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Biodiplomacy – Bringing "Life" to International Negotiations

By Brendan Tobin

Does your breakfast cereal contain genetically modified organisms? Is the new wonder drug for weight loss based on knowledge pirated from indigenous peoples? Is stem cell research the precursor to human reproductive cloning?

Concerns such as these have incited public protest against globalization and the World Trade Organization (WTO), led to uprooting of plantations of genetically modified organisms, and inspired mass protests against biopiracy. Non-governmental organizations (NGOs), meanwhile, have brought to light cases such as the dubious patenting of human bloodlines, or the unapproved and uncompensated use of genetic resources and traditional knowledge.

As the potentials (both positive and negative) of biotechnology and the irreplaceable value of biodiversity have become more apparent over the past three decades, there has been growing acknowledgement of the need to fully incorporate the life sciences into national and international regulation. Among the major challenges for regulators, however, are how to develop law and policy that effectively respond to the rapid advances in biotechnology yet do not stifle innovation, and how to prevent potentially irreversible impacts to the environment and existing biological, genetic, and cultural integrity. Negotiators must confront not only technical and economic concerns, but also sensitive ethical, social, and cultural issues.

The result has been the development of an expansive area now known as "biodiplomacy".

A Bolivian elder shares traditional knowledge with community members. (Photo: Rhodri Jones/Panos Pictures)

In this issue

The biodiplomacy challenge

Biodiplomacy[1] encompasses a complex set of negotiation processes that seek to regulate scientific innovation, biotechnology, and trade in natural products, while also recognizing the non-commercial values of biodiversity and the potential for innovative responses to global food and health needs based on traditional knowledge systems.

Holistic development strategies are often perceived to be at odds with the commercial and industrial globalization principles and norms as regulated by international bodies such as the WTO, World Intellectual Property Organization (WIPO), and World Bank. Intellectual property rights (IPR), in particular, have become the focus of challenges to the international trading system, and the flash point of conflict between disparate world views. On one side is a dominant development theory based on maximum exploitation of resources and minimal mitigation; on the other is support for development strategies inspired by concepts of responsibility and reciprocity between humankind and the environment.

The dynamic created by the tension between these two philosophical standpoints creates the opportunity for emergence of new development paradigms that put "life" at the centre of policy-making. Biodiplomacy provides the framework for the evolution of these new paradigms, drawing upon the wisdom of centuries and the technology of the moment to design responses to global environmental, social, economic, and cultural challenges.

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Current negotiations in the realm of biodiplomacy are testing the capacity of international governance mechanisms to develop global principles on issues, such as equity and ethics, whose subjective natures resist the definition of absolutes and frequently preclude the formation of consensus. The consequent need for flexibility and respect for diversity of national and cultural realities is proving a difficult challenge for the international community.

Ongoing negotiations include, for example, work under the Convention on Biological Diversity (CBD) to develop an international regime on access to genetic resources and benefit-sharing (ABS), and to develop mechanisms for protecting the rights of local and indigenous peoples over their traditional knowledge. Protection of rights over traditional knowledge is also being addressed within WIPO, while the Food and Agriculture Organization of the United Nations (FAO) is working to promote implementation of an international treaty that establishes a multilateral ABS system for important crops.

Another important focus of biodiplomacy negotiations relates to work within the United Nations to develop measures on bioethics. This includes the negotiation and adoption of a Declaration on Human Cloning by the UN General Assembly, and ongoing work within UNESCO to draft a Universal Declaration on Bioethics. Other hot topics include work to ensure effective implementation of the Cartagena Protocol to the CBD, promoting adherence to the Kyoto Protocol, and continuing work to promote effective implementation of international law on bioweapons.

UNU-IAS research and development on biodiplomacy

This edition of *Work in Progress* spotlights a number of major issues confronting biodiplomacy, with a focus on the work of the UNU Institute of Advanced Studies (UNU-IAS) "Biodiplomacy Initiative", a programme established to aid relevant international processes through policy research, outreach activities, and capacity development.

The following articles discuss key biodiplomacy topics and related UNU-IAS activities under four thematic areas: access to genetic resources and benefit-sharing; traditional knowledge, IPR, and the public domain; bioethics; and capacity development.

In recent years, ABS has taken centre stage in the field of international environmental legislation. Five articles look at key aspects of the ABS issue, providing:

- an overview of efforts to achieve effective international ABS governance (page 6),
- an examination of the role that "certificates of origin" could play in facilitating the exchange of genetic resources (for both commercial and not-for-profit uses) while protecting the rights of countries of origin and indigenous and local communities (page 9),
- an introduction to research on national measures for implementation of prior informed consent procedures (page 12),
- a look at bioprospecting activities in Antarctica, and the patenting of products and processes developed using polar resources (page 14), and
- a consideration of why, although the CBD and all recent major multilateral environmental agreements recognize the importance of technology transfer for sustainable development, developing countries generally do not consider that pertinent commitments have been met (page 17).

Development of international law on access and benefit-sharing is closely linked to debates ongoing within the CBD and other forums regarding the nature of protection for traditional knowledge, the influence of IPR on the realization of fair and equitable benefit-sharing, and the nature of the public domain. The three articles in this grouping look at:

- the potential and limitations of customary law, intellectual property rights, and databases to protect the interests of indigenous peoples (page 19),
- the tensions between the public domain and traditional knowledge-sharing spaces (page 22), and
- national-level legal and institutional design and issues of intellectual property protection, drug R&D, and access to medicines (focusing on the work of UNU Institute for New Technologies, page 23).

Two articles address the controversial issue of bioethics from distinct perspectives, focusing on:

- the ethical basis for a ban on human cloning, and the reasons for the failure of recent UN negotiations on a treaty to regulate cloning research (page 25), and

- the potential to enhance public health services through more effective incorporation of traditional knowledge and medicine into public health policy (page 27).

Wrapping up this edition of *Work in Progress* are two articles on capacity development:

- the role of capacity development in helping developing countries to formulate and implement relevant ABS law and policy, and the lessons to be learnt from global programmes for capacity development on biosafety (page 30), and
- efforts in Central Asia countries and Mongolia to establish a regional Bioresources and Biosecurity Network and ABS capacity development programme that responds to local priorities (page 33).

Biodiplomacy has changed the way we look at the world. It provides an avenue for promoting respect for diversity and expressing our humanity in a manner that reflects the higher nature to which we can aspire, rather than the power we wield. As such, biodiplomacy brings "life" into the centre of the international agenda. It is to be hoped that as recognition of the relationship between the biosciences and human and environmental welfare grows, recognition of the role of biodiplomacy at the heart of good governance also increases.

We are grateful for this opportunity to bring the UNU-IAS Biodiplomacy Initiative to your attention, and we look forward to hearing your comments and suggestions. Most of all, we look forward to building an ever-increasing network of organizations, both within and beyond the UN family, with whom we collaborate to promote sound and informed decision-making in this crucial area of international affairs.

1 The term "biodiplomacy" was coined by Professor Calestous Juma and Ambassador Vicente Sanchez in a book they edited, *Biodiplomacy: Genetic Resources and International Relations,* in 1994.

The Biodiplomacy Initiative: Informing Equitable and Ethical Decision-Making for Present and Future Generations

By A.H. Zakri, Sam Johnston, and Brendan Tobin

The biotechnology debate

One of the hottest and most controversial issues currently facing the international community is how to respond to the opportunities, challenges, and fears regarding the so-called "Bio Revolution". On one end of the debate are those who claim that biotechnology will benefit humanity by unlocking the scientific, health, food, and commercial potential contained within biological diversity – more specifically, within genetic resources. On the other end are a range of social, scientific, and community actors who decry the dangers inherent in manipulation of genetic diversity and the release of genetically modified organisms into the environment. Opponents also dispute the claim that humankind as a whole will benefit from biotechnology, highlighting the use of intellectual property rights, technologies restricting seed fertility, and cost as means to maintain market domination and inhibit access to biotechnologies by developing countries and the poor. At the same time, there is concern about the ability of international law to effectively regulate access and benefit-sharing (ABS) relating to genetic resources and traditional knowledge.

Biodiplomacy may be seen as the international negotiation process leading to the development of new legal and policy frameworks to respond to these challenges – guided by principles of equity and the need to ensure global sustainable development. These frameworks are necessary to regulate scientific and commercial exploitation of genetic diversity in accordance with emerging precepts on ethics, rights, obligations, and responsibilities, which are potential harbingers of a new social contract between the commercial and scientific communities, industrialized countries and developing countries, and scientific, industrial, and local community stakeholders.

The focus of the United Nations University Institute of Advanced Studies (UNU-IAS) Biodiplomacy Initiative is on topics that link the key themes of developments in bioscience, biosecurity (environmental, economic, and social security), and bioethics – issues that have many implications for academic freedom, value systems, national sovereignty, and international security. First presented at the 6th Conference of the Parties of the Convention on Biological Diversity (CBD) in 2002, the Biodiplomacy Initiative has received endorsement by, among others, the UN Secretary-General, United Nations Environment Programme (UNEP), Food and Agricultural Organization of the United Nations (FAO), and CBD.

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The UNU-IAS Biodiplomacy Initiative manages a comprehensive and diverse portfolio of activities on capacity development, research, publication, and awareness-building. The Initiative has maximized its research and outreach capability through collaborations with a range of national authorities, international organizations, research institutions, industry associations, and non-governmental and

indigenous peoples organizations, and undertaken a global programme of roundtables, workshops, and capacity development activities targeting these and other stakeholder groups.

The Initiative is fast establishing a reputation for the preparation of timely policy papers on issues as diverse as intellectual property, databases and protection of traditional knowledge, documentation of genetic resource flows and ABS governance, and options for international regulation of human cloning. These papers have been fed into international negotiation processes at the World Intellectual Property Organization (WIPO), CBD, and UN, thereby increasing awareness of the important role that UNU-IAS can play in supporting and informing negotiations on biodiversity-related issues.

During the past couple of years, the UNU-IAS Biodiplomacy Initiative has been focused primarily on the international negotiation process relating to access to genetic resources and benefit-sharing, and the associated issue of protection of traditional knowledge. This has led to the preparation of a number of policy documents that have had a significant impact on the international debate, including a report on "user measures"[1] that played an influential role in the development of terms of reference for international negotiation of an ABS regime, and a report on bioprospecting in Antarctica[2] (an area outside the scope of the CBD) that rapidly became the most widely cited UNU report by international media in recent years. Recent publications on ABS include a follow-up report on bioprospecting in Antarctica, and a study on bioprospecting in the high seas (see report on facing page)[3]. The next ABS report will focus on certificates of origin.

Crucial to the Biodiplomacy Initiative's success has been its 'BioTeam', made up of UNU-IAS staff members as well as postdoctoral, Ph.D., and junior research fellows. Building upon the strengths of the BioTeam on ABS-related issues, UNU-IAS has worked to facilitate international debate on development of an international regime on ABS. Publication of a number of useful policy briefs has been accompanied by progressive outreach programmes (including a series of international workshops and annual Paris Roundtables on ABS governance) as well as a comprehensive capacity development programme that stretches from Latin America through the South Pacific to Central Asia and Mongolia.

Partners in sustainable development

Collaborations with researchers from prestigious research institutions around the world, as well as with international organizations such as the Secretariat of the CBD, WIPO, UNEP, and United Nations Development Programme (UNDP) have further facilitated the development of the Biodiplomacy Initiative. Most recently, this has included collaboration with the Smithsonian Institution, Royal Botanic Gardens, Kew, and the National Biodiversity Institute of Costa Rica (INBio) in the preparation of a study on certificates of origin and their potential role in tracing genetic resource flows. Preliminary results of this study were presented as an information document at the third meeting of the Working Group on ABS, held in Bangkok in February 2005. Collaboration with the Institut du Développement Durable et des Relations Internationales (IDDRI) and the Centre for Philosophy of Law (CPDR) at the Catholic University of Louvain has led to development of a research and outreach programme on ABS governance, intended to complement and assist the ongoing international debate on ABS issues through the provision of policy papers and an informal space for discussion. UNU-IAS is also working as part of the MOSAICS[4] project funded by the European community to identify standard documentation procedures for microbial collections.

Local communities and traditional knowledge

Closely linked to the ABS issue is the question of protecting traditional knowledge. A Biodiplomacy Initiative report on the issue of traditional knowledge registers and databases[5] highlights the potential and limitations of such mechanisms for effectively protecting indigenous and local community rights over their knowledge. It draws attention to the "Catch 22" position under which indigenous peoples must place their information in the public domain in order to protect it against biopiracy. Following on from this

Endorsements of the Biodiplomacy Initiative

"This multifaceted Initiative represents a timely response to the crucial need for more research on and discussion of various aspects of biotechnology." Kofi Annan, UN Secretary-General of the United Nations, 4 April 2002, New York

"[T]his Initiative involves a number of related activities that, together, are aimed at facilitating dialogue, raising public awareness, capacity development, and the production and targeted dissemination of timely policy research on key issues and dilemmas." Klaus Toepfer, Executive Director of UNEP, 20 March 2002, Nairobi

"I consider the various components of the [Biodiplomacy Initiative] ... to be important and very much needed at both the national and international level." Jose T. Esquinas-Alcazar, Secretary, Commission on Genetic Resources for Food Agriculture Interim Committee for the International Treaty on Plant and Genetic Resources, FAO, 6 May 2002, Rome

The "Biodiplomacy Initiative rightly highlights some of the most pressing issues of our time... Future international governance and cooperation on these area will increasingly challenge the diplomatic and policy making community." Hamdallah Zedan, Executive Secretary, Convention on Biological Diversity, 27 February 2002, Montreal

research work is the ongoing investigation of issues associated with intellectual property rights, traditional knowledge, and the public domain. Work is also commencing to identify the true resilience of indigenous and local community knowledge systems, and development strategies that can promote community welfare while minimizing knowledge loss or displacement.

Biosafety and technology transfer

Another area of international concern relates to biosafety. The Initiative's current work in this field includes a global programme to evaluate existing capacity development programmes on biosafety. Technology transfer is a key element of most multilateral environmental agreements (MEAs), and a crucial factor for their effective implementation. The Biodiplomacy Initiative is carrying out research into the effectiveness of the CBD in securing technology transfer, as part of a more detailed comparative study of technology transfer under MEAs in collaboration with the UNU-IAS Science and Technology Development Programme.

