by sector, as does the nature of the transformation which each industry applies to natural resources.

In this respect, it may be useful to compare a modern pharmaceutical to a loaf of bread. Clearly, a loaf of bread is a product resulting directly from use of a genetic resource. Intuitively many

react to this observation by protesting that the CBD was not supposed to cover bread. Nevertheless, according to the definitions, bread is a perfect example of a product which should be subject to access and benefit-sharing. One of the things that the designers of the IR will have to consider is what should be excluded, but they must do so in a way that does not discriminate against innovation, and they must be able to offer a rationale for each exclusion.

In contrast, pharmaceuticals are not like loaves of bread. They very rarely contain any trace of any natural resource that might have been used in their development or manufacture and when they do, there is little physical relationship between the pharmaceutical and the resource found in nature. In this respect, it is important to underline the poorly-understood difference between pharmaceuticals, herbal medicines and other natural healthcare products.

The lack of resemblance between a modern pharmaceutical and a traditional medicine based on natural products is a cause for confusion. Indigenous communities who have provided access to their medicinal heritage find it incomprehensible that a modern multinational cannot make a medicine out of something they know to have medicinal properties. From the pharmaceutical companies' perspective, they are required to meet standards of quality, safety and efficacy that no traditional product could possibly reach in its original form. As a result, most natural product research programmes end in failure -- to the bewilderment of indigenous communities and the disappointment of companies. It is this question of what companies add to the genetic resources they receive that is so poorly understood.

It was also noted that certain countries have recently asserted sovereignty over pathogens found on their territories, perhaps entirely consistently with the CBD. Yet if we look behind the principle of sovereignty, we see the idea of stewardship, and in this context, the idea that a country has a duty to conserve, for example, the AIDS virus seems completely illogical and even dangerous. EFPIA believes that the CBD would be well-advised to exclude disease pathogens from the IR and endorse a public health-based approach to their management, led by the World Health Organization.

The first session of the seminar described the strong historical tradition of sourcing medicines from natural resources. However, it noted the progressive disinvestment from natural products research. The causes of this trend were discussed. It was noted that while regulatory barriers to research can be addressed, there are also major technological changes underway that are irreversible. Natural products research is in competition with other paradigms. At the same time, the presentation underlined that the industry's potential use of "natural products" is much richer and more diverse than is commonly understood, although the situation where the natural product becomes the final medicine is indeed rare. Opinions vary regarding the future of natural products research, but the international regime could help or hinder realization of its potential.

Through a better understanding of the process of R&D and the experience of successful partnerships, the Parties can draw conclusions about the appropriate form of the Regime.

The second session described one company's concrete experience with natural products research. It underlined that programmes of this sort are viewed as highly speculative and are often the first to be cut when research budgets must be controlled. Aside from the scientific challenges involved in natural products research, the session served to highlight that companies attach great importance to legal compliance, and this has severely limited the ability of companies to form partnerships with Parties that do not have functioning national access procedures. The examples given provided a strong rejoinder to those who fear a "race to the bottom" in ABS terms. Modern sophisticated companies want modern sophisticated partners in source countries.

In the final session of the event, EFPIA proposed some basic principles for the IR.

The Regime should guide, not prescribe. It should reflect the CBD, not seek to expand or amend its scope. It should be respectful of the circumstances and sovereignty of individual source countries.

It must be "user friendly" in terms of its scope, and substance and the legal and commercial security it provides.

A well-designed regime has the potential to facilitate access and, therefore, benefit-sharing. A poorly designed regime will have the opposite effect.

In the presentation, the highly negative effect of the "patent disclosure obligation" was discussed and some caution expressed about the effectiveness of certificates.

Perhaps the most critical message was that the IR must be evidence-based. It must address itself to real and identified problems.

EFPIA would like to thank the CBD Secretariat for making the side-event possible. Copies of the presentations are available from Brendan Barnes at brendanbarnes@efpia.org

**Fifth Meeting of the Ad
Hoc Open-Ended Working
Group on Article 8(j) and
Related Provisions (WG8J-5)**

Montreal, 15–19 October 2007

16. FIFTH MEETING OF THE AD HOC OPEN-ENDED WORKING GROUP ON ARTICLE 8(J) AND RELATED PROVISIONS (WG8J-5)

Solidarity Deeds and Social Welfare Foundation / NGO

Progress in the implementation of the programme of work on Article 8(j) and related provisions and on the integration of the relevant tasks into the thematic programmes of work under the convention and at the national level.

17. SYNTHETIC BIOLOGY—EXPLORING THE IMPLICATIONS

Action Group on Erosion, Technology and Concentration

A patent for the first human-made species has been applied for. What are the implications of synthetic life for the environment? for intellectual property? For how we define life?

18. INDIGENOUS PEOPLE AND MODEL FORESTS

Canadian Forestry Service

Presented the concepts of the Canadian Model Forests and the contribution of Aboriginal people in their success. The presentation described the International Model Forest Network and underlined the importance of Indigenous collaboration in achieving their implementation.

19. PRESENTATION OF THE REGIONAL NETWORK FOR INDIGENOUS PEOPLES IN SOUTHEAST ASIA (RNIP), BASED IN THE PHILIPPINES

Leiden University, Institute of Environmental Sciences

Presentation of the network, its activities and its projects.

20. QUEBEC'S PRACTICAL EXPERIENCE IN THE CONSULTATION PROCESS OF INDIGENOUS AND LOCAL COMMUNITIES

Bureau d'audiences Publiques sur l'environnement du Québec—BAPE (Quebec's Environmental Public Hearings Board)

On October 16, Mr. Qussaï Samak, member of the BAPE (**Quebec's Environmental Public Hearings Board**), gave a presentation before 20 guests as a side-event to the *Fifth meeting of the Ad Hoc Open-ended Working Group on Article 8(j) of the Convention on Biodiversity and Related Provisions held in Montreal*. The presentation, entitled *Quebec's practical experience*

in the consultation process of indigenous and local communities, provided an overview of the creation of the Albnel-Temiscami-Mount Otish Park, the largest reserve of biodiversity representative of the boreal forest in Quebec and Canada.