This report is available for download from http://www.ias.unu.edu/binaries2/DeepSeabed.pdf

Capacity development

Capacity development is a key aspect of the Initiative. One of its first activities, in 2001, was to organize a workshop in Jakarta in cooperation with ASEAN countries to train government policy makers and negotiators on issues of ABS, biodiversity and trade, and biosafety. In 2002, work continued with organization of an international workshop on capacity development for ABS in Kuala Lumpur to assist the activities of the CBD Secretariat.

The Biodiplomacy Initiative has developed a comprehensive capacity development programme involving work relating to bioresources and biosecurity from the steppes of Central Asia, the reefs of the South Pacific, and the Andes to the jungles of Peru. This work is expanding with projects in collaboration with UNEP and UNDP to support capacity development on ABS around the world, and with establishment of a network of partner organizations to assist in developing a comprehensive package of materials, methodologies, and expertise to ensure the long-term sustainability of ABS capacity development programmes.

Biodiplomacy for future generations

The Biodiplomacy Initiative's rapid development and growth during the past few years has been influenced by a number of factors, such as:

- increased public awareness of the need to find a balance between scientific advances, human and environmental health and well-being, and ethical concerns;
- strong in-house research capacity, coordinated through the Initiative's BioTeam;
- the experience and expertise of UNU-IAS visiting faculty;
- the preparation of timely policy papers on leading-edge issues;
- an active outreach programme to support research activities; and
- extensive collaboration both within and beyond the UN family, including with colleagues at UNU-IAS, UNU Centre, and other UNU Research and Training Centres and Programmes.

With biodiversity, biotechnology, biosecurity, and bioethics all high on the international agenda, biodiplomacy (which spans both trade and environmental concerns) may serve to help unite the pillars of sustainable development decision-making and serve as the basis for more long-term planning. Building on the concept of what indigenous peoples of Colombia termed a "*life plan*" – policy making that breaks with the 3–5 year planning cycles associated with the private sector and elected government, and plans 50–100 years ahead – biodiplomacy negotiators will need to approach their task with an eye on the millenary evolutionary process and multigenerational responsibilities.

The Biodiplomacy Initiative[6] aims to help bring about greater understanding of these challenges. It also provides an opportunity to revise national and international development strategies in a manner that can ensure an ever-increasing quality of life based upon respect, reciprocity, and responsibility, and endowed with an understanding of the importance and value of diversity. The Biodiplomacy Initiative seeks to expand its international role in advancing better governance towards sustainable development, particularly with regard to the relationship between humankind and the environment, through its broad perspective of this relationship and open-minded approach to policy research and facilitation of informed and participative dialogue.

1 Available online at http://www.ias.unu.edu/binaries/UNUIAS_UserMeasures_2ndEd.pdf.
2 Available online at http://www.ias.unu.edu/binaries/UNUIAS_AntarcticaReport.pdf.
3 This report was released on 9 June 2005 at the Informal Consultative Process on Oceans and the Law of the Sea at the UN Headquarters in New York. It provides a comprehensive review of the scientific, legal, and policy issues involved in deep seabed bioprospecting.
4 The Micro-Organisms Sustainable Use and Access Management Integrated Conveyance System (MOSAICS) is coordinated by the Belgian Co-ordinated Collections of Micro-Organisms consortium.
5 Available online at http://www.ias.unu.edu/binaries/UNUIAS_TKRegistersReport.pdf.
6 The broad programme of the Biodiplomacy Initiative has been made possible through support from a wide range of funding bodies, including the Asia-Europe Foundation (ASEF), The Christensen Fund, the Japan Bioindustry Association (JBA), the Rockefeller Foundation, the Swiss Agency for Development and Cooperation, UNEP, the World Conservation Union (IUCN), and the Directorate General of the European Commission through the Belgian Federal Science Policy Office. The Initiative has also received continuing support from the Japanese Government through its funding of UNU.

Towards an International Regime on Access and Benefit-Sharing for Genetic Resources and Associated Traditional Knowledge

By Brendan Tobin, Wendy Elliott, Sam Johnston, and Carmen Richerzhagen

Long recognized as a key element for successful implementation of the Convention on Biological Diversity, the issue of access to genetic resources and benefit-sharing has, in recent years, moved from a side event to the centre stage of international environmental law-making. The UNU-IAS Biodiplomacy Initiative is working to support effective international ABS governance through policy research, outreach activities, and capacity development.

Negotiating an international regime on access to genetic resources and benefit-sharing (ABS) may, for many, appear to be a relatively light-weight venture in the grand scheme of environmental governance, given the magnitude of such issues as climate change and desertification. Even within the scope of the Convention on Biological Diversity (CBD) itself, the importance of ABS may be seen to pale against the backdrop of the pressing issue of biodiversity loss. While much has been made of the value of genetic resources and the potential for benefit-sharing, some countries have tended to put the issue on the back burner in the face of more pressing demands such as poverty reduction and food security.

ABS, however, has proven to be one of the most dominant themes in the CBD; almost half of all the decisions of the Conference of the Parties (COP) address the issue of ABS. The most of ambitious of these – the Bonn Guidelines – sets out a range of complementary (but voluntary) ABS measures that both "provider countries" and "user countries" should consider adopting in order to promote realization of the CBD's ABS objectives. These guidelines represent one of the major achievements of the convention process. At the same time, regional initiatives within the Andean Community, the African Union, and Association of South-East Asian Nations (ASEAN), and national efforts by Parties to the Convention, have led to development of regional and national ABS regimes involving a mixture of regulatory, contractual, and policy measures.

Despite this attention, the issue remains contentious, both within the convention process and in other forums, leading to a call by the World Summit on Sustainable Development (WSSD) for negotiation of an international regime on benefit-sharing relating to genetic resources within the framework of the CBD. As a result of these endeavours, the COP to the CBD gave a mandate to the ad-hoc ABS Working Group to negotiate an international regime, which for many countries means a Protocol on ABS.

A collective responsibility for ABS governance

Since the adoption of the CBD in Rio in 1992, there has been much debate regarding measures needed to give force to the third objective of the CBD on ABS. Three dominant positions that emerged during this debate have been:

- It is the responsibility of countries where resources are obtained to regulate and control access and negotiate benefit-sharing (the position of many industrialized countries).
- It is the responsibility of countries that have large biotechnology, pharmaceutical, and agro-industrial capacity to ensure resources used in their territories have been obtained with prior informed consent (PIC) and subject to mutually agreed terms (MAT) (the position of developing countries).
- All bioprospecting is biopiracy, as the international system of intellectual property rights facilitates expropriation of rights over genetic resources and traditional knowledge through the granting of patents without requiring PIC and MAT (the position of many non-governmental organizations (NGOs) and indigenous peoples).

Decision 6/24 adopted at COP 6 in The Hague covered a package of issues incorporating the Bonn Guidelines and a number of associated sections, including one on intellectual property rights, that were key to overcoming the political impasse inherent in these positions. The guidelines include measures addressed at countries both as providers and as users of genetic resources, thereby recognizing the need for action by all countries to implement ABS law and policy. While it is recognized that all countries are users of genetic resources, it is clear that the emphasis in the Bonn Guidelines is primarily on user countries with strong biotechnology, pharmaceutical, and agro-industrial capacity. The guidelines have already inspired varying levels of action in developed countries to commence adoption of user measures. Countries such as Belgium, Denmark, Germany, Japan, Switzerland, and, most notably, Norway have in recent years adopted legislative and or policy measures in this area, and others such as Australia and Canada are making positive steps in this direction.

The UNU-IAS Biodiplomacy Initiative has played a prominent role in building awareness on the importance of user measures and in promoting policy research in this area. In 2003, UNU-IAS published an influential study[1] that was welcomed by many as being the first of its kind and helping to place in context the debate on possible user measures.

The Institute also promoted international debate on the issue by hosting a high-level roundtable meeting in Paris in November 2003, through a collaboration with the Institut du Développement Durable et des Relations Internationales (IDDRI). The roundtable brought together more than 40 government, NGO, industry, and indigenous stakeholders to discuss the role of user measures in ABS governance. This collaboration has now been strengthened by the addition of the Centre for Philosophy of Law (CPDR) of the Catholic University of Louvain. The second Paris Roundtable on ABS Governance, held in November 2004, focused on the issue of certificates of origin.

Section C of Decision 6/24 is potentially its most significant element, as it marks the first time that the CBD had adopted a Decision that specifically addressed the issue of intellectual property rights, calling upon countries to encourage the declaration of the origin of genetic resources and the source of traditional knowledge in patent applications. Although the CBD itself recognizes that intellectual property rights (IPR) should support and not run counter to its objectives, both the International Committee on CBD (ICCBD), which met prior to the entry into force of the Convention, and, subsequently, the COP demonstrated a reluctance to discuss IPR-related issues. With the adoption of Decision 6/24, the CBD broke that trend, setting out the possibility that future negotiations may lead to further efforts by the CBD to define measures to ensure IPR

support its objectives.

The Biodiplomacy Initiative has been active in helping to promote informed debate on issues relating to IPR and ABS, in particular through its policy studies on issues relating to disclosure of origin, certificates of origin, and the role of registers and databases in protection of traditional knowledge.[2]

Decision 6/24 has, therefore, aided the development of international law on ABS by:

- establishing soft law guidelines that are both comprehensive and functional,
- securing recognition of the obligation of countries as both providers and users to adopt ABS measures,
- acting as a catalyst for the adoption of user measures, and
- affirming the mandate for the CBD to address IPR issues in so far as they affect the realization of the Convention's objectives.

In doing so, it has provided a clear framework for negotiators to build upon.

From theory to practice

COP 7 prescribed the terms of reference for the ABS Working Group to "elaborate and negotiate an international regime on access to genetic resources and benefit-sharing". The nature of the proposed regime was defined only in broad terms, however, with no specific objectives.

One of the key issues of focus, therefore, for the third meeting of the Ad Hoc Open-ended Working Group on Access and Benefit Sharing (ABS), which met from 14 to 18 February 2005 in Bangkok to begin the negotiations on an international regime on access and benefit-sharing, was the need to establish clear objectives for any regime. During the early part of the debate in Thailand, a draft text was prepared for consideration by delegates that included a wish list of possible objectives, from regulating access through protection of traditional knowledge to the issue of poverty alleviation. UNU-IAS provided input to this debate, suggesting that in developing the regime's objectives, delegates should not restrict themselves to the objectives of the CBD, but also draw upon other sources such as the Millennium Development Goals and the Plan of Implementation of the WSSD for inspiration.

During the week of negotiations, two sub-working groups discussed the elaboration of the international regime (scope, objectives, and elements) and addressed the use of terms that are not defined in the CBD; additional approaches to complement the Bonn Guidelines on ABS, such as an international certificate of origin/source/legal provenance, measures to ensure compliance with prior informed consent and mutually agreed terms; and options for indicators for ABS, to be used for evaluating progress in the implementation of the CBD's Strategic Plan. A UNU-IAS report on "The Feasibility, Practicality and Cost of a Certificate of Origin System for Genetic Resources" served as an information document for the negotiation process. (This comparative study of procedures to document transfers of genetic resources and a proposal for an international certification scheme are discussed elsewhere in this issue.)

This report is available for download from http://www.ias.unu.edu/binaries/UNUIAS_UserMeasures_2ndEd.pdf

By the end of that week, and after long negotiations, the delegates agreed on several final documents. The documents included recommendations on further work, annexes on an international regime on ABS (options on nature, scope, potential objectives, elements clustered by subject matter, potential additional elements, and options), and a matrix to identify and analyse the gaps in international instruments. Parties and others are invited by the Working Group to undertake further analytic work and submit more information on an international regime, existing national definitions and other relevant terms, an international certificate system, the disclosure of origin/source/legal provenance, and options for ABS indicators.

The results of the meeting are modest, but as much as could have been expected in the first round of negotiations. A further meeting of the Working Group (ABS-4) will take place in Spain in early 2006, prior to COP 8 in Brazil later that year.

During ABS-3, UNU-IAS, IDDRI and CPDR jointly held a side event to present and discuss the results of the Second Paris Roundtable on "Practicality, Feasibility, and Cost of Certificates of Origin". Another side event was jointly organized by UNU-IAS and the Japan Bioindustry Association (JBA) to present the results of the international symposium on "ABS: Experience, Lessons Learned and Future Vision", held in Tokyo in October 2004.

Knowledge gaps in the negotiations

The success of the negotiation process will depend in no small part on the extent to which delegations have access to sound policy analysis of options for ABS law and policy, user measures, and the components of an international regime. Some of the more critical issues that need to be considered are:

- the effectiveness of existing international ABS measures;
- the role of intellectual property rights;
- the effectiveness of contractual mechanisms for securing equitable benefit-sharing;
- the role of *sui generis* regimes for protection of rights over traditional knowledge;
- the role of customary law and practices of indigenous peoples in regulating access to genetic resources and traditional knowledge;
- the role of scientific and technical policy;
- mechanisms for securing technology transfer;
- compliance mechanisms and access to justice;
- the effectiveness of voluntary measures;
- the tracing of gene flows, certificates of origin, and disclosure of origin requirements; and
- the capacity development needs of stakeholders.

Bringing clarity to these issues will be important for ensuring the adoption and effective implementation of any regime. Many of the hurdles that need to be overcome in the process of developing an effective system of international ABS governance have been

apparent since the entry into force of the CBD. However, commitment to providing the funds necessary for in-depth policy analysis relating to them has not been as forthcoming as might have been hoped regarding the importance of this issue for both developing and developed countries, for food security and industrial growth, not to mention for the protection of the ancestral and human rights of indigenous peoples. The measure of commitment of countries to the effective development of a regime on ABS that secures fair and equitable sharing of benefits and facilitates access to resources may be gauged from the level of support given to ensure the negotiations are carried on in a manner which is conducive to full and informed participation of all stakeholders.

The UNU-IAS Biodiplomacy Initiative is committed to supporting the negotiation process through its policy research outreach activities and capacity development programme. As part of this process, UNU-IAS together with IDDRI and CPDR have developed a collaborative research and outreach programme that will include a range of roundtables and workshops as well as research on cutting-edge issues relating to international ABS governance. The programme is intended to complement and assist the ongoing international debate of ABS issues through the provision of an informal arena for discussion of complex issues of ABS governance, in particular through the annual Paris Roundtables on ABS governance. A steering committee of leading experts in ABS, IPR and traditional knowledge issues – drawn from a range of national, international, NGO, academic, and civil society actors – has been formed to provide guidance on the focus for the programme, the annual roundtable, and associated research activities.[3]

The Biodiplomacy Initiative is also looking into issues relating to traditional knowledge and its relationship to ABS governance from a number of different angles (discussed elsewhere in this issue). These include the links between intellectual property rights, traditional knowledge, and the public domain, and the role of customary law and practice in regulating ABS and protecting traditional knowledge.

An important element of the Biodiplomacy Initiative's work on ABS is to turn policy into practice. To this end, the Initiative places great emphasis on capacity development and is actively involved in promoting the development of a global capacity development programme on ABS. Work has also included capacity development workshops in the Pacific, Latin America, and Central Asia.

UNU-IAS has begun to develop capacity development initiatives that seek to promote the implementation of The Action Plan on Capacity Building for Access and Benefit-Sharing adopted by COP 7 in its Decision VII/19. This Action Plan acknowledges that capacity for access and benefit-sharing is an integral part of efforts to manage and develop genetic resources. Furthermore, the Action Plan provides a framework for identifying country, indigenous, and local community priorities and mechanisms for implementation and funding.

One area of particular interest for UNU-IAS has been Small Island Developing States (SIDS). This interest has stemmed from the recognition that SIDS – a large component of the Parties to the Convention – have special vulnerabilities and constraints, especially in the area of resource management. As a research and capacity development institution, UNU-IAS has been involved in capacity development in SIDS through a project (with the South Pacific Environment Programme, International Marine Project Activities Centre, Christensen Fund, and United Nations Environment Programme) that focused on the Role of Customary Law and Practice of Indigenous and Local Communities in Natural Resource Management. UNU-IAS will continue its engagement of SIDS by reviewing ABS capacity development in SIDS at the national and sub-regional levels, and providing input and research efforts to assist SIDS in relation to the International Regime on Access and Benefit-Sharing.

Creating a link between theory and practice is crucial to development of an effective system of ABS governance. The Biodiplomacy Initiative is well positioned to make this link due to the experience of UNU-IAS senior staff and research fellows on ABS issues, and as a result of its hands-on involvement in capacity development and its cutting-edge applied research agenda.

It is hoped that this, in turn, will attract top-level Ph.D. and post-doctoral graduates working on ABS, traditional knowledge, and intellectual property rights to apply to the UNU-IAS fellowship programme. Attracting these fellows, and providing the opportunity for their direct involvement in the negotiation process and preparation to participate in the development of national, regional, and international ABS law and policy, responds to the Institute's educational mandate, and is intended to be one of the most important aspects of the programme in the long term.

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1 "User Measures: Options for Developing Measures in User Countries to Implement the Access and Benefit-Sharing Provisions of the Convention on Biological Diversity", UNU-IAS report available online at http://www.ias.unu.edu/binaries/UNUIAS_UserMeasures_2ndEd.pdf.

2 Ibid. See also, "The Role of Registers and Databases in the Protection of Traditional Knowledge: A Comparative Analysis", UNU-IAS report available online at http://www.ias.unu.edu/binaries/UNUIAS_TKRegistersReport.pdf; and B. Tobin, D. Cunningham and K. Watanabe (2004), "The Feasibility, Practicality and Costs of a Certificates of Origin System for Genetic Resources", a working paper submitted by UNU-IAS to the Secretariat of the Convention on Biological Diversity and presented at the third meeting of the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing, Bangkok, 14–18 February 2005.

3 A summary of the 2nd Paris Roundtable results is available online at http://www.iddri.org/iddri/telecharge/biodiv/workshop-abs.pdf.

Tracking Genetic Resources and International Access and Benefit-Sharing Governance: The Role of Certificates of Origin

By David Cunningham, Carmen Richerzhagen, Brendan Tobin, and Kazuo Watanabe

Certificates of origin may have a useful role to play in facilitating the continuous flow of genetic resources for commercial and not-for-profit uses, while protecting the rights of the owners of genetic resources and associated traditional knowledge. Could an international certificate of origin system be used to implement access and benefit-sharing provisions of the Convention on Biological Diversity?

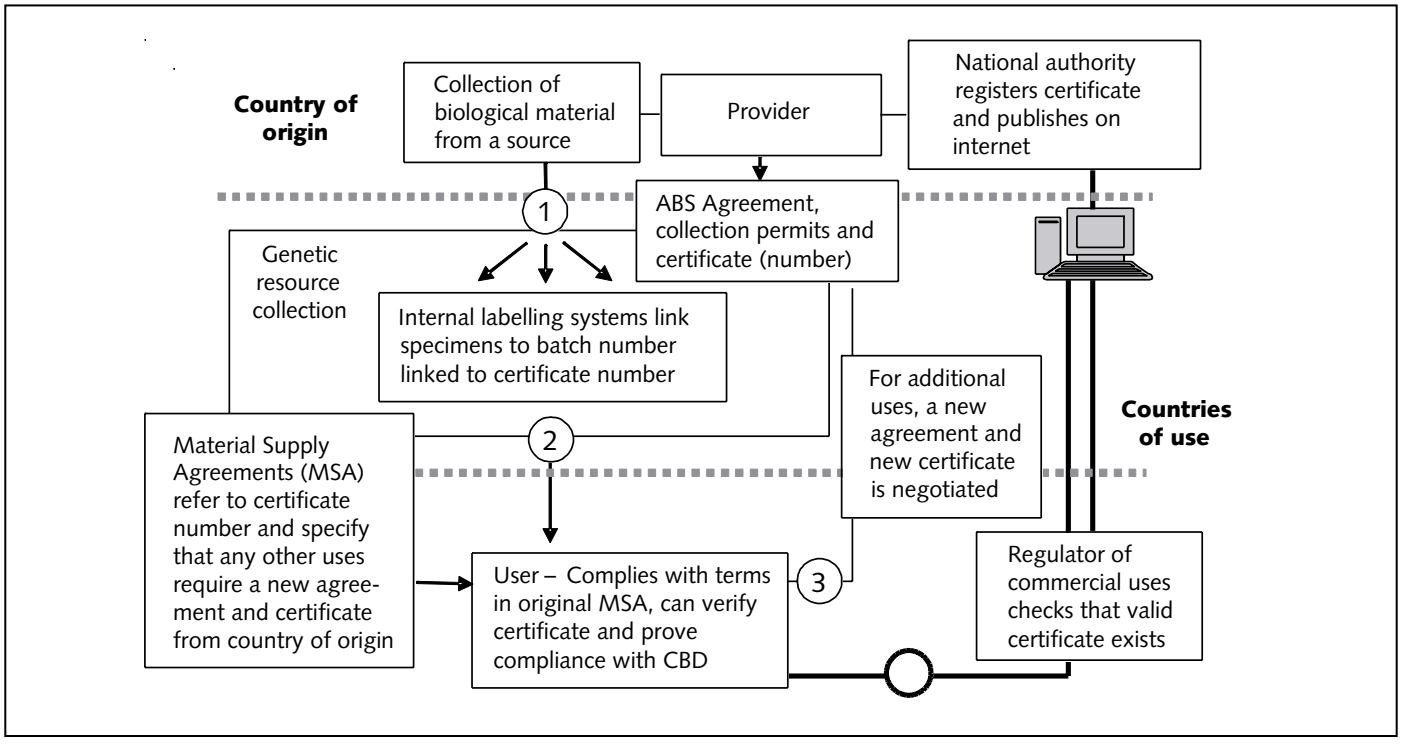
In the more than 10 years since the entry into force of the Convention on Biological Diversity (CBD), progress by countries in enacting legislation to implement its access and benefit-sharing (ABS) provisions have been limited and uneven. One reason put forward is that while virtually all countries wish to protect their interests as providers of genetic resources, few wish to assume responsibility to regulate the use of imported resources; thus, legislation has focused on controlling access rather than on creating incentives and mechanism for maximizing benefits and ensuring they are fairly shared.

During negotiations leading to the adoption of the Bonn Guidelines on ABS, at the 6th Conference of Parties (COP 6) to the CBD in The Hague in 2002, the concept of "user measures" was developed to respond to the concerns of developing countries that they could not control use of their resources once outside their jurisdiction. User measures as set out in the Bonn Guidelines are designed to promote action by all countries – but in particular, those with highly developed biotechnological, pharmaceutical, and agricultural industrial sectors – to help ensure that use of genetic resources and traditional knowledge complies with the ABS objectives of the CBD. While the Guidelines emphasize the obligations of users of genetic resources under the CBD, many developing countries left COP 6 with a feeling that equity in ABS will not be achieved without a legally binding international instrument, in part because there is no enforcement mechanism and no way of monitoring whether benefits have been shared equitably. This concern led to the call for negotiation of an international ABS regime by the World Summit on Sustainable Development.[1]

Work has since advanced within the framework of the CBD to establish terms of reference for the negotiation of an international regime. As part of this process, it has become increasingly clear that there is a need for mechanisms to assist in identifying where genetic resources originated, and for providing evidence of compliance with regulations on prior informed consent (PIC) and mutually agreed terms (MATs) for their use. One proposal that is receiving ever-increasing attention as a potentially key element of any international regime on ABS is for a system of what has been termed "certificates of origin".

A possible role for certificates of origin

The term "certificate of origin" was coined in 1994 to describe a proposal for use of patent application procedures as a means for ensuring that use of genetic resources and traditional knowledge was subject to PIC.[2] The original concept was that the patent offices should require disclosure of the origin of genetic resources and associated traditional knowledge, as well as evidence of PIC, as a condition for receiving applications for grant of patents. It was



Hypothetical model of a certificate of origin traceability system for genetic resources (prepared by D. Cunningham)

suggested that establishment of a standardized certificate of origin, which would act as evidence of prior informed consent, would exempt patent officers from the need to examine all of the documentation related to an ABS agreement to verify compliance with the CBD.

The term has since been utilized to encompass "cradle to grave" tracking of flows of genetic resources, as well as documenting evidence of the right to use those resources.

COP 6 tasked the secretariat to the CBD to undertake further information gathering and analysis of the feasibility of an international certificate of origin system. As discussion of the proposal has advanced, so too has debate about what should be certified, and proposals have emerged for certificates of source and legal provenance as well.

This led COP 7 in 2004 to decide to undertake further examination of an internationally recognized certificate of origin/source/legal provenance of genetic resources and associated traditional knowledge as part of the negotiation of an international regime on ABS. COP 7 identified the feasibility, practicality, operational functionality, and costs of any international certificate system as the key issues to be investigated. Investigation is also to focus on the potential role certificates might play regarding the disclosure of origin of genetic resources and associated traditional knowledge in applications for intellectual property rights.

Analysis of feasibility, practicality, and cost

The UNU-IAS Biodiplomacy Initiative has collaborated with a number of major collections of biological resources around the world – including the Smithsonian Institution (USA); Royal Botanic Gardens, Kew (UK); Instituto Nacional de Biodiversidad (Costa Rica); and selected microorganism collections – in the preparation of case studies of procedures for documenting collections of biological and genetic resources. These case studies have served as input for a comparative analysis of documentation procedures, with a view to determining the feasibility, practicality, and cost of developing an international certificate of origin system. The results of this study, together with research into the potential modalities for establishing a certification system, have been set out in a preliminary report[3] that was submitted as an information document to the third meeting of the CBD's Ad Hoc Open-ended Working Group on Access and Benefit-Sharing in Thailand in February 2005.

The case studies highlight the importance of ensuring that a certification system does not create new administrative burdens for basic research. Collection, movement, storage, and transfer of biological and genetic resources are subject to a wide array of permission and approval procedures, which involve extensive bureaucracy, human and economic resources, and a range of mechanisms for the documentation, monitoring, and control of exchanges and use of resources. These range from paper to electronic records, and from batch to individual records associated with specimens through barcode labelling.

As a significant majority of biological and genetic resource collection activities and transfers are for non-commercial purposes related to basic science, there are no monetary benefits from such activities to support an expensive tracking system. However, it appears that collections could potentially benefit from the rationalization of access, collection, export, and other permission procedures if it did indeed streamline the system rather than creating a new layer of bureaucracy. A standardized international system that documents genetic resource flows up to the point of entry into individual collections, and at the point of exit, could help to facilitate access to genetic resources and transfers between and among collections.

While traceability between institutions may be relatively simple, whole supply chains (from geographic source to end use and marketing) are more difficult to track. For most bioproducts, the supply chain arrangements vary from sector to sector, so that a "one

Insects collected from jungle canopy await taxonomic identification at the Smithsonian Institution, Washington, DC, 2004. (Photo: David Cunningham)

size fits all" solution would be unworkable. Furthermore, as the value of most genetic resources is poorly defined at the time of collection, it can be difficult to demonstrate the benefit of an expensive tracking system. Likewise, the time frame from acquiring a resource to deriving any benefit may extend for decades, making it more difficult to detect unauthorized use of resources.

Developing a certificate of origin system

Any certificate of origin scheme would need to protect the interests of resource providers without being so restrictive as to prevent desired flows of genetic resources for scientific purposes linked to the conservation objectives of the CBD. A certificate of origin system that provides evidence of a clean title for use of resources would enhance the value of the resources and create greater private sector interest in the natural products market. The private sector would be one of the main beneficiaries of a standardized system for demonstrating the origin of biological and genetic resources and rights to use them.

A preliminary list of the information that may perhaps be included in a certificate of origin has been proposed in a policy brief on user measures by UNU-IAS.[4] These include:

- particulars of the provider and user;
- particulars of the indigenous or local communities party to the agreement;
- details of genetic resources or traditional knowledge;
- details of the approved use which may be made of the resources;
- details of any restrictions on use;
- period of the agreement;
- conditions relating to transfer of rights to third parties; and
- details of the issuing authority.

One potential embodiment of a certificate of origin may be likened to a passport that accompanies genetic resources, either through their entire history from collection to use ("cradle to grave") or only for certain transactions such as patent applications or border crossings.