Mr. Samak, who chaired this consultation process which was carried out under the aegis of the BAPE in 2006, presented the project as an example of a collaborative initiative between the Cree Nation, as a partner and an active participant, and the Quebec Government in the creation of this park.

The presentation was followed with great interest and gave rise to many questions from the delegates attending the event. In the course of entertaining these questions Mr. Samak stressed the fact that many elements of Quebec's consultation process — and the Albnel-Temiscami-Mount Otish Park in particular — provided a functional model that is highly relevant to the implementation of provisions related to the *Article 8(j) of the Convention on Biodiversity*. **According to him, this is particularly the case insofar as protection of, and reliance on, traditional knowledge, together with the equitable sharing of benefits, are concerned.**

21. THE FOURTH NATIONAL REPORT OF THE CBD: ASSESSING PROGRESS TOWARDS THE 2010 TARGET

Secretariat of the Convention on Biological Diversity

A total of four presentations were made at the side event. SCBD introduced the guidelines for the fourth national report, by highlighting key information expected from Parties. The SCBD presentation also contained suggestions for the process of preparing the fourth national report, with emphasis on involving various stakeholders in reviewing implementation. SCBD also made a presentation on behalf of UNDP on a program being approved by the GEF for funding national assessment of progress towards the 2010 Target as well as the preparation of the fourth national report. This side event also provided an opportunity for countries to exchange experience in their national implementation of the Convention. Brazil introduced its experience in developing its national biodiversity strategy, including national targets for achieving the 2010 Target. Norway shared its experience in mainstreaming biodiversity into relevant sectors as well as its work on biodiversity at national and international level. There was some discussion after each presentation.

A dozen of delegates participated in the side event. Some of them indicated strong interest in such a side event and relevant materials provided to them.

22. INDICATORS RELEVANT FOR INDIGENOUS PEOPLES AND THE CONVENTION ON BIOLOGICAL DIVERSITY AND INDIGENOUS INITIATIVES ON CEPA

TEBTEBBA Foundation (Indigenous Peoples' International Centre for Policy Research and Education)

This side event shared the outcome and future work on indicators relevant for indigenous peoples. Initiatives by indigenous peoples on Communication, Education and Public Awareness were also discussed.

23. PERSPECTIVES ON INDIGENOUS PEOPLES FOOD SYSTEMS FOR FOOD SECURITY AND THE RIGHT TO ADEQUATE FOOD

Centre for Indigenous Peoples' Nutrition and Environment (Cine), McGill University

Traditional indigenous diets and lifestyles tend to protect against chronic diseases such as coronary heart disease and diabetes. However, encroachments on indigenous land and resources undermine access to these foods, and thus the food security of Indigenous Peoples. This session discussed food security indicators for Indigenous Peoples and Indigenous Peoples' right to adequate food. It will be by Ms. Harriet Kuhnlein, Founding Director of the Centre for Indigenous Peoples' Nutrition and Environment (CINE), McGill University Montreal, and Siri Damman, Visiting Scholar from the International Project on the Right to Food in Development at the Norwegian Center for Human Rights and Department of Nutrition, University of Oslo, Norway.

24. IN-DEPTH REVIEW OF THE EXPANDED PROGRAMME OF WORK ON FOREST BIOLOGICAL DIVERSITY

Secretariat of the Convention on Biological Diversity.

The presenter, Mr. Tim Christophersen, Environmental Affairs officer for forest biodiversity at the CBD Secretariat began by providing a description of all of the Elements and Goals and pertinent objectives, as they relate to the indigenous community of the CBD expanded programme of work (PoW) on forest biodiversity. Following this, Mr. Christophersen presented the major draft findings of the in-depth review which can be found on the Secretariat's website <http://www.cbd.int/doc/reviews/sbstta/sbstta-13/draft-sbstta-13-03-en.doc>. The information document providing background information on the review can be found at http://www.cbd.int/doc/reviews/sbstta/sbstta-13/_Toc179259451.

In summary, the draft findings are:

- (a) Despite many efforts to implement the PoW, the loss of forest biodiversity continues at a highly alarming rate. In particular, tropical and boreal forests are under high pressure from unsustainable use and land conversion.
- (b) Deforestation and forest degradation are the most significant causes of forest biodiversity loss. Notable progress in reducing the rate of deforestation has been made by some countries. At the global level, deforestation and conversion of primary and modified natural forests continue unabated, and have accelerated in some regions. Response activities to climate change through avoided deforestation present new opportunities for forest biodiversity.
- (c) Climate change has far-reaching consequences for forest biodiversity. Analysis of the integration of climate change impact and response activities within the PoW reveals that while there is adequate coverage within the text of the PoW, only a few Parties are reporting on implementation.
- (d) The coverage of forest protected areas has increased considerably in recent years, but the protection, recovery and restoration of forest biodiversity is often severely hampered by a lack of funding, particularly in developing countries.
- (e) Regional and international cooperation has resulted in significant progress in implementation of the PoW. Successful examples include the activities of the Collaborative Partnership on Forests, and regional processes such as the Amazon Cooperation Treaty Organization (ACTO), the Ministerial Conference for the Protection of Forests in Europe (MCPFE), and the initiatives on forest law enforcement and governance (FLEG).
- (f) Bioenergy production, if undertaken sustainably with due regard to net carbon accounting, offers potential benefits for mitigating climate change, but at the same time poses a significant threat to forest and other biodiversity through land conversion and water use increase for plantations and agricultural expansion. These impacts should be monitored carefully and should be addressed where appropriate.
- (g) Despite the importance of forest biodiversity for the economic and spiritual well-being of indigenous and local communities, forest decision-making processes often do not take their rights and concerns sufficiently into account.
- (h) While the PoW does not require additional goals or objectives at this stage to meet identified challenges for forest biodiversity, implementation efforts need to be strengthened considerably to meet the 2010 target, in particular in the field of reducing threats and mitigating impacts of drivers of biodiversity loss such as climate change, unsustainable use, land conversion, habitat fragmentation, forest fires, and invasive alien species, and in the field of forest biodiversity monitoring. Cooperation, exchange of experience, and technology transfer on the implementation of the PoW regarding these and other programme areas at regional and global level are limited.