Concerns that identification of the "origin" of resources may prove impossible in many cases have led to proposals for "certificates of source" or "certificates of legal provenance". But these proposals are not without difficulties, as such certificates may provide loopholes that could prevent realization of the CBD's objectives. A certificate of source would track the genetic resource only as far as the place where the user obtained it, while legal provenance would be decided by the laws of the country where the resources were sourced. A question to be considered in determining which form of certification to promote will be whether any system needs to apply to all transfers of biological and genetic resources, including those from pre-CBD collections. In order to avoid loopholes in any system, it may also be necessary to ensure that transfers of genetic resources held in private collections, universities, and other research centres, as well as by individual scientists, are included within the framework of a certification system.

UNU-IAS's preliminary report on the issue suggests that, rather than seeking to design a single form of certificate to cover all cases, it may be worthwhile to consider the use of a range of certificates as the basis for a more comprehensive certification scheme. In this case, a certificate of origin would be granted by a national authority in the country of origin of specific biological and/or genetic resources. A certificate of legal provenance could be issued by a biological collection, such as a gene bank or herbarium, or by a national authority in a country other than the country of origin. A certificate of source would be required to accompany any transfer of resources for basic non-commercial research if a certificate of legal provenance or certificate of origin was not available. The report also recommends further investigation of the potential for development of an online certificate system that could be used to validate certificates and link them to the access and benefit-sharing agreement under which the resources were obtained.

The results of UNU-IAS research on certificates of origin have been cited in detail in an official report prepared by the Executive Secretariat of the CBD (SCBD) for the third meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-Sharing",[5] which considers the certificate of origin/source/legal provenance scheme as a potential approach to implement the CBD. The SCBD analysis draws upon the UNU-IAS study in highlighting further issues for consideration, such as the information to be covered by a certificate, its format, check points, subject matter, differences between scientific and commercial research, and the balancing of costs and benefits arising out of a certificate system. The SCBD report supports UNU-IAS's conclusion that an international certificate system would have to be developed in a way which ensures that access to genetic resources is facilitated for research purposes while also ensuring that proper controls are established for those genetic resources used for commercial purposes.

Paris Roundtable

In November 2004, UNU-IAS, together with the Institut du Développement Durable et des Relations Internationales (IDDRI) and the Centre for Philosophy of Law, Catholic University of Louvain, organized the 2nd Paris Roundtable on ABS Governance. The roundtable brought together a wide range of experts to discuss the potential role of certificates of origin in ABS governance, challenges in developing an international certificate of origin system, certificates of origin and disclosure of origin, and certificates of origin and international trade rules.

The roundtable discussed the opportunities that a certificate of origin scheme may offer for creating economic incentives for the conservation of biological diversity, as well as for facilitating the exchange of genetic resources by tracking flows, providing evidence of legal title to use resources, simplifying and harmonizing existing ABS procedures, and promoting compliance with ABS law and policy. The roundtable concluded that clear objectives have to be identified and formulated to establish the basis for an effective system, and that these should be linked to the conservation objectives of the CBD.

Amongst the main conclusions of the roundtable were that any system has to be cost-effective, simple, and flexible; benefits need to outweigh transaction costs; and, where possible, existing infrastructure, check points, and human resources should be used, and increased bureaucracy and administrative complexity avoided. A simple and flexible scheme can address the nature of genetic resources in the innovation process and can be used by different

stakeholders for different purposes (e.g., in material transfer agreements, in patent applications, or in the process of product approval for commercialization). Any system should be designed to avoid unnecessary impacts on trade to circumvent any conflicts with World Trade Organization agreements.

The participants of the roundtable concluded that a certificate of origin scheme will need to consider and balance the heterogeneity of users and providers of genetic resources by addressing the interests of the research community, the business community, local and indigenous communities, and provider countries. Any regime has to be developed with full participation of all stakeholders; only then can it protect the interests of resource providers, in particular with regard to traditional knowledge, without being restrictive and preventing desired exchanges of genetic resources. The participants also suggested that the design of any regime should be guided by "the four Ts": transparency, traceability, tractability, and trust.[6]

While further research is necessary, the Paris Roundtable highlighted that the need for implementation of a functional ABS regime at the global level requires action in the near future. Development of a certificate system to support the enhanced effectiveness of international ABS governance requires prompt attention, and could be adopted with a view to progressive implementation, regular review, and modification as part of a process towards the consolidation of an international ABS regime.

Future directions for certificates of origin

The best way to test a system will be through pilot studies. Case studies could be conducted with partners in a range of genetic resource provider countries to see how (and if) countries could implement a certificate system. The feasibility of implementing a certificate of origin system for traditional knowledge could also be investigated. One interesting proposal would be to incorporate pilot studies into capacity development projects relating to ABS that are being developed with the support of the Global Environmental Facility.

Many complex questions will need to be addressed. What authority can legitimately provide access and issue a certificate? What happens when a resource may be obtained from a range of countries, and knowledge from a range of local communities in one or more countries? How far could a resource be traced in practice, and what measures could be put in place for penalties, liability, and redress? These questions also apply to the related issue of traditional knowledge, innovations, and practices associated with biodiversity.

Further research is required to investigate how these challenges could be met when it comes to implementing a model in practice. An analysis of the economic impacts and implications of any certificate of origin system would help to identify the true potential of the model to effectively support the objectives of the CBD and advance its implementation.

1 See also the article about the international regime for ABS on page 6.
2 Brendan Tobin, "Alternative Mechanisms for Protection of Indigenous Rights", paper presented at the "Symposium of Indigenous Peoples of Latin America: Indigenous Peoples, Biodiversity and Intellectual Property", Santa Cruz, Bolivia, 27–30 September 1994. See also Brendan Tobin, "Certificates of Origin: A Role for IPR Regimes in Securing Prior Informed Consent", in Mugabe et al. (editors), *Access to Genetic Resources*, ACTS Press, Nairobi 1997, http://www.ias.unu.edu/binaries2/Tobin_Certificates_of_Origin.doc
3 Brendan Tobin, David Cunningham, and Kazuo Watanabe, "The Feasibility, Practicality and Cost of a Certificate of Origin System for Genetic Resources – Preliminary Results of a Comparative Analysis of Tracking Material in Biological Resource Centres", UNU-IAS, December 2004.
4 C.F. Barber, S. Johnston, and B. Tobin, "User Measures: Options for Developing Measures in User Countries to Implement the Access and Benefit-Sharing Provisions of the Convention on Biological Diversity," 2nd edition, UNU-IAS, 2003.
5 UNEP, "Analysis of Measures to Ensure Compliance with Prior Informed Consent of the Contracting Party Providing Genetic Resources and Mutually Agreed Terms on which Access was Granted, and of Other Approaches, Including an International Certificate of Origin/Source/Legal Provenance", UNEP/CBD/WG-ABS/3/5, 10 December 2004.
6 The first three "Ts" formed the basis of a keynote presentation to the roundtable by Leonard Hirsch of the Smithsonian Institution.

Prior Informed Consent and Access to Genetic Resources and Benefit-Sharing: Paralysis or Prudence?*

By Sofia R. Hirakuri and Brendan Tobin

Prior informed consent is at the very heart of the Convention on Biological Diversity's compact on access and benefit-sharing. Results of UNU-IAS's comparative research on national implementation of prior informed consent highlights the need for a balanced approach to avoid paralysis of desirable scientific and commercial research.

Adoption of effective prior informed consent (PIC) procedures in both provider and user countries has a crucial role to play in achieving realization of the Convention on Biological Diversity's (CBD's) objective of ensuring equity and fairness in benefit-sharing, and in consolidating international access and benefit-sharing (ABS) governance. However, excessive bureaucracy can lead to a virtual paralysis in access to genetic resources.

For instance, only two genetic resources projects (out of 37 applications) have been approved by the competent national authority in the Philippines since its enactment of national ABS regulations in 1996. That regulation has been seen as impeding scientific research, including that carried out by national researchers, bringing it to a virtual halt and leaving research programmes bereft of foreign

funding. In Brazil, while legislation adopted in the wake of the adoption of the Bonn Guidelines on ABS has proved less onerous, only 11 projects out of 31 applications were approved during the period 2001–2003. And more than eight years since the development of the Andean Community's regional regime on ABS, some countries in the region still have not adopted national implementing legislation; many commentators have suggested the regime needs to be reviewed, in part because of difficulties associated with establishing a clear mechanism for PIC.

Prior informed consent is not a new concept, but derives from the medical practice whereby patients are considered to have a right to be provided with sufficient information to make informed decisions regarding important personal health matters.[1] PIC emerged most prominently in international environmental law in the context of the transboundary movement of hazardous and dangerous substances, with the first legally binding instrument on PIC being the 1998 Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade. In contrast to the conventional application of PIC, which focuses on risk, prior informed consent within the context of the CBD is also intended to act as a guarantee of equitable benefit-sharing and, therefore, plays a contractual as well as a regulatory role.

CBD provisions on prior informed consent

The CBD did not set down specific steps for PIC; that came later, with the Bonn Guidelines (adopted in 2002) that outline practical procedures for the implementation of ABS, including PIC. The Bonn Guidelines recognize that both countries and stakeholders face responsibilities to ensure that the CBD's ABS objectives relating to the acquisition of genetic resources and benefit-sharing are realized. The Guidelines set out the basic principles and elements for a PIC system that cover such issues as establishment of a competent authority, timing and deadlines, specification of use, mechanisms for consultation with relevant stakeholders, procedures for obtaining PIC, and the process of issuing a permit or license. The Guidelines also set out basic requirements for mutually agreed terms, which are the contractual provisions reflecting PIC.

Among the basic principles for a system of PIC laid out in the Guidelines are the following:

- There should be legal certainty and clarity;
- Access to genetic resources should be facilitated at minimum cost;
- Restrictions on access to genetic resources should be transparent, and not run counter to the objectives of the CBD; and
- PIC from the government of the provider country and any relevant stakeholders (such as indigenous and local communities) should be obtained according to the circumstances and applicable domestic laws.

The CBD recognizes the need for equitable sharing of benefits arising from the use of traditional knowledge, innovations, and practices relevant to the conservation of biodiversity and the sustainable use of its components. The Fifth Conference of the Parties to the CBD decided that "Access to traditional knowledge, innovations and practices of indigenous and local communities should be subject to prior informed consent or prior informed approval from the holders of such knowledge, innovations and practices."[2]

Comparative analysis of PIC implementation

The history of PIC procedures in ABS is extremely short. However, two distinct policy contexts can be discerned, depending upon whether the regimes were developed before or after the adoption of the Bonn Guidelines. The Philippines and Andean Pact regimes were both established prior to the Bonn Guidelines. On the other hand, Australia and Brazil are federal countries whose ABS regimes were implemented following the adoption of the Bonn Guidelines. The PIC procedures in these countries are particularly interesting, given their federal complexity and influence of the Bonn Guidelines.

PIC procedures in the countries examined demonstrate many similarities. The first step for an individual or organization requiring access to genetic resources is to apply to a competent national authority within the country. If access is granted, it is through a bilateral agreement that is based on mutually agreed terms. Prior informed consent from the provider, for either *in-situ* or *ex-situ* sources, is a precondition for mutually agreed ABS terms.

In Brazil, the Council on Management of Genetic Resources (Conselho de Gestão do Patrimônio Genético), which is part of the Ministry of Environment, is the competent authority. A new draft law, however, establishes two competent authorities for issuing authorization of access to genetic resources, depending on the purpose. In the Philippines, more autonomy is granted to the local community, with the competent authority being the Inter-Agency Committee on Biological and Genetic Resources, which is responsible for enforcement and implementation of the bioprospecting regulations. In Australia, the Commonwealth Environment Ministry assesses biological resource permit applications in Commonwealth areas, whereas in non-federal areas the competent authority in each state or territory is responsible for granting permission to access genetic resources. In contrast, the Andean Decision 391 gives total power to the government, thereby emphasizing the role of the government as the main negotiator of access.

In each of the case studies, the national government has sovereign rights over genetic resources; nevertheless, all regulations establish a basis for recognition of indigenous peoples and local community rights. The extent of this recognition varies among the countries. The Andean community, Philippines and Australia give recognition of local peoples, communities, and landowners' rights over genetic resources, and the Andean Pact Decision 391 further encourages the strengthening and development of their capacities.

One of the most complex issues with regard to PIC relates to the measures involved in obtaining permission from indigenous and local communities in order to collect resources. In Brazil, for instance there is a requirement that PIC be obtained from each concerned indigenous group or local community. This has caused confusion and delays in the process, as often there is sharing of the same resources and knowledge across communities, peoples, and regions. There are cases in Brazil where PIC has been obtained from three indigenous groups, but subsequently a fourth group challenges the validity of the PIC. A new Brazilian Draft Bill outlines an innovative mechanism called the "Benefit Sharing Fund", which intends to secure a percentage of the benefits to mitigate oversight in participation.

In Australia, PIC is obtained through a University Ethics Committee. First, the applicant submits a research proposal to the

committee, and if approved the proponent must then get PIC from the provider of the genetic material. However, it is the committee that gives final consent. This procedure has been criticized, as it is considered that this formula does not allow the local provider an opportunity to make free and informed consent regarding PIC and to fully engage in the process of negotiating benefit-sharing arrangements, leaving both the provider and the potential users fate in the hands of the committee.

The Bonn Guidelines provide that the decisions on applications for access should be taken within a reasonable period of time, but it does not actually set a timeframe. However, Australian, Andean, and Philippine legislation all specify 30 days for an evaluation decision.

Common challenges

Countries concerned about preventing loss of control over genetic resources have tended to establish highly restrictive regimes. This reflects a number of concerns, including a lack of confidence that national rights will be respected when resources leave the jurisdiction, lack of national capacity to negotiate and enforce ABS agreements, and the difficulties of regulating PIC for local and indigenous communities due to a lack of traditional knowledge-related laws and policies.

The earliest ABS laws tended to establish complex access procedures for both commercial and scientific research purposes. Subjecting all scientific research activities to lengthy and costly access procedures, even when carried out by national scientists without commercial intent, has impeded much potentially beneficial research. Following much criticism in this regard, the Philippines recently modified its procedures to distinguish access to genetic resources for research and commercial purposes. Similarly, the Australian NCA distinguishes between uses for commercial research and non-commercial public interest research, while the Malaysian ABS Bill does not apply to pure scientific research. The Andean Pact and the Brazilian ABS laws, however, do not distinguish access to genetic resources for research from that for commercial purposes, in terms of the bureaucratic paperwork needed to obtain a permit for access.