- (i) The available information on the potential impacts of genetically modified trees in the long term is largely confined to hypotheses at this stage. Considerable scientific uncertainty remains, and a continued application of the precautionary approach is recommended. An information document on this topic is available on the Secretariat website <http://www.cbd.int/doc/reviews/sbstta/sbstta-13/draft-sbstta-13-inf-xx-en.doc>.

The floor was then opened to comments and questions from the participants.

25. TRADITIONAL KNOWLEDGE, FOLKLORE AND GENETIC RESOURCES: DEVELOPMENTS AT WIPO AND OTHER MULTILATERAL FORA

Center for International Environmental Law

The issues of folklore, traditional knowledge, and genetic resources that are being discussed and addressed in multiple fora at multiple levels. Indigenous and other local communities will be particularly affected by the outcomes of these discussions and it is important to ensure that developments in one forum do not negatively affect progress in others. The Center for International Environmental Law (CIEL) will present this update at the CBD as part of its work at cross-fora capacity-building and information sharing aimed at ensuring coherent and positive outcomes for indigenous and other local communities in multilateral processes of traditional knowledge, folklore and genetic resources.

26. INDIGENOUS WOMEN'S BIODIVERSITY NETWORK (IWBN) PRESENTATION

The Netherlands Centre for Indigenous Peoples (NCIV)

This event allowed the Indigenous Women's Biodiversity Network (IWBN) to present themselves and the on-going work they have been doing.

**Sixth Meeting of the Ad
Hoc Open-Ended Working
Group on Access and
Benefit-Sharing (ABS WG-6)**

Geneva, 21–25 January 2008

Monday, 21 January 2008

27. PROBENEFIT—LESSONS LEARNED FROM AN ABS RESEARCH PROJECT IN ECUADOR

VDI Technology Centre

Many regulations and guidelines on ABS exist — but how can these ideas and principles be implemented in practice? Five years ago, the German-Ecuadorian research project ProBenefit started with the aim of developing procedures for a fair and transparent agreement on ABS in the Amazon lowlands of Ecuador. For this purpose, the project did cooperate closely with the national Ecuadorian authorities, indigenous organizations, local communities and a medium-sized pharmaceutical company from Germany. The project has now come to an end.

The side-event presented results and lessons learned of the project. Participants had the chance to discuss the experience with the following experts involved in the project:

- ▶ Carsten Krück, VDI Technology Center, Germany
- ▶ Christiane Ploetz, VDI Technology Center, Germany
- ▶ Axel Paulsch, Institute for Biodiversity, Germany
- ▶ Antonio Matamoros, Ministry of Environment, Republic of Ecuador

The side-event was attended by more than 50 participants. Since many of them came from Spanish-speaking countries, a translation from English to Spanish was provided. Both members from delegations and representatives of NGOs, companies and indigenous organizations were present.

PRESENTATIONS AND DISCUSSION

Introduction and Project Overview (*Christiane Ploetz*)

The main aims of the project are:

- ▶ To Implement the ABS principles stated in the CBD.
- ▶ To develop transparent negotiation procedures with all relevant stakeholders

The project is divided into two subsequent phases:

- ▶ Phase 1: develop transparent negotiations that lead to an agreement on ABS
- ▶ Phase 2: plant screening, extract testing

The following activities and results form milestones of the project:

2003	Kick-off, First contacts with Ecuador	▶ Contact with Ministry of Ecuador and Indigenous Organizations
2004	Socio-political analysis, legal analysis, Workshop in project region	▶ Contact with and information of >40 stakeholder organizations in Ecuador ▶ “Consulta previa” as element of Ecuadorian draft proposal on ABS ▶ Strong indigenous criticism of current consulta practice
2005	Agreement ProBenefit — FONAKIN	▶ Aim: establish an indigenous group of experts who work out an ind. proposal for the consultation process ▶ Decision on training course
2006	Capacity building and training in project region	▶ 6-module course for indigenous representatives from the project region ▶ Formation of a working group ▶ Phase of communication stand-still during 2nd half of 2006
2007	Proposal of Working Group Project closure	▶ No ABS contract to be reached within ProBenefit ▶ Start of evaluation and analysis

Participation and Stakeholder Consultation in the ProBenefit Project (Axel Paulsch)

Training and capacity building was a vital precondition for indigenous participation:

- ▶ First workshop in the project region resulted in a need for more information expressed by indigenous representatives
- ▶ A capacity-building and training course was carried out in the project area (6 modules taught and designed by Ecuadorian experts)
- ▶ These experts should then inform and consult the local communities and organizations.

Participants appreciated explicitly that:

- ▶ Development of programme and selection of contents was done by indigenous and national experts.
- ▶ Presentations and moderation were done by national experts.
- ▶ Industrial partner personally present at certain modules.
- ▶ Real-Life examples and role playing.
- ▶ First extensive capacity building on ABS in the region.

Project appreciated that:

- ▶ Stable group of participants over all modules, gender-balanced.
- ▶ Expert group for the design of a consultation process could be formed.
- ▶ Documentation distributed to organizations, communities, government, experts and homepage.

FONAKIN main assembly decided:

- ▶ not to allow consultation design unless a broad capacity building campaign to be financed by the project or the applicant (15 months, 130.000 dollars) for all communities in the area
- ▶ then to meet again and decide, if development of a consultation design should be allowed
- ▶ then the applicant has to finance the consultation campaign
- ▶ this was impossible due to financial and time constraints

Some Conclusions and Lessons (Carsten Krüick)

Challenges of the process

- ▶ “Consulta previa” requires the coordination and representation of numerous ethnic, community and organizational indigenous levels with overlapping authorities and competencies.
- ▶ Considerable time and resource constraints for identifying and gathering stakeholders and generating a dialogue.
- ▶ The national Ecuadorian and regional (CAN 391) legal framework provides minimum requirements but few rules for implementation.
- ▶ Design, negotiation and implementation of a PIC process and ABS agreement left to companies and indigenous organizations.
- ▶ High transaction costs in the face of high reputational risks and uncertain outcomes.

Lessons learned

A transparent, bottom-up, participative approach remains the preferable approach to ABS. But: The transaction costs are prohibitive unless all interested parties invest substantially in their own institutional capacity:

Governments

- ▶ Engage in trust-building exercises with indigenous communities.
- ▶ Establish more precise guidelines for ABS and PIC procedures to lower entry barriers, allow for learning exercises and make the process more calculable for interested parties.

Indigenous organizations

- ▶ Strengthen the stability, transparency and accountability of organization structures to become more reliable for conceivable ABS partners.
- ▶ Build up a knowledge basis and train experts for ABS.
- ▶ Envision and draft specific benefits and justifiable consultation schemes.

Companies

- ▶ Communicate profit interests and constraints (e.g., R&D costs, drug approval barriers, portfolio and pipeline problems, marketing costs) to qualify bioprospection myths (“oro verde” etc.) and convey the importance of IPR.
- ▶ Develop a clear framework for benefit options to encourage negotiation and decision-making.
- ▶ Display and communicate possible licensing and patenting options available to negotiating parties (e.g., patent granted to NGO, university, government, park; joint ownership of patent; licensing of patent to company).
- ▶ Look for strong counterparts which claim and enforce strong positions.

Science

- ▶ Invest even more in working out a stakeholder analysis before entering the field.
- ▶ Get to know more about interethnic knowledge.
- ▶ Explore in more depth the dynamics and resolution of nested, multi-level bargaining situations.
- ▶ Sharpen the concept of capacity-building.

Development cooperation

- ▶ Carry out information and training on ABS issues to contribute to a stable expertise basis.
- ▶ Take seriously Rio principles such as: fostering a civil society, promoting capacity building, endorsing good governance.

Please refer to the Secretariats website for the presentation (www.cbd.int).

28. BOOK LAUNCH: THE FUTURE CONTROL OF FOOD: A GUIDE TO INTERNATIONAL NEGOTIATIONS AND RULES ON INTELLECTUAL PROPERTY, BIODIVERSITY AND FOOD SECURITY

Quaker International Affairs Programme

This event celebrated the launching of the book “The Future Control of Food: A Guide to International Negotiations and Rules on Intellectual Property, Biodiversity and Food Security” produced by the Quaker International Affairs Programme (QIAP) and the International Development Research Centre (IDRC). The decision to produce this book was a response to concerns negotiators in various multilateral negotiations raised about the need for such a guide as well as an observation that negotiators or groups working in one area were often unaware, and sometimes undermining, what was happening elsewhere that we encountered in the Quaker programme of work in this area. Some copies of the book were available at the

meeting. The book is the first wide-ranging guide to the key issues of intellectual property and ownership, genetics, biodiversity, and food security. Proceeding from an introduction and overview of the issues, comprehensive chapters cover negotiations and instruments in the World Trade Organization, Convention on Biological Diversity, UN Food and Agriculture Organization, World Intellectual Property Organization, the International Union for the Protection of New Varieties of Plants and various other international bodies. The final part discusses the responses of civil society groups to the changing global rules, how these changes affect the direction of research and development, the nature of global negotiation processes and various alternative futures. This event provided an opportunity to hear from the book co-editors and several contributors.

29. REAL WORLD EXPERIENCES IN ABS: BUILDING SUCCESSFUL SYSTEMS BY LEARNING FROM THE PAST

American Bioindustry Alliance (ABIA), Biotechnology Industry Organisation (BIO), and Crop Life International (CLI)

The industry side event, entitled, “Real World Experiences in ABS: Building Successful Systems by Learning from the Past,” provided presentations from technology transfer practitioners and long-time experts in ABS in health care and agriculture, with additional perspectives from two mega diverse states: an Indian Ayurvedic health care company and a Brazilian ABS legal expert. The event, which was organized by the ABIA, BIO and CropLife International (CLI), attracted a standing-room only crowd of approximately 100 CBD delegates and representatives from across the broad spectrum of ABS stakeholders, including educational institutions, NGOs, indigenous groups and industry.

The ABIA/BIO/CLI program was moderated by Mrs. Susan K. Finston, Executive Director of the ABIA. Speakers included:

- ▶ Anatole F. Krattiger, MPhil PhD, Chair, bioDevelopments-International Institute, “*Best Practices in Intellectual Property (IP) Management for ABS-related Agriculture and Healthcare Innovation in Developing Countries;*”
- ▶ Himanshu Vyas, Director, Ayurnet Healthcare Pvt. Limited, “*Importance to Development of Ayurvedic Industry of Patent Reform for Genetic Resource Inventions.*”
- ▶ Bernard Le Buanec, PhD Senior Advisor, International Seed Federation (ISF), “*Practical ABS Issues for Plant Breeding: Possible Solutions;*”
- ▶ Gustavo de Freitas Morais, Partner, Dannemann Siemsen “*Operation of Brazil’s ABS Regime: Problems and Prospects under Proposed Reforms*”

PRESENTATIONS

Anatole Krattiger, a long-time CBD expert with direct experience in both technology transfer and ABS in developing countries, provided an overview on why mechanisms to protect intellectual property (IP) are important for innovation and innovators in both the public and private sectors alike. Drawing on his experiences around the world, Anatole reviewed the key determinants that encouraged product innovation (viz. research, regulations, production, access to markets, trade and IP) with emphasis on how the important (though imperfect) intellectual property component relates to ABS. He also introduced the *Executive Guide to IP Management in Health and Agricultural Innovation: A Handbook of Best Practices*, which provides practical guidance for policy makers, heads of R&D institutions, scientists and licensing executives on how to use IP effectively to promote innovation in agriculture and health. (The IP Handbook, whose distribution at the side-event was underwritten by the ABIA, is available free of charge to developing countries; more information is available at www.ipHandbook.org.) Anatole stressed the importance of capacity building to support effective ABS systems and to counter any imbalance in information. He warned against the construction of complex and burdensome bureaucratic systems that would lead to the stagnation of innovation and product development in both developing and developed countries urging participants instead to develop incentives for deals to take place and flexibility creative deals to be forged.