Countries also face institutional hurdles for the implementation of ABS law and policy – including, for instance, the difficulty of identifying one focal point to approach for consent because of sectoral interests of different ministries or divisions of the government dealing with genetic resources issues. Another difficulty is the lack of institutional and technical capacity to implement ABS law at the legal, administrative, and technical levels. Generally, in the cases examined, an overly bureaucratic and complex process to procure PIC, rather than the lack of PIC procedures, may be seen as the key barrier to accessing genetic resources.

Conclusion

Development of functional PIC systems must be seen as a multifaceted process rather than merely a technical or legal challenge. Implementation of the Bonn Guidelines provisions on PIC by countries, as both providers and users of genetic resources, may play an important part in the development of an effective international ABS regime. The major challenge is to translate the international regulation into legislation and practical policy at the national level.

The effectiveness of the PIC procedures of a country will be determined by the country's technical and institutional capability to implement them, and the assurance that prior informed consent has been obtained properly through consultation with the stakeholders. Meeting these challenges implies a commitment to capacity development and development of international mechanisms to support national implementation.

* This article discusses preliminary results of a paper in progress.
1 Discussion paper on "Facilitating Prior Informed Consent", CIEL, 19 May 2004.
2 UNEP/CBD/COP/5/23, Decision V/16/5.

Bioprospecting in Antarctica

By Sam Johnston and Dagmar Lohan

Though research institutes and multinational corporations have feigned a lack of interest in the Antarctic region, UNU-IAS has uncovered significant bioprospecting activities in the region, and associated patenting of products and processes.

What does the ice-cream in your freezer have in common with an extremely salty Antarctic lake? Not much at the moment, perhaps, but in the future that could change. Uniliver, the food giant, has patented an anti-freeze protein found in the bacterium *Marinomonas protea,* which lives in Antarctic lakes. This protein might someday be added to ice-cream to keep it creamy even when thawed.

This is just one example of the potential value that genetic resources of the world's last frontiers, such as Antarctica, represent for researchers and corporations. Bioprospectors' interest in Antarctica stems from two factors. First, the lack of knowledge surrounding Antarctic plant and animal life provides an opportunity to discover novel organisms of potential use in biotechnology. Second, Antarctica's environmental extremes (cold temperatures and extreme aridity and salinity) present conditions in which life forms have evolved unique characteristics for survival. Bioprospecting opportunities thus include, inter alia, the discovery of novel active principles in species found in cold and dry terrestrial habitats, new pigments found in hyper-saline lakes, and anti-freeze metabolisms in sea-lakes.

Research vs. commerce

So far, biological prospecting activities in Antarctica have been carried out by universities, research centres, and biotechnology and pharmaceutical companies.[1] Bioprospecting activities in Antarctica have tended to be conducted by consortia comprising a mixture of public and private bodies, making it difficult to draw a clear distinction between scientific research and commercial activities. MICROMAT,[2] for example, is an academic-industrial consortium whose partners include the University of Nottingham (UK), University of Liège (Belgium), University of Ghent (Belgium), University of Bordeaux (France), Genencor International (multinational), Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (Germany), Merck Sharp & Dohme (multinational), and BioSearch Italia SPA (Italy). Even scientists working on a strictly academic project may identify and exploit an organism's valuable uses, thus blurring the line between scientific research and commercial activity.

This report is available for download from http://www.ias.unu.edu/binaries/UNUIAS_AntarcticaReport.pdf

The time between collection and marketing can be very long – sometimes more than two decades – and the cost of developing a successful product can require an investment of hundreds of millions of dollars. Still, there is considerable interest in conducting research into commercially useful genetic resources and biochemical processes in Antarctica. In 2003, for example, the database of the US Patent Office revealed 92 applications for patents that referred to Antarctica. Many of the newly discovered Antarctic Actinobacteria species belong to genera with strong track records for producing pharmaceutically active compounds.

Biotechnology trends

As a general trend, the biotechnology industry is expected to continue to experience significant growth despite a downturn in global markets. In the US alone, biotechnology industry revenues mushroomed from $8 billion in 1992 to $39.2 billion in 2003. While it is difficult to quantify the contribution that natural resources make in this industry, the magnitude of the commercial use of biodiversity can be illustrated by considering that 62 per cent of cancer drugs approved by the US Food and Drug Administration are of natural origin or modelled on natural products.

Based on global biotechnology trends, it can be assumed that bioprospecting in Antarctica will increase. However, a number of unanswered questions are inhibiting bioprospecting activities in the region: How can ownership be properly acquired, and what procedures need to be followed to ensure that the use is legitimate? What, if any, approvals are necessary to ensure that the patent application is valid? Is benefit-sharing required and, if so, with whom?

UNU-IAS Biodiplomacy Initiative

To raise awareness of these issues and provide policy makers with adequate information to tackle them, UNU-IAS is conducting research on bioprospecting in Antarctica as part of its Biodiplomacy Initiative. This research area has obvious links with UNU-IAS work on access and benefit-sharing, intellectual property rights, and traditional knowledge.

Given the novelty of the topic, a desktop case study to outline possible research questions was initially conducted. The report "The International Regime for Bioprospecting: Existing Policies and Emerging Issues for Antarctica" (see at left), published in August 2003 and presented to the 26th session of the Antarctic Treaty Consultative Meeting (ATCM XXVI), concludes that the Antarctic Treaty System (ATS) does not directly regulate biological prospecting activities. In particular, the report identifies a number of important issues that the ATS does not clearly address, including:

- Who "owns" the Antarctic's genetic resources?
- How can scientists working in the Antarctic Treaty area legitimately acquire these resources?
- What measures do scientists have to take to protect these resources?
- Is benefit-sharing feasible (and, if so, with whom)?
- Who has rights to the commercial products resulting from these resources?
- What is the relationship between the ATS and other international policies?
- Is bioprospecting contrary to Article III of the Treaty (on international scientific cooperation)?

The research also points at a number of agreements whose provisions may be relevant in considering the issue of bioprospecting in Antarctica, such as the Antarctic Treaty, its Protocol on Environmental Protection (Madrid Protocol), and the Convention on the Conservation of Antarctic Marine Living Resources (CCAMLR). The Convention on the Regulation of Antarctic Mineral Resources Activities (CRAMRA) may also provide some guidance for developing measures for regulating bioprospecting activities. On the other hand, the Convention on Biological Diversity (CBD) does not apply to Antarctica, and while the International Treaty on Plant Genetic Resources for Food and Agriculture provides an interesting model for multilateral benefit-sharing, it covers only a specific set of genetic resources considered important in terms of world food security and a "common concern of all countries".

The Antarctica bioprospecting report attracted considerable interest from the international press and rapidly became the most widely cited UNU report by the international media in recent years, even provoking questions to the Prime Minister in the UK Parliament. The report recommends that more research is needed in this area, including a further survey of the relevant activities in Antarctica, the sectors using genetic material from the region, the research programmes most directly involved, and records of the appropriate patent offices.

As a response to the decision by the Antarctic Treaty Consultative Meeting to include the issue of bioprospecting on the agenda of its

27th session (May 2004), UNU-IAS conducted a follow-up study based primarily on interviews with industry representatives and academics, as well as on records in publicly available patent databases. That study aimed to answer some of the above-mentioned questions, particularly those relating to which sectors use Antarctic genetic material, and determine what indications records of patent offices give regarding these sectors' focus on Antarctic-based commercialization.

The research also helped to revise some of the assumptions about this topic made in the first report. For example, it emerged that the focus of Antarctic organism research is very much on developing the knowledge base; industries point to this as the reason for their limited focus on Antarctic organisms. The high risk and cost involved in pursuing this largely unexplored field also contribute to restricting the number of companies involved in funding Antarctic research, screening samples, and applying for Antarctic-based patents. Factors that seem to influence a company's interest in Antarctic samples are not only its financial situation, but also its focus on research and development, and its existing expertise in working with extremophiles (organisms adapted to "extreme" environmental conditions).

This report is available for download from http://www.ias.unu.edu/binaries2/antarctic_bioprospecting.pdf

Some noteworthy discoveries based on Antarctic organisms, and with potential commercial applications, have been made in collaboration with industrial partners. However, it appears that none of these discoveries has yet led to commercialization. Possibly the closest to commercialization is the development of an anti-cancer drug involving an enzyme from an Antarctic organism, which was isolated by the University of Cambridge (New Zealand) and is undergoing clinical testing by PharmaMar, a pharmaceutical company based in Spain. Recently, though, this work has stalled due to financial difficulties.

While products or processes based on Antarctic organisms have not yet been commercialized, the scope for such development exists. Not only do some Antarctic extremophiles exhibit potentially exploitable characteristics, but industry has also displayed an interest in screening these organisms.

UNU-IAS research findings

UNU-IAS research shows that patent applicants so far are largely pharmaceutical, chemical, and food companies. Further, most patents are process rather than product based, and centre around active compounds isolated from organisms (frequently from the yeast Candida antarctica) rather than a synthetic derivative. The number of patents issued appears to support the interpretation that, following a period of great anticipation regarding the opening of a new "frontier", companies have reduced the intensity of their involvement in the light of the yet-to-be-developed knowledge base. In addition, lack of ownership of the samples, and uncertainty relating to intellectual property rights and commercial exploitation, are likely to have acted as disincentives. Given that the largest part of inventions is of relevance to the pharmaceutical industry, a breakthrough commercialization can be expected to attract a significant amount of publicity and, thus, revive interest among companies.

UNU-IAS research indicates that arrangements between industrial and academic partners relating to the ownership of samples and to the sharing of potential benefits range from "gentlemen's agreements" that foresee negotiations to this end once product development is imminent, to specific agreements on royalties and instalment payments to be made to the isolating institution. The role of the "state" whose claimed territory the sample was collected from is neither always clear nor addressed. Ostensible "ownership" of the samples generally lies with the academic partner. Interviewees attributed delays in the exchange of data and information more to practical matters (such as insufficiently user-friendly databases) than to patent restrictions or conscious withholding of information.

From the research conducted so far, it emerges that rules regarding access, sample ownership, benefit-sharing, and intellectual property rights would provide certainty to both academic researchers and industries and, therefore, are likely to be favourably received. If bioprospecting is to continue in a similar form as it has to date – i.e., as part of wider research projects and with the sampling being undertaken by academic researchers – it should be in the interest of the international community as a whole to develop a framework under which the commitments of the Antarctic Treaty are honoured, and the opportunity for developing necessary products or processes is maintained.

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1 These include the University of Bordeaux (France), the Australian Academy of Technological Sciences and Engineering, and multinational corporations Genencor International and Merck Sharp & Dohme.

2 MICROMAT aims to improve knowledge of the biodiversity of bacteria, algae, amoeba and fungi in Antarctic microbial mats and to test this biodiversity for novel compounds of potential biotechnological use. See http://www.nerc-bas.ac.uk/public/mlsd/micromat/ for further information.

Technology Transfer under Multilateral Agreements: Wishful Thinking?

By Peilei Fan, Sam Johnston, David Mutekanga, and Brendan Tobin

Although all major multilateral environmental agreements adopted in the last two decades have provisions that recognize technology transfer as a primary pillar for sustainable development, there is a clear perception among developing countries that commitments on technology transfer have not been met.

During the past thirty years or so, Multilateral Environment Agreements (MEAs) have become one of the most significant tools of governance for sustainable development. Covering a wide diversity of issues – ranging from wetlands protection to control of ozone-depleting substances – a central element of all agreements is technology transfer. Whether as a means to address "brown issues" of environmental health or "green issues" of ecological sustainability to prevent harm, or to promote development,[1] the underlying principle for technology transfer is that unless we share our knowledge, technology, and wealth, sustainable development in one part of the world will be offset by increasing poverty, illness, and environmental degradation elsewhere. Despite the promise inherent in many MEAs, it is unclear to what extent these agreements have led to increased technology transfer for many developing countries.

The UNU-IAS Biodiplomacy Initiative began research on this subject by focusing on technology transfer under the Convention on Biological Diversity (CBD), addressing the question from a number of perspectives. Work has included consideration of what influence perceptions of a failure to meet commitments to transfer of technology under the CBD have had on calls for negotiation of an international regime on access and benefit-sharing (ABS), as well as study of technology transfer to Africa under the CBD and its links to poverty alleviation. A third phase of this research will involve extensive comparative study of technology transfer under some major MEAs: the CBD, United Nations Framework Convention on Climate Change (UNFCCC), and United Nations Convention to Combat Desertification (UNCCD). This third phase of research will be coordinated by the UNU-IAS Programme on Science Policy for Sustainable Development, with the support of the Biodiplomacy Initiative.

MEAs represent a modern approach to international governance. While no new international governance organizations (IGOs) have been established in the past three decades, nearly 100 MEAs have been adopted since 1972. Technology transfer has been a central element and a cornerstone of recent major MEAs, particularly relating to use of the seas, protection of the ozone layer, movement of hazardous waste, biodiversity conservation, climate change, desertification, biosafety, and persistent organic pollutants (see the table at right). In all of these agreements, essential conditions for securing developing countries' participation have included commitments to providing financial support, capacity development, and technology transfer.

Technology transfer and the CBD

Technology transfer is crucial to the realization of the three objectives of the CBD: conservation, sustainable use of resources, and sharing of benefits. The CBD adopted a number of strategies for promoting technology transfer:

- Capacity building (Article 18),
- Strengthening of use of scientific and traditional knowledge (Article 16),
- Mutually agreed terms for negotiations (Article 16),
- Transfer of technology (Articles 16 and 19), and
- Funding (Global Environment Facility (GEF), etc.).

Technology transfer may be seen as one of the key elements of the deal between developing and developed countries on the CBD. The Convention specifies obligations for transfer of technology for conservation and sustainable use of biological diversity; transfer to countries providing genetic resources of the technologies developed through their use; and transfer of biotechnologies. These transfers are to be on fair and "most favourable" terms (or, where appropriate, on concessionary terms). Countries are also obliged to take legislative, administrative, and policy measures to achieve these ends, as well as to ensure that the private sector makes available the technologies that it has developed.

A significant provision of the CBD specifies that intellectual property rights (IPR) are to support and not run contrary to the objectives of the Convention. At the same time, the Convention requires that transfers of technologies are to be done with due respect for IPR. These provisions on IPR have been at the heart of conflicts over the CBD and its impact on the private sector, and are widely seen as having led to the failure of the USA to ratify the Convention.

More than 10 years after the Convention entered into force, there is still a dearth of information on measures taken by national governments to implement the CBD's provisions on technology transfer. The consequence is a sense that technology transfer under the CBD is not happening and, consequently, of a need to revisit international commitments and regulation of ABS.

Pilot research carried out under the Biodiplomacy Initiative on technology transfer under the CBD indicates the existence of markedly different perceptions of the situation among developing country recipients and industrial provider countries. In at least some instances, this difference in perception appears to be related to the manner in which technology is being transferred. For instance, the European Community, in its reporting under the CBD, has identified a wide portfolio of projects involving technology transfer. However,

Recent Major MEAs with Commitments on Technology Transfer

1982	United Nations Convention on the Law of the Sea (UNCLOS)
1985	Vienna Convention for the Protection of the Ozone Layer
1989	Basel Convention on Hazardous Waste
1992	Convention on Biological Diversity (CBD)
1992	United Nations Framework Convention on Climate Change (UNFCCC)
1994	United Nations Convention to Combat Desertification (UNCCD)
1995	Conservation and Management of Straddling Fish Stocks and Highly Migratory Fish Stocks
1997	Kyoto Protocol
2000	Cartagena Protocol on Biosafety
2001	Stockholm Convention on Persistant Organic Pollutants

this transfer is primarily to the private sector and bypasses national authorities, which frequently remain unaware of these projects and allocation of funds for technology transfer. As a result, they do not appear in (or are not recognized as being elements for inclusion in) national reports on technology transfer by the recipient countries.

Challenges for technology transfer

Despite the importance, the urgent needs of developing countries, and the promises of MEAs, several factors have hindered technology transfer, both from the provider and from the receiver sides. Two of the most important issues raised by policy makers and negotiators are lack of resources and IPR.

Perhaps the principal impediment for technology transfer has been lack of sufficient financial support. Many developing countries – in particular, least developed countries (LDCs) – have limited resources to invest in technology transfer; the demands of poverty and health overshadow investment for the future. Furthermore, international donors such as the GEF have often been reluctant to fund capacity development and technology transfer because it is hard to quantify benefits or do cost analysis.

While some developing countries have set up relevant national policies to enable and encourage technology transfer, many (especially African countries) do not have the necessary capacity to ensure effective transfer. This lack of capacity has led to supply-side initiated transfer rather than demand-side initiated transfer, as well as poor communication between the government, the private sector, and non-governmental organizations. Securing long-term effective transfer requires attention to both pre-transfer and post-transfer steps, which have the same importance as the transfer itself and are linked with an effective and reliable private sector as well as the market mechanism.

Opinions regarding the influence of IPR on technology transfer tend to take one of two forms: either IPR regimes are viewed as a means for securing increased access to technology and, therefore, contributing to development, or IPR are seen as consolidating market domination, increasing costs, and impeding development. International agreements – in particular, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) – have in the past ten years extended the sphere of influence of IPR regimes from a narrow base of developed countries to all member countries of the World Trade Organization.

Evidence now shows that adoption of IPR regimes does not, in itself, promote technology transfer. Pedro Roffe of the United Nations Conference on Trade and Development (UNCTAD), in a keynote address at the Paris Roundtable on ABS Governance organized in 2003 by UNU-IAS and Institut du Développement Durable et des Relations Internationales (IDDRI), provided evidence that factors such as market capacity, human resources, and stability are primary determinants of the potential for effective technology transfer. For instance, although over half of African countries have put in place IPR systems with a view to creating an enabling policy and legal environment for technology transfer, to date this appears to have done little to enhance the rate of technology transfer. Thus, adding stronger IPR laws may not only fail to enhance technology transfer, but may actually make technologies more expensive and difficult to access.

The Technology Transfer Focus of Selected MEAs

Technology Transfer Focus	MEA
Biotechnology	Cartagena Protocol on Biosafety
Renewable energy technology	United Nations Framework Convention on Climate Change
Water desalination technology	United Nations Convention to Combat Desertification
Fisheries technology	Conservation and Management of Straddling Fish Stocks and Highly Migratory Fish Stocks

Technology transfer to combat ozone depletion

Development of effective mechanisms for implementation of technology transfer under MEAs can take a significant amount of time. To date, perhaps the most successful case of MEAs securing technology transfer relates to a collection of agreements developed over a number of years that together seek to combat ozone depletion, and which over an extended period developed the necessary instruments in a progressive fashion to ensure the realization of their objectives.

The Vienna Convention for the Protection of the Ozone Layer, adopted in 1985, was general in nature and involved no significant participation from the developing countries. The Montreal Protocol on Substances that Deplete the Ozone Layer in 1987 set out targets to regulate the production and consumption of ozone-depleting substances (ODS) and a timetable for their elimination. Obligations for developing countries to comply with the Montreal Protocol's commitment on ODS is dependent upon the effective implementation of the provision on training cooperation and technology transfer. While the Protocol set stronger commitments on capacity development and technology transfer, it did not allocate the resources to follow through.

In 1990, the London Amendments established a multilateral fund to facilitate technological cooperation and technology transfer, with US$2.0 billion for technological assistance. Since then, the use of ODS has fallen dramatically and, as a result, the ozone layer appears to be recovering. (Some claims suggest it may recover fully by 2045.) This experience tends to suggest that in order for MEAs to effectively secure technology transfer, there is a need for not only political will but also clearly defined standards and goals and committed funding.

In evaluating the effectiveness of technology transfer, a focus on a single MEA may give a distorted picture of the overall reality. In many cases, MEAs focus on different types of technology intended to respond to different real and perceived environmental and developmental objectives, as shown in the table at left. This may imply extensive commitments for providing countries under a range of MEAs, each of which requires action and funds for technology transfer.

In order to get an accurate picture of the real extent of technology transfer from developed to developing countries, a comprehensive study is required across a range of MEAs. Such a study would help to identify synergies that could be achieved between MEAs, and could also demonstrate the extent to which technology transfer across MEAs may be raising the level of human and institutional capacity in developing countries and building expertise and ability to deal with environmental, social, economic, and development challenges.

Conclusion

Obligations on technology transfer in MEAs have little practical effect where the bulk of the technology lies in the private sector. The private sector is not directly bound by the provisions of the CBD or other MEAs and has no obligation to transfer technology other than in accordance with relevant national law. Technology transfer is, in the absence of national law and policy to promote transfer, reliant on the good will of the private sector, and securing this good will is largely dependent upon ensuring that market conditions are favourable so that the private sector stands to benefit economically or otherwise by supporting an MEA's implementation.

At the end of the day, it appears that including provisions on technology transfer in MEAs will have little practical impact unless supported by adequate funding and mechanisms to secure protection of intellectual property rights. Unfortunately, while much has been done to secure the latter, funding has not been so readily forthcoming.

If it cannot be shown that there has been a significant increase in the transfer of technologies as a direct or indirect result of the entry into force of MEAs, developing country negotiators may well wish to reconsider the weight to be given to technology transfer provisions in the negotiation of future MEAs. UNU-IAS is conducting ongoing research that is intended to help inform this analysis while also providing a review of options and best practices for defining the nature, scope, and mechanisms for funding of technology transfer in MEAs in order to secure their more effective implementation in the future.

1 Advocates of the "Green Agenda" and the "Brown Agenda" often disagree over which environmental problems should be tackled first. The Green Agenda concentrates on reducing human impacts on the world's natural resources and ecosystems, whereas the Brown Agenda focuses on the environmental threats to health in poor areas. See *Sustainable Development Update*, Issue 6, Volume 3, 2003.

Protecting and Strengthening Traditional Knowledge Innovation Systems

By Nicolas Brahy and Brendan Tobin

Traditional knowledge was long considered little more than unscientific and irrelevant hocus pocus of witchdoctors or slavish repetition of outdated farming methods by unsophisticated peasants. It is now, however, increasingly being recognized as a complex and dynamic system of knowledge developed over centuries through research, investigation, application, modification, and innovation by indigenous and local communities – and deserving of protection.

Far from being an outdated form of science, traditional knowledge remains the primary means for securing and sustaining the livelihoods of a majority of the global population, and for responding to their health, food, clothing, and housing requirements. In terms of public health alone, over 80 per cent of the population in developing countries is estimated to depend upon traditional medicine for their daily needs. Traditional knowledge, far from being expendable, is a crucial part of our present and future scientific knowledge base, and requires both conservation and nurturing.

Despite its importance, traditional knowledge is under threat from a number of internal and external pressures. These include not only unapproved commercial and scientific exploitation (commonly referred to as "biopiracy") but national health, education, agricultural, and fisheries extension programmes that downplay the importance of traditional knowledge in favour of external or imported knowledge. Likewise, the influx of foreign religions has frequently led to displacement of traditional rites and festivities that are important tools for the transfer of knowledge. Loss of indigenous language, culture pride, and identity are other key factors in this lamentable trend.

Ironically, increased interest during recent years by the scientific and commercial sectors in the potential of traditional knowledge to assist in the identification of valuable biological and genetic resources has served as a catalyst for the revaluation of traditional knowledge, and has inspired a global movement dedicated to the protection of indigenous peoples' rights over their knowledge. Emblematic cases of biopiracy involving turmeric from India, ayahuasca from the Amazon, beans from Mexico, and maca from the Andes have served to create an environment of distrust and confrontation that has placed the issue of protection of traditional knowledge high on the international agenda.

The Convention on Biological Diversity (CBD) has established a Working Group dedicated to investigating the means to protect and strengthen traditional knowledge systems, including development of *sui generis* systems[1] of property rights over knowledge. At the same time, the World Intellectual Property Organization's InterGovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (WIPO-IGC) is researching potential options for the protection of traditional knowledge, and promoting research into a number of potential mechanisms for protection of rights (such as contracts, registers, and databases). Meanwhile, the 2001 Doha Declaration stipulates that in its review of Article 27.3(b) of the World Trade Organization's (WTO) Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement "which deals with patentability or non-patentability of plant and animal inventions, and the protection of plant varieties", the TRIPS council "should also look at: the relationship between the TRIPS Agreement and the UN Convention on Biological Diversity; [and] the protection of traditional knowledge and folklore".[2]

The UNU-IAS Biodiplomacy Initiative has developed a wide-ranging research programme on a number of key issues related to the protection and strengthening of traditional knowledge systems. These include:

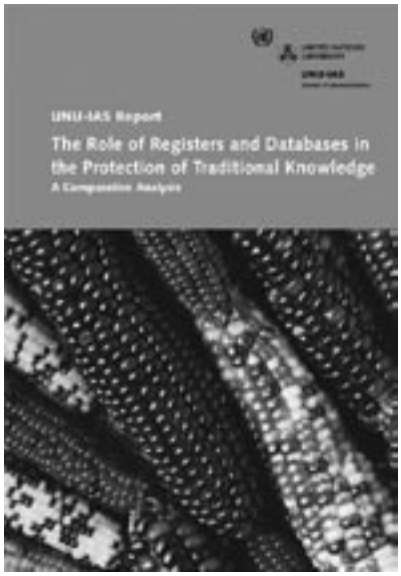
- intellectual property and *sui generis* protection of traditional knowledge;
- the role of databases and registers in the protection of traditional knowledge; and
- the interface between customary decision-making processes of local and indigenous communities, and national law and policy on access and benefit-sharing (ABS) and traditional knowledge.

Intellectual property and *sui generis* protection

Underlying traditional knowledge holders' claims for protection of their rights over their knowledge, three broad objectives can be identified. First, there is a need to support and strengthen the continuing use of traditional knowledge as the best way to conserve and develop it. (This includes use by its custodians, by other traditional knowledge holders, as well as by Western scientists and companies, provided proper conditions are ensured.) Second, there is a need to prevent traditional knowledge from being appropriated by third parties. Third, there should be equitable sharing of benefits derived through the use of traditional knowledge. (This benefit-sharing can be justified by reasons of equity, but above all as an incentive for maintaining traditional knowledge and for continuing innovation).

While seeking recognition of their rights, indigenous peoples have expressed concerns that framing those rights in the context of intellectual property rights (IPR) could lead to significant changes to the nature of the knowledge systems and to the exhaustion of their traditional rights to the knowledge generated. They have, therefore, proposed that protection be framed through appropriate *sui generis* regimes. The World Intellectual Property Organization has responded with the development of draft principles for the protection of traditional knowledge. To stimulate open dialogue on the nature of these principles and the theoretical bases underlying them, UNU-IAS organized a side event during the 7th meeting of the WIPO-IGC in Geneva in November 2004, with a keynote address by Professor Jerome Reichman of Duke University on the potential role of a compensatory liability regime in protecting traditional knowledge.

The UNU-IAS Biodiplomacy Initiative will continue to hold informative workshops during WIPO-ICG sessions. These events will have the aim of enabling leading academic commentators on IPR and traditional knowledge issues to discuss their proposals with government negotiators, custodians of traditional knowledge, non-governmental organizations, and relevant international organizations. A workshop was held at the 8th meeting of the WIPO-IGC in Geneva in June 2005 which discussed the notion of misappropriation and the role of databases in protecting traditional knowledge.



This report is available for download from http://www.ias.unu.edu/binaries/UNUIAS_TKRegistersReport.pdf

Role of databases and registers

The recent proliferation of IPR in several economic sectors creates a risk of reducing access to knowledge and raises concerns that it may hinder innovation. This has led to an intense debate in the IPR and scientific communities regarding the need to find the right balance between the granting of IPR to reward innovation and the need to maintain the vibrant, free, and open access to information through the public domain. At the same time, there are concerns that an ever-increasing body of traditional knowledge is being documented by academic researchers and published in databases or academic journals. As a result, this traditional knowledge is being placed in the "public domain" in the sense that it becomes available for use without permission of the traditional knowledge holders, and any rights that traditional knowledge holders may have been entitled to seek based upon legal notions of novelty and trade secret are effectively lost.