Himanshu Vyas explained that his company, Ayurnet Healthcare Pvt., Ltd. (<http://ayurnethealthcare.com/index.html>), based in Gujarat, India, manufactures and markets traditional health care products derived from agricultural products and based on research conducted at the Foundation for Revitalization of Local Health Traditions (FRLHT) <http://www.frlht.org/>. Himanshu provided an explanation of India's alternative health care systems in wide use throughout the country. He underscored the long history of Ayurvedic health care principles, which date back more than 2500 years. Ayurveda is based on sound and universal scientific principals that are now being re-validated in the modern era. Due to low levels of private investment and the generally small size of the enterprises, however, at this stage India has only captured 1.6% of the global market for alternative therapies. Based on his own experience in establishing Ayurnet, Himanshu stressed the importance of full patent protection for genetic resource (GR)/Traditional Knowledge (TK) inventions to drive investment into the field and help Indian SMEs to grow and gain a greater share of the world market.

Bernard Le Buanec stressed the inter-dependence of the developing and developed world in the context of plant development and seed varieties. Using a number of complex family trees for staple crops in developing countries, including rice and wheat, Bernard demonstrated how products thought to be indigenous to one country or region are actually the result of long-term cross-breeding which brings genetic inputs from the North American and European states to South America, Asia, Africa and the Middle East. Buanec explained why the plant breeding industry believes that it is important for sectoral differences to be taken into account and for CBD Parties to avoid a "one-size fits all" approach in the elaboration of the

international regime on ABS. In addition, Bernard pointed to the importance of a multilateral, and not a bilateral, approach, similar to that taken by the International Treaty on Plant Genetic Resources (ITPGR), with its reliance on Material Transfer Agreements (MTAs), which have shown to be effective in wide use in the real world.

Gustavo de Freitas Morais, an ABS legal expert based Sao Paulo, Brazil, outlined the general approach to ABS taken by mega-diverse Brazil, with its emphasis on enforcement and prevention of biopiracy. Gustavo described the legal bases in Brazil for ABS: the 1988 Federal Constitution; Provisional Measure N° 2186-16 — June 2000 regulating access to GRs, associated TK; and Brazilian PTO Resolution N° 134 of December 2006. The latter, which implements Brazil's patent disclosure requirement, makes patent protection conditional on disclosure of source. Gustavo provided his perspectives as a practitioner with “on the ground” direct experience in navigating the difficult and complex ABS regime currently in place in Brazil. Gustavo noted that it is very difficult in the present system to satisfy bureaucratic requirements and therefore little bioprospecting activities take place in Brazil at this time. He also reviewed the proposed changes to the Brazilian regime which, if adopted, would maintain the discrimination against foreign organizations or companies and make it more difficult to foster international collaboration and sustainable commercialization of Brazil's biodiverse patrimony. Gustavo concluded that the proposed regulations would continue patent disclosure obligations and sweeps a broader array of resources, including all derivatives and products, into the regime. Proposed exemptions to permit requirements, apparently aimed at reducing barriers to bio-prospecting, will make it even more difficult to meet Brazil's continuing patent disclosure obligations.

CONCLUSIONS

In keeping with the exhortations of the ABS Co-Chairs and drawing from the presentations in the side-event, moderator Susan Finston, ABIA Executive Director, underscored the need that deliberations in the ABS negotiations focus on the core objective: “Enabling fair and equitable sharing of benefits from scientific research, sustainable development and commercialization of GR acquired in accordance with the CBD consistent with the sovereign rights of states.”

Based on the priorities outlined by each of the speakers, an international ABS regime could include the following key components:

- ▶ Non-discriminatory national regimes that provide measures regulating Access, Benefit Sharing, and User measures; and,
- ▶ International Mechanisms/External Resources (Capacity Building, Best Practices, Model Provisions, and a Global Fund).

The speakers also identified the following tools that would be useful in establishing enabling regimes for ABS:

- ▶ Material Transfer Agreements (MTAs),
- ▶ Traditional Knowledge Digital Libraries (TKDLs),
- ▶ Trademarks,
- ▶ Research Exchange,
- ▶ Capacity Building, especially in dealmaking
- ▶ Other effective front-loaded monetary and non-monetary benefits;

In combination with:

- ▶ Balanced enforcement/User measures.

In sum, the well-attended industry event on 21 January provided insights into best practices to promote bio-pharmaceutical and agricultural innovation in developing countries; experiences on the ground from Brazilian and Indian perspectives, and doing business issues relating to plant breeding, along with practical assistance in the form of copies of the MIHR/PIPRA IP Executive Guide for developing country delegates.

Tuesday, 22 January 2008

30. MAINSTREAMING GENDER IN THE CONVENTION ON BIOLOGICAL DIVERSITY

IUCN and Secretariat of the Convention on Biological Diversity

The side event for the presentation of the Gender Plan of Action of the CBD, held on Tuesday, January 22nd, 2008, was co-chaired by the Executive Secretary of the Convention, Ahmed Djoghlaif; the Gender Focal Point of the CBD, Marie Aminata Khan, and the Senior Gender Adviser of IUCN, Lorena Aguilar. The Plan of Action was elaborated with the collaboration of the SCBD staff, women from local communities and indigenous groups and gender experts, based on the web of institutionalization of Karen Levy. The actions proposed for the four institutional spheres (delivery, constituency, policy and organizational) were discussed with 40 people that attended the side event. Participants which included representatives of indigenous and local communities, potential donors, and Parties, welcomed the initiative and looked forward to receiving the finalized plan which will be submitted to COP as an information document Convention.