Over the centuries, an extensive body of traditional knowledge has fallen into the "public domain" and brought little benefit to traditional knowledge holders. There is, therefore, a need to protect traditional knowledge holders' intellectual rights; the challenge that faces regulators is how to achieve this end without unnecessarily restricting use and access, or negatively affecting the nature and underlying bases of traditional knowledge systems. In the long run, although they may approach the issue from different perspectives, the IPR community and traditional knowledge holders both face the same challenge: the need to balance the mechanism for protection of rights over the product of intellectual effort (mechanisms predominantly based upon the notion of IPR at the present, but increasingly involving the development of *sui generis* regimes) and access to knowledge.

The UNU-IAS Biodiplomacy Initiative has begun a multi-year research programme that seeks to address the relationship between information exchange, intellectual property rights, and the public domain. This research commenced with the preparation of a UNU-IAS policy report "The Role of Registers and Databases in the Protection of Traditional Knowledge" (see at left), based upon a comparative study of experiences in the development of traditional knowledge databases and community registers. Further research examined knowledge-sharing from an indigenous standpoint, drawing upon research of aboriginal concepts of knowledge-sharing in Australia. Work is continuing with the preparation of a policy report on the potential role of databases to support an international regime on protection of traditional knowledge.

This research addresses the issue with attention to a recent proposal by the WIPO secretariat in a negotiation document distributed at the 7th IGC in Geneva in November 2004,[3] in which the concept of "misappropriation" is used

as an organizing principle to explain the objectives of traditional knowledge protection and the justification for protection, and to describe its content. In addition, the negotiation document includes a list of issues to be met by a legal regime protecting traditional knowledge. UNU-IAS research seeks to clarify the principle of misappropriation, a concept drawn from competition law, and to further examine the potential objectives and justification for a regime to protect traditional knowledge. It also will examine how existing laws on database protection can help to answer some of the questions identified by WIPO in its paper. Consideration is being given to how a combination of databases, IPR, contracts, and licenses may be utilized to strengthen the enforcement of and respect for traditional knowledge holders' customary laws and community protocols.

Customary law/practice, ABS, and traditional knowledge

Traditional knowledge is a complex holistic system that permeates every area of indigenous people's lives; it includes not only information but also a comprehensive system of laws and practices that regulate both the manner and the right of use of knowledge. The UNU-IAS Biodiplomacy Initiative is working together with a range of partners in the Pacific region to develop a research programme to examine the existing status of customary law and practice relating to traditional management of natural resources. The region has been identified as one of the most propitious for such research as over 80 per cent of land and a significant portion of coastal marine areas are subject to customary rights.

UNU-IAS has been actively involved in organizing a number of workshops in the Pacific region. The first of these, for Melanesian countries, was held in Townsville, Australia, in November 2003 and coordinated by the International Marine Project Activities Centre (IMPAC) with the sponsorship of the Christiansen Fund. The second, for Micronesian countries, held in Palau in May 2004, was organized by UNU-IAS in coordination with the Office of Environmental Response and Coordination (OERC), and supported by United Nations Environment Programme and the South Pacific Regional Environment Programme.

A regional Pacific Workshop is planned for the latter half of 2005. As part of this, UNU-IAS is coordinating the preparation of a number of national case studies to identify best practices in the development of effective interfaces between national legal regimes and community decision-making processes.

These workshops are part of the Biodiplomacy Initiative's capacity development programme, which is designed to provide greater opportunity for indigenous and local communities to influence the development of law and policy on protection of traditional knowledge with reference to their own realities, customary law, and practices. Work has also included a series of workshops on ABS and traditional knowledge in Central Asia and Mongolia and a workshop for Amazonian, Andean, and Afro-Peruvian indigenous organizations in Peru to develop a proposal for a national consultation process on traditional knowledge.

Working together with the Uzbek patent office and WIPO, UNU-IAS is organizing a regional workshop for Central Asia and Mongolia on IPR and traditional knowledge, to be held in Tashkent in September 2005. This workshop is intended to bring together representatives of local and indigenous communities, experts in protection of traditional knowledge, and representatives of patent offices to discuss the opportunities and challenges faced by countries of the region in establishing effective mechanisms to protect traditional knowledge.

Conclusion

UNU-IAS believes that protection of traditional knowledge cannot be addressed from a purely defensive standpoint that seeks to prevent or control commercial and scientific use. Nor can it be achieved by relying solely on government regulation and international aid. Protecting traditional knowledge requires an understanding of the nature of indigenous and local community knowledge systems, respect for their knowledge-sharing practices, and support for their customary laws and practices. It requires a proactive policy of nurturing traditional knowledge systems, identifying the threats they face, and creating incentives and opportunities for increased use of traditional knowledge and respect for the innovative capacity and guardianship role of its custodians.

UNU-IAS seeks to support and facilitate the debates surrounding protection of traditional knowledge through its research, outreach, and capacity development activities, thereby engendering increased opportunities for indigenous peoples and local populations to participate in an informed and effective manner in decision-making processes.

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1 "*Sui generis* system" literally means "a system of its own kind". Developing a *sui generis* system for protection of rights over traditional knowledge implies a new and specific system of property rights rather than adoption of a system based upon existing intellectual property rights.

2 See the WTO website at http://www.wto.org/english/tratop_e/trips_e/art27_3b_background_e.htm.

3 WIPO, "Protection of Traditional Knowledge: Overview of Policy Objectives and Core Principles", WIPO/GRTKF/IC/7/5, 2004.

Rethinking the Public Domain: A Challenge for Knowledge-Sharing Societies in the Information Age

By Margaret Raven

Historically treated as the heritage of humankind, biological and genetic resources are now the subject of an ever-increasing struggle over ownership involving governments, corporations, research institutions, and indigenous and local communities. Information management and traditional knowledge-sharing practices are creating a dilemma for the concept of public domain.

International negotiations are increasingly recognizing the importance of access to information and the issue of information ownership, and are trying to catch up with the ever-increasing digital revolution. The Convention on Biological Diversity (CBD, 1992), World Summit on Sustainable Development (WSSD, 2003), and World Summit on the Information Society (WSIS, 2003) have all highlighted the important role that technology, information, and knowledge play in helping to secure sustainable development and biodiversity conservation.

The availability of information about biodiversity is unsurpassed. International organizations, non-governmental organizations, research institutes, and indigenous organizations are only some of the many sources of online information. The CBD's Clearing House Mechanism, for example, aims to promote and facilitate scientific and technical cooperation by developing a global mechanism for exchanging and integrating information on biodiversity through national, regional, and thematic clearing-house focal points. Some of the thematic clearing-house focal points, such as NatureServ and BirdLife,[1] include electronic online databases. These databases contain vast amounts of information that is accessible to anyone who has access to the Internet.

The Consultative Group on International Agricultural Research (CGIAR) is another example of an organization that maintains open and free access to information and resources. CGIAR has placed over 600,000 samples of crop, forage, and agro-forestry genetic resources in the public domain, with 533,000 designated as "in trust" for the world community under agreements with the Food and Agriculture Organization of the United Nations (FAO). Organizations such as IUCN – The World Conservation Union, United Nations Environment Programme World Conservation Monitoring Centre (UNEP-WCMC), and Inter-American Biodiversity Information Network (IABIN) also maintain conservation databases and database networks. Such is the extent of these database networks that IABIN, which represents only the Americas, has access to over 70 databases on its website.[2]

Property rights vs. public domain

Online databases provide easy access to biodiversity information, but many of them have been set up quickly, often without a clear understanding of (or guidelines on access to and ownership of) the information that they hold. This outflow of information has been championed by those who believe it necessary to maintain the boundaries of the so-called "public domain". Public domain has generally been used to refer to information and resources that are freely available to the public (not secret) and whose use is for the public good.[3] Traditional Western wisdom classified "products of nature, scientific theory, and folk knowledge to be public goods, belonging to the public domain".[4]

The traditional boundaries of the public domain are now being challenged, however, by both the introduction of biotechnology (which can create new biological processes and life forms) and advanced information and communication technologies (which can store and transport large amounts of information at minimal cost). As a result, the classification of information and resources as "public" or "private" is beginning to change. Likewise, as new plant varieties become subject to patent law, and information about a particular species stored in databases is subject to private rights, it is becoming increasingly difficult to determine whether biological and genetic resources and associated traditional knowledge are public or private resources.

Free and open access to information and biological and genetic resources is an important tool for sustainable development and biodiversity conservation. Efforts to maintain and protect the public domain have led organizations such as the Creative Commons to promote new forms of intellectual property rights (IPR) that allow the provider to define a spectrum of access possibilities between full copyright (all rights reserved) and public domain (no rights reserved).

Traditional knowledge and the public domain

To date, the majority of attention on the public domain has focused on the challenge posed by IPR for public access to scientific knowledge, biological and genetic resources, and software and databases. The relationship between the public domain and rights over indigenous and traditional knowledge has generally been overlooked. With the assertion that access to information is a key factor in sustainable development and biodiversity conservation, and in recognition of the economic value of information, the "information commons" is seen as a field ripe for harvest and, thus, under increasing threat. This creates a scenario in which the claim of "public domain" can be used as justification for the misappropriation of indigenous and traditional knowledge.

Direct criticism of the application of "public domain" to indigenous and traditional knowledge has been made by, among others, the Tulalip Tribes of Washington, at the 5th session of the World Intellectual Property Organization's InterGovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, held in July 2003 in Geneva. Their contention is that "the concept of public domain is not accepted by many indigenous peoples for their knowledge", and that "open sharing ... does not automatically confer a right to use the knowledge".[5] Under this view, the notion of public domain as it now stands is seen as a colonial tool for the misappropriation of indigenous and traditional knowledge. This leads to the conclusion that the definition of public domain needs to accommodate a number of different world views with regards to the sharing of knowledge, in ways that are respectful of different indigenous and traditional means of knowledge-sharing.

Much traditional knowledge has been published without the prior informed consent of the owners, and is now considered to be in the public domain. In this light, the concept of public domain can be used

as a means for the expropriation of indigenous and traditional knowledge, and the push for access to information for biodiversity conservation and biotechnology development could be seen as a threat to the commons of indigenous and traditional peoples that could potentially lead to even further loss of control and increased misappropriation.

The UNU-IAS report on "The Role of Registers and Databases in the Protection of Traditional Knowledge"[6] examines both the strengths and limitations of registers and databases for protecting traditional knowledge, and proposes the possibility that databases holding traditional knowledge should assume a voluntary trust arrangement that treats all traditional knowledge as being held on behalf of indigenous peoples. The report highlights the "Catch 22" position whereby indigenous peoples are required to have their knowledge registered in the public domain to prevent biopiracy, but in doing so lose control over its subsequent use.

Revising the concept of public domain

The dominant discourse on public domain tends to present a view that there is only one public domain. A contrasting view however, may be proposed based upon the experience of aboriginal peoples in Australia who have their own systems for sharing knowledge governed by specific customary law and practice. This leads to a proposal that there is not one, but rather a number of different, overlapping public domains or knowledge-sharing spaces – each defined according to a range of national, international, or community laws and practices. Indigenous peoples, for instance, have knowledge-sharing spaces that have served many purposes, including the conservation of information, knowledge, and biological and genetic resources. These spaces allow for access to relevant information subject to compliance with specific cultural norms and practices, which may differ from those applicable under national or international law. Information shared freely within one knowledge-sharing domain may be shared subject to certain constraints on subsequent use; such sharing does not, therefore, necessarily imply an intention that the relevant information should become a part of the global public domain.

It is increasingly clear that we need to revisit the notion of "the public domain". Examples such as the Peruvian "Protection Regime for the Collective Knowledge of Indigenous Peoples Derived From Biological Resources" and the South Pacific proposed model law on traditional knowledge directly challenge the belief that traditional knowledge is the common heritage of humankind, and cannot be protected after it has fallen into the public domain. These experiences demonstrate nascent attempts to develop appropriate mechanisms to secure traditional knowledge rights so that further loss of control and misappropriation cannot continue, and so that biodiversity conservation can continue in a fair and equitable manner.

1 See the NatureServe Explorer database at http://www.natureserve.org/explorer/ and the World Bird Database at http://www.birdlife.net/datazone/.
2 See http://www.iabin.net/english/bioinformatics/databases.shtml.
3 Elizabeth Longworth, "The Role of Public Authorities in Access to Information: The Broader and More Efficient Provision of Public Content," *Infoethics 2000*, p. 5, UNESCO.
4 Stephen Brush, "Bioprospecting the Public Domain," *Cultural Anthropology* 14 (4):535-555, 1999.
5 Tulalip Tribes of Washington, *Statement by the Tulalip Tribes of Washington on Folklore, Indigenous Knowledge and the Public Domain July 09, 2003,* Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Fifth Session, Geneva, July 15-17, 2003.
6 Available online at http://www.ias.unu.edu/binaries/UNUIAS_TKRegistersReport.pdf.

Access Regimes and Intellectual Property Rights: Exploring the Interface for Drug Research

By Padmashree Gehl Sampath

Advancing the discussion on the interface between access regimes and intellectual property rights requires focus on questions of legal and institutional design at the national level, and calls for positioning of bioprospecting strategically within broader challenges in the area of intellectual property protection, drug R&D, and public health.

The policy interface between access regimes and intellectual property rights has been amongst the hardest to resolve in the debate regarding the relationship between the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and the Convention on Biological Diversity (CBD). This is due in part to the polarization of issues amongst countries, and in part to the overarching impact of intellectual property rights (IPR) on most issues within bioprospecting. Among the main aspects of this interface that have received widespread attention in the past decade are:

- the limitations of an IPR-like *sui generis* right for protection of traditional knowledge;
- the potential of IPR to undermine benefit-sharing with local and indigenous communities;
- the documentation of traditional knowledge as "prior art" to prevent its undue appropriation;
- the viability of a certification system to trace the origin of genetic resources and/or traditional knowledge; and
- the inter-relationships between IPR and sustainable use and conservation of genetic resources.