The plan consists of four objectives:

- ▶ To mainstream gender perspective in the implementation of the Convention and the associated work of the CBD Secretariat;

- ▶ To promote gender equality in achieving the three objectives of the CBD and the 2010 Biodiversity Target;
- ▶ To demonstrate the benefits of gender mainstreaming in biodiversity conservation, sustainable use and benefit sharing from the use of genetic resources; and
- ▶ To increase the effectiveness of the work of the CBD Secretariat.

The Plan outlines a framework for integrating a gender perspective within all CBD Secretariat Divisions and Units during the period 2008–2012. It establishes strategies with reachable targets and proposes instruments to address gender concerns in the CBD programmes of work and cross cutting issues and thematic areas.

31. SECO/IISD LAUNCH OF THE ABS-MANAGEMENT TOOL: BEST PRACTICE STANDARD AND HANDBOOK FOR IMPLEMENTING GENETIC RESOURCE ACCESS AND BENEFIT-SHARING ACTIVITIES

Swiss State Secretariat for Economic Affairs (SECO) International Institute for Sustainable Development (IISD)

The event highlighted use and further implementation of the ABS-Management Tool (ABS-MT), a best practice standard and a handbook that provides guidance and tools on ABS practice to help companies, researchers, local and indigenous communities, and governments ensure compliance with the Bonn Guidelines and ABS requirements under the Convention on Biological Diversity. It provides users and providers of genetic resources with a structured process for participating in, and making decisions about, ABS negotiations and the implementation of ABS agreements for access to and agreed use of genetic resources.

32. PRIORITIES IN DISCUSSIONS ON A CERTIFICATE—PRACTICALITY, FEASIBILITY, AND DECISION MAKING PROCESSES

Japan Bioindustry Association

What do we gain with a certificate? What do we lose with it? Who are the beneficiaries? What kinds of costs do we have to bear? The presentation tried to answer these questions by using economic tools. It specified issues to which priorities should be given for certificate discussions and proposed desirable decision making processes. In the discussion, practicality and feasibility were highlighted. Regarding feasibility, the roles of costs and benefits were explained. Processes that would be inevitable to maximize the benefits for the stakeholders were presented.

Wednesday, 23 January 2008

33. NEGOTIATING BIODIVERSITY, TRADE AND IP: IMPLICATIONS OF FREE TRADE AGREEMENTS

International Centre for Trade and Sustainable Development

A side event on “Negotiating biodiversity, trade and intellectual property: Implications of regional and bilateral trade agreements” was organized by the International Centre on Trade and Sustainable Development (ICTSD) in the context of the sixth meeting of the CBD Working Group on Access and Benefit Sharing, which took place from 21 to 25 January 2008, in Geneva. The event aimed to provide a platform for discussion of provisions relating to biodiversity, trade and intellectual property in recent bilateral and regional free trade agreements, as well as for the consideration of their implications for relevant multilateral discussions and negotiations in the context of the Convention on Biological Diversity (CBD), the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement) of the World Trade Organization (WTO), and the World Intellectual Property Organization (WIPO).

A growing number of bilateral and regional trade agreements incorporate intellectual property (IP) provisions, which tend to go beyond, either in scope or level of protection, of the standards established at the multilateral level. Provisions on patents and plant variety protection, among others, are thus likely to have a direct impact on the development and implementation of an international regime on access and benefit-sharing at the CBD, including on issues such as preventing misappropriation of genetic resources and traditional knowledge associated with such resources, ensuring compliance with prior informed consent and equitable benefit sharing.

After introductory comments by *Ahmed Abdel Latif*, Programme Manager, Intellectual Property, ICTSD, panelists expounded on the various developments on IP and biodiversity in the context of bilateral and regional trade agreements, and stressed the relevance of these processes for multilateral negotiations.

Mónica Rosell, of the Consejo Nacional de Medio Ambiente in Peru, gave an overview of the work to date by the Peruvian government to prevent the misappropriation of local biodiversity. She examined how IP and biodiversity issues have arisen in the several bilateral and regional trade negotiations that Peru has been engaged in, including in the recently concluded agreement with Canada. Rosell noted the risks for biodiversity protection posed by some of the IP provisions proposed by developed countries, but also highlighted the possibility of achieving some positive results in these negotiations by developing countries, including a recognition of the need to effectively protect traditional knowledge against misappropriation and to work towards an international solution to this issue.

Dalindyabo Shabalala, of the Center for International Environmental Law (CIEL) in Geneva, focused IP and biodiversity in Economic Partnership Agreements (EPAs), emphasizing the

importance for developing countries to formulate a “positive agenda” on traditional knowledge and genetic resources in these negotiations. Nevertheless, Shabalala recognized the difficulties in designing and advancing such an agenda. There will be little benefit in negotiations for developing countries, he noted, unless national or regional systems of protection are already in place. A positive outcome for negotiations would require an EU recognition and enforcement of these national or regional systems, as well as a commitment to avoid the patenting of the traditional knowledge of other countries.

Guilherme Patriota, of the Mission of Brazil to the WTO, looked at the implications of these national and regional developments for the disclosure of origin discussions at the WTO. Patriota highlighted the importance of an amendment to the TRIPS Agreement to introduce a mandatory disclosure of origin requirement to prevent the misappropriation of biological resources and related traditional knowledge. He emphasized that this amendment was now backed by some 60 WTO members. Nevertheless, the increasing number of bilateral and regional trade agreements may be setting negative precedents for IP and biodiversity negotiations in Geneva, as well as fragmenting the legal solutions to the problem of misappropriation. In this regard, Patriota noted that introducing a disclosure requirement in the TRIPS Agreement was becoming “a race against time.”

Jorge Cabrera Medaglia, of the Instituto Nacional de Biodiversidad in Costa Rica, considered the impact of addressing biodiversity in bilateral and regional trade negotiations for the development of an international regime on access and benefit-sharing (ABS) in the CBD. Cabrera Medaglia briefly analyzed the potential positive and negative impacts of a range of trade provisions on the various components that may form part of an international regime, looking not only at intellectual property but also at services, investment, technical barriers to trade, and capacity building rules.

The event was chaired by *María Julia Oliva*, Senior Programme Officer for Environment at ICTSD. Nearly 70 participants attended the side event, including negotiators from developed and developing countries, senior officials from international organizations — such as the CBD, WTO, WIPO, and the International Union for the Protection of Plant Varieties, and civil society representatives. Participants underlined that the issue of bilateral trade agreements and biodiversity had never been raised in the CBD context, and that the presentations made clear that such consideration was important. Indeed, many issues raised in the presentations and discussions merit further consideration and analysis.

The side event was featured in an article published by Intellectual Property Watch (“Pan-Elites See High Impact of Bilateral Trade Deals on Geneva Policymaking,” 30 January 2008, www.ip-watch.org) and Cabrera Medaglia expanded on his presentation in an article for the ICTSD BioRes Review (“Biodiversity and FTAs: Implications for access and benefit-sharing negotiations,” Year 2, Number 1, March 2008). A paper on “Traditional Knowledge and Genetic Resources in Economic Partnership Agreements: Elements of a Positive Agenda for

ECOWAS Countries” had also been written by Shabalala for ICTSD in May 2007 (available at www.iprsonline.org/ictsd/Dialogues/2007-05-30)

34. IMPLICATIONS FOR PHARMACEUTICAL R&D IN COLLABORATION WITH PARTNERS IN DEVELOPING COUNTRIES

International Federation of Pharmaceutical Manufacturers Association (IFPMA)

There is no information available for this side-event.

Thursday, 24 January

35. DISCLOSURE OF ORIGIN AT THE CBD, WIPO AND THE WTO: CONFLICT, COHERENCE OR COMPLEMENTARITY?

The Center for International Environmental Law and the South Centre

PANEL DISCUSSION:

The issue of misappropriation and biopiracy has received significant attention in recent years and efforts are currently underway at various international forums to find possible solutions. The current patent system, as governed by international common binding norms has been seen as the primary enabling mechanism for biopiracy, a viewpoint that has triggered an intense global debate. Biodiversity rich countries (many in the Global South), as well as indigenous and other local communities have long faced constant socio-economic pressure due to an intellectual property system that allows exclusive private appropriation of genetic resources without fair and equitable sharing of the benefits accruing from such use. Many argue that disclosure of origin of genetic resources and traditional knowledge will allow countries to formulate a basis for determining issues of benefit sharing and access to genetic resources. Discussions pertaining to the disclosure of origin on genetic resources have involved the CBD, WIPO and the WTO and various proposals have been put forth to seek measures concerning the same. However, it has also presented us with new challenges in building coherence and compatibility among measures sought through such proposals.

The panel discussed the different approaches to the disclosure of origin issue at the WTO, WIPO and the CBD and examined areas of overlap, potential areas of conflict and the future of disclosure of origin provisions in the three fora.

The final agenda of the meeting is available here (link to agenda):

- ▶ A webcast of the event is available at: <http://southcentre.blip.tv>

Media reports of the event are available at:

- ▶ http://www.southcentre.org/southface/South_Face_IAKP-CBD-Jan-2008.pdf
- ▶ <http://www.ip-watch.org/weblog/index.php?p=898>

The meeting was chaired by **Dr. Xuan Li**, Coordinator, Innovation and Access to Knowledge Programme, South Centre, who gave the introduction.

The first speaker was **Mr. Dalindyabo Shabalala**, Staff Attorney and Director, IP and Sustainable Development Project, Center for International Environmental Law (CIEL), who discussed *WIPO and the CBD Relationship on Disclosure*.

Mr. Shabalala's presentation was followed by **Dr. Pierluigi Bozzi**, from the Faculty of Economics, University of Rome 'La Sapienza', Italy, who presented on *The Rationale of the CBD: The Coherence of the Genetic Resource Certificate of Origin*.

Mr. Yusong CHEN, from the Permanent Mission of China to the WTO, Geneva, then presented on *Disclosure of Origin at WTO — Article 29bis and China's perspective*.

The final presentation was by **Ms. Le'a Kanehe**, Legal Analyst, Indigenous Peoples Council on Biocolonialism, USA, providing an *Indigenous perspective on Disclosure — A Critique of the Approaches*.

Please refer to the Secretariats website for the aforementioned presentations (www.cbd.int).

Questions following the presentation focused on the perspective of indigenous groups, and on the limitations that some of the Disclosure of origin approaches have. Some participants expressed some difficulty with concepts of indigenous group demands for autonomy and ownership of traditional knowledge and in situ genetic resources. The issue of how to accommodate demands for full and informed prior informed concept and sovereignty within the framework of the CBD was raised, with some comments noting that these demands are rooted in human rights law.

Comments from one participant emphasized that the Article 29bis proposal at the WTO was limited and narrow and was not meant to address all instances of misappropriation. Several pointed to the work being done at WIPO, as a possible arena to address broader issues of misappropriation of genetic resources and traditional knowledge. However, others pointed to the CBD as an arena where such issues should also be addressed in a manner more likely to meet the needs of developing countries and indigenous communities.

The meeting closed, with final comments from the chair, Ms. Xuan Li from the South Centre.

36. BIODIVERSITY AND THE PATENT SYSTEM: INDICATORS AND INCENTIVE MEASURES

ESRC Centre for Economic and Social Aspects of Genomics

The patent system features prominently in debates on an international regime for ABS. However, trends in the patenting of biodiversity and traditional knowledge remain obscure. This side event presented the results of a review of international patent indicators for biodiversity and traditional knowledge. The analysis suggests that proposals for disclosure of origin and certificates of origin could be operationalized through the use of existing patent indicators. In view of the wide diversity of actors, technologies and markets involved in patent activity, indicators could be used to develop targeted Adjustable Incentive Measures (AIMs) to encourage desired forms of behaviour under an international regime. The side-event thus provided a forum for discussion of the role of indicators in the development and implementation of an international regime for ABS.

37. INFORMAL MEETING ON CAPACITY DEVELOPMENT FOR ACCESS AND BENEFIT-SHARING

The Co-chairs of the Ad Hoc Working Group on Access and Benefit-sharing, Mr. Fernando Casas of Colombia and Timothy Hodges of Canada, convened and chaired an informal meeting on capacity development for access and benefit-sharing, on 24 January 2008, on the margins of the sixth meeting of the Working Group.

The purpose of the meeting was to provide an opportunity for Parties and stakeholders to share their views and experiences related to capacity-building for ABS. After a short introduction by the Co-Chairs, and the Executive Secretary of the SCBD, Mr. Ahmed Djoghlaif, a panel composed of representatives from the Global Environment Facility (GEF), the United Nations Environment Programme (UNEP) and the Dutch-German ABS Capacity Development Initiative for Africa were invited to present capacity development activities related to access and benefit-sharing. The presentations were followed by a question and answer period. Approximately 45 participants attended the event.

Panelists:

- ▶ Ms Paz Valiente, Program Manager, Biodiversity, GEF, on GEF activities in support of capacity development for access and benefit sharing,
- ▶ Ms. Elizabeth Mrema, Senior Legal Officer, Division of Environmental Law and Conventions (DELIC), UNEP, on capacity development needs for access and benefit sharing from a UNEP perspective, and
- ▶ Dr. Andreas Drews, GTZ, on access and benefit-sharing — an emerging issue related to biodiversity conservation, poverty alleviation, and good governance.

Ms. Paz Valiente presented past, current and future GEF activities in support of capacity development for access and benefit-sharing. Under the GEF-3 biodiversity strategy, capacity development for access and benefit-sharing was covered by enabling activities as well as some biodiversity projects. Due to a lack of endorsement from proposed participating countries and the absence of additional financial resources, proposed stand-alone ABS projects from UNEP and UNDP were not funded. With respect to GEF-4, Ms. Valiente underlined GEF's new approach involving Focal Area Strategies and Strategic Programming Framework. She also referred to investments under the resources allocation framework (RAF) and national allocations for biodiversity projects. She stressed that countries are responsible for prioritizing investments, projects and programs through national dialogues and other processes. However, she pointed out that despite the fact that ABS is one of the clear strategic objectives in the GEF-4 biodiversity strategy, ABS projects have not emerged as immediate priorities. Ms. Valiente suggested that, as the development of an international regime on ABS is still under negotiation, countries may be waiting for a second phase of RAF to address access and benefit-sharing and choose to use their biodiversity allocation for other activities.

Ms. Elizabeth Mrema identified capacity development and awareness raising at different levels as a prerequisite for a future effective and useful international regime on ABS. Moreover, Ms. Mrema gave a short overview of UNEP's past ABS capacity development activities. These included case studies on ABS in six African countries to be launched at COP-9, as well as a study published in collaboration with WIPO in 2005 addressing the role of intellectual property rights in ABS. UNEP also supported the development and harmonization of national ABS legislation and conducted national training on ABS in different African countries. Presently, UNEP is developing under its programme on Compliance and Enforcement of MEAs an issue based module on ABS to help Parties to better implement their obligations under CBD. UNEP is also organizing and facilitating national and regional meetings and courses for MEA negotiators, which cover ABS. For the ACP countries, a 4-year programme (2008-2012) on capacity building for the implementation of MEAs has started. However, ACP countries will need to identify ABS as a priority in order for the programme to focus on this issue. Finally Ms. Mrema concluded that future activities need to be more innovative to build ownership and long term sustainability. She called for a review and reconsideration of the current piecemeal approach and stressed the fact that any capacity-building initiatives need to be coupled with appropriate follow up and assessment of their effectiveness.

Mr. Andreas Drews presented the Dutch-German ABS Capacity Development Initiative for Africa. He described how the initiative had taken off and provided details regarding its objectives and expected results. He highlighted, among others, that ABS is a tool for poverty alleviation and the importance of having a substantive contribution of the African Group in the negotiation process of the international regime on ABS. Mr. Drews explained the seven components of the Initiative, i.e. multi-stakeholder workshops, issue or stakeholder-focused trainings, peer-to-peer knowledge exchange, ABS practices with the private sector, knowledge management and information exchange, regional background studies and African inputs

on ABS to relevant meetings. He pointed out that these instruments tackle needs at different levels, from the local to the international levels. Mr. Drews also gave an overview of concrete projects for 2008, such as an African delegations briefing prior to COP-9, integration of ABS into university curricula, negotiation skills training and a regional workshop for West Africa and Maghreb. Finally, Mr. Drews pointed out that the Initiative hopes to secure funding until 2011 (after COP-10) and wants to provide more support towards national implementation and foster collaboration with others towards ABS capacity development.

During the **discussion** following the presentations, participants highlighted the need for a specific action plan on capacity building for indigenous and local communities and the need for capacity-building to focus in particular on substantive training in order to assist Parties and stakeholders with the implementation of ABS. A number of participants recommended greater focus on ABS capacity building by multilateral institutions (including for example GEF and UNEP) as well as by officials and stakeholders at the national and sub-national levels.

One main **conclusion** drawn from this event is that there is still a great need for capacity building on ABS in the developing world, including for indigenous and local communities. It was also highlighted that a comprehensive approach is required, which includes identification of concrete needs in the beginning and a follow-up and assessment of the results of the capacity building activities. Only then can lessons learned continuously feed into new activities and new areas of focus be identified and/or adjusted. However, in some countries ABS is obviously not a priority yet. Thus, there is a particular need for awareness-raising among government officials to get ABS on the political agenda. Finally, the Dutch-German Initiative on ABS demonstrated their rich experience and know-how. Their offer to foster collaboration with other supporters of ABS capacity development should encourage new initiatives for other regions of the world.

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