Avid controversy on the interface between access regimes and IPR has ensued in various international forums, with several organizations (such as the World Intellectual Property Organization (WIPO), the Conference of the Parties to the CBD, and the World

Trade Organization) actively involved.[1] Whereas some of these issues require multilateral consensus and are being considered in the context of the international access and benefit-sharing (ABS) regime (as discussed in other articles herein), other issues in the access-IPR interface need to be sorted out at the national level. Therefore, moving the discussion on resolving the interface forward requires that countries focus on questions of legal and institutional design at the national level, and that they position bioprospecting as one activity within broader science and technology policy needs of developing countries in the health sector.

In this context, two sets of thematic issues assume importance:

- Which issues need to be resolved at the national level, such that national access regimes and IPR on drug-related products can be designed in a compatible way, in order to achieve the objectives of the CBD?
- How can countries use national access regimes and bioprospecting venues strategically to deal with broader challenges in the area of intellectual property protection, drug research and development (R&D), and public health?

Making access regimes and IPR more compatible for drug research

The experiences of several host countries, both in enacting legal frameworks and in concluding bioprospecting contracts, show that defining and enforcing rights in isolation from the drug discovery and development process can result in a failure to realize the economic potential of bioprospecting for sustainable development and biodiversity conservation. A process-oriented perspective that helps to achieve consensus about appropriate rights' definitions and institutional structures for access and traditional knowledge is one of the most important prerequisites for resolving many of the frictions between access regimes and IPR. Some of the main questions that can be answered through such a perspective are:

- What kinds of knowledge holdings exist in the case of traditional medicinal knowledge at the local levels, and what are their contributions to modern drug R&D?
- Does IPR present a viable option for protecting them?
- Can bioprospecting create sufficient incentives for conservation of genetic resources (and if so, under what circumstances)?
- Under what circumstances do discovered medicinal values lead to unsustainable use, and what kinds of legal solutions can solve this problem best?
- How can countries negotiate for technology transfer in return for access to genetic resources, and under what circumstances will this help build local capacity?

Recent UNU-INTECH work deals with many of these questions. A forthcoming book, *Regulating Bioprospecting: Institutions for Drug Research, Access and Benefit Sharing,* employs an interdisciplinary law and economics methodology to derive optimal property rights structures and institutional mechanisms for regulating bioprospecting for drug research. The focus of the analysis is on the economics of contracts in the drug discovery and development process, using genetic resources to show that the rights exchanged at each stage of the process are complementary. The thrust of the argument is that attempts to define and enforce the rights on access to genetic resources and traditional knowledge in isolation from the drug discovery and development process (and the IPR therein) result in a failure to realize the economic potential of bioprospecting for both sustainable development and biodiversity conservation in host countries. These analytical results are substantiated by examples of bioprospecting collaborations in several countries, and a critique of the institutional and contractual factors that led to their success or failure.

A UNU-INTECH technology policy brief on "Some Interrelationships Between the TRIPS Agreement and the Convention on Biological Diversity"[2] also looks at questions of positive versus defensive protection of traditional knowledge, technology transfer and the CBD, and future directions pursuant to Paragraph 19 of the Doha Declaration on the TRIPS Agreement and Public Health.

Bioprospecting in the context of broader health sector needs of developing countries

Recent literature and policy negotiations have underscored the need to look at bioprospecting as one activity within the broader health sector needs of developing countries, for several reasons:

- Bioprospecting as a new source of medicines and the promise of benefit-sharing from the international drug industry have, unfortunately, found little corroboration in the past decade. Although natural products continue to be a promising source of new drugs (see Newman et al., 2003)[3], the legal uncertainty surrounding the process and the availability of other techniques in the drug discovery process have both contributed to a hiatus in large bioprospecting collaborations.
- The public health crises in many developing countries, caused by diseases like HIV/ AIDS and malaria, have focused attention on the impact of stronger IPR regimes on affordable access to medicines and alternate ways of building local capacity, at least to boost local manufacturing capabilities.[4]
- The large-scale reliance on traditional medicine for health care in developing countries (discussed in the article on page 27) also calls for exploring ways of strengthening these systems within developing countries for reasons of enabling better local health facilities rather than for the promise of "benefit-sharing".

The last two factors, in particular, call for a more proactive stance in developing countries in order to promote innovation in the health sector.

UNU-INTECH has initiated several research projects to explore the intellectual property-innovation-development nexus in the health sector, and to suggest concrete policy interventions to developing countries on how to boost local technological capacity. The UNU-INTECH project on Health for Development is a comparison of the efficiency properties of alternate IPR instruments that have been proposed to foster R&D into neglected diseases (such as patent pools, prizes, and a global research fund), with a strong emphasis on the potential of building local capacity as a solution. It employs a national systems of innovation framework to survey local capacity in pharmaceutical biotechnology in two Asian and three African countries (Bangladesh, India, Nigeria, South Africa, and Zambia) to suggest concrete policy options for building local capacity.

The recently concluded UNU-INTECH project on the Nigerian (Bio)pharmaceutical System of Innovation, taken up on the initiative

of the Nigerian National Biotechnology Development Agency, similarly surveys the Nigerian sectoral system of innovation in pharmaceutical biotechnology to propose policy interventions. UNU-INTECH has also conducted research on (bio)pharmaceutical systems in Cuba, Egypt, Ghana, India, and Taiwan to demonstrate different pathways to building local capacity in this sector for developing countries. These studies are intended to be published as part of a forthcoming book on bioprospecting.

1 Various decisions of the Conference of the Parties to the CBD have dealt in great detail with aspects of the interface between access regimes and IPR. WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore also has been actively involved in this area. More recently, Paragraph 19 of the Doha Ministerial Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/1) instructs the TRIPS Council to examine the interrelationship between the TRIPS Agreement and the CBD, and the protection of traditional knowledge and folklore, apart from other new developments that may emerge from the implementation of Article 71.1 of the TRIPS Agreement.

2 Available online at http://www.intech.unu.edu/publications/technology_policy/tpb_v3_02_2004.pdf.

3 David J. Newman, Gordon M. Cragg, and Kenneth M. Snader, "Natural Products as Sources of New Drugs over the Period 1981-2002," *Journal of Natural Products,* Vol. 66 (2003), pp. 1022-1037.

4 The Doha Declaration on the TRIPS Agreement and Public Health and the 30 August decision of the WTO on implementation of Paragraph 6 of the Declaration deal with allowing countries that have no local manufacturing capabilities to make use of compulsory licensing as contained in Article 31 of the TRIPS Agreement. This has been followed by extensive debate on how local manufacturing capabilities can be built, at least within a select group of least developed countries.

The Role of Customary International Law in Governance of Human Cloning

By Chamundeeswari Kuppuswamy, Darryl Macer, Mihaela Serbulea, and Brendan Tobin

Efforts at the UN to develop a convention banning human reproductive cloning have failed. Instead, a non-binding declaration was adopted. As a result, research into human cloning will likely continue, and birth of the first cloned human may be only a matter of time. UNU-IAS research examines the ethical basis for a ban on cloning and the status of customary international law in this area.

One of the most highly controversial and emotive issues in the global bioethics debates is the issue of cloning of human embryos. Since the cloning in 1997 of the first mammal (a sheep named Dolly), there have been numerous cases of animal cloning in about 10 species of mammals. Animal cloning has brought with it both the pros and cons of human cloning. Ethical concerns related to the uncertainty of scientific outcomes, and issues of individual identity and human dignity, are at the heart of a wide consensus in the international community on the need to ban reproductive cloning, at least in the short term.

There are, however, a growing number of countries – along with numerous scientists and patients' groups – who insist on the merits of what is known as "research" or "therapeutic" cloning. Many believe research cloning holds the possibility of cures for millions of people suffering from various conditions such as Alzheimer's disease, spinal cord injury, and diabetes mellitus.

Debate on these issues has found its way to the UN, where there has been extensive discussion on the need for an international convention on cloning. Although widespread consensus for the banning of reproductive cloning appeared to exist, lack of unanimity on research cloning led to a stalemate – as a result of which, plans for a convention have been shelved. A compromise solution proposed by Italy led to the adoption of a non-legally binding UN Declaration on Cloning in early March 2005.

The Declaration, adopted following a divisive vote, has been the subject of severe criticism from a number of angles; in particular, use of the term "human life" is seen as an attempt to prescribe all forms of cloning activity. The failure of negotiators to overcome ideological and ethical differences provides maverick scientists, determined to clone human embryos, with an opportunity to seek out countries that d not ban reproductive cloning in order to carry on their experiments. At the moment, only a limited number of countries have banned cloning. The impasse at the UN, therefore, makes it almost inevitable that research on cloning of human embryos will continue.

Research carried out at UNU-IAS examines the distinction between reproductive and research cloning and gives an overview of the ethical arguments relating to each. A preliminary report based upon this research notes that the apparent consensus on the need to ban reproductive cloning is, in part, based upon concerns regarding the state of technological capacity and not merely upon ideological and religious or other moral objections to cloning per se. The report argues that obtaining the consensus necessary to adopt a binding legal instrument to ban reproductive cloning may prove more difficult in the future as technology advances and the risks of harm and deformities decrease.

A UNU-IAS study has identified an emerging principle of customary international law supporting a ban on human reproductive cloning, which may strengthen the basis for international efforts to prevent such activities in the absence of a binding international instrument. However, failure to adopt a binding convention will be argued by some to be evidence that there is insufficient international consensus to support claims for the existence of a customary ban of reproductive cloning.

Action by the UN on cloning

The UN General Assembly has considered several proposals that would outlaw reproductive or all forms of nuclear-transfer cloning (including interspecies). In 2001, France and Germany suggested the UN should develop moral guidelines that would lead Member States to enact national legislation and prevent those who have vowed to clone human beings from taking advantage of the legal vacuum that exists in most parts of the world. The Vatican, which has observer status at the UN, was the first to propose that the draft convention be expanded to include a ban on research cloning as well. The Catholic Church argues that embryos should be considered to be "human persons" and is opposed to all research on embryos. A group of nations, led by the United States and Costa Rica, also supported a comprehensive ban, making it unlikely that proposals for a treaty banning just reproductive cloning would be successful, despite a strong consensus in favour of outlawing the practice.

Another group of countries, including many European Union members, wanted to limit any ban to only reproductive cloning. These nations favour the regulation of research cloning, which they think should be left to individual countries. The United Kingdom stated to the General Assembly, in December 2003, "that all types of stem cell research, including therapeutic cloning, should be encouraged". The UK argued that "it would be indefensible to stop this research and deny millions of people – and their families – the chance of new treatments which could save their lives."

There are a number of dilemmas facing regulators on this issue. In the first place, if research cloning involving the use of embryonic stem cells is allowed, this provides opportunities for development and refinement of cloning technology and, with it, the possibility that human cloning will occur. On the other hand, if all research cloning is banned, potentially important life-saving medical technologies will be lost to science. Permitting such research could, however, sustain and expand the existing market in fetuses for research purposes, bringing with it even more ethical dilemmas.

Countries that have regulated therapeutic cloning have adopted varied approaches, with a split between those which ban it outright, a number which allow for use of "spare" embryos from in-vitro fertilization (including Australia, Canada, and Singapore), and those which allow for a wide level of freedom in stem cell research (such as China, Japan, and the UK). During UN discussions of a total ban on cloning research, a number of countries stated that they would not modify their national law and policy in this area. While this does not, in itself, mean the UN is prevented from advancing on the issue of regulating reproductive cloning (including the regulation of therapeutic cloning practices to avoid the chances of reproductive cloning), the success of any legal instrument needs to weigh this division.

In November 2004, efforts to promote a convention on cloning were abandoned when it became apparent that neither the Costa Rican proposal, which had amassed the support of over 60 countries, nor an alternative Belgian proposal, which would have banned reproductive cloning but left countries free to permit research cloning, would obtain the requisite support.

Instead, the UN General Assembly's Legal Committee met in February 2005 to finalize the text of a United Nations Declaration on Human Cloning, on the basis of a draft resolution (A/C.6/59/L.26) submitted by Italy. On 8 March, the General Assembly adopted the UN Declaration on Human Cloning, which calls on world governments to prohibit all forms of human cloning that are "incompatible with human dignity and the protection of human life". The Declaration was adopted by a vote of 84 in favour to 34 opposed, with 37 abstentions. (Countries including the UK and China said they had voted against the Declaration due to references to "human life", which could be interpreted as the basis for a total ban on all forms of human cloning, including that related to stem cell research.)

Despite opposition to the declaration and concerns by scientists that it may lead to restrictions on what they see as desirable therapeutic cloning research, the net effect is a continuing legal vacuum with regard to human cloning. This is seen by some as detrimental to carrying on legitimate research while doing nothing to prevent "forum shopping" for conducting experimental reproductive cloning. Concern regarding the consequences of allowing unregulated research on reproductive cloning led UNU-IAS to begin investigation in 2004 of potential governance options for controlling such research. One early finding of this work is that there appears to be an emerging principle of international law banning reproductive cloning.

International law and cloning

International law derives its authority from four main sources: treaties and conventions, customary law, general principles of law, and the opinions of highly qualified jurists. The most effective and widely established source is an international treaty or agreement that states sign and ratify. In the absence of such a treaty or agreement, or while it is developing, customary international law can also be formed. Customary international law is created and sustained by the constant and uniform practice of states and other subjects of international law. For the formation of customary international law, there needs to be state practice backed by *opinio juris* (i.e., the conviction of states that the consistent practice is required by a legal obligation.). Many countries have legislated on the issue of cloning, either prohibiting or allowing it. Countries like Germany, Spain, and the USA have banned all types of cloning. Others have been selective about a ban and have opted for a highly regulated environment, like the UK. However, there is a near universal ban on reproductive cloning amongst these regimes.

To identify customary international law, we need to look at national legislation and state practice in this area. In April 2004, UNESCO prepared a report on national legislation concerning reproductive and therapeutic cloning showing that 29 countries have adopted legislation prohibiting human reproductive cloning, either explicitly or implicitly. A further 3 countries have moratoriums, 6 have furnished guidelines expressing positions against reproductive cloning, and 13 are drafting legislation for the same objective. This is strong evidence of formation of customary law prohibiting reproductive cloning, since the objective and subjective criteria required for the formation of customary international law are present.

Any declaration by the international community banning reproductive cloning will strengthen the formation of customary law prohibiting such activity, while non-action of the international community will nevertheless allow the formation of customary law. It seems appropriate to identify the adoption of the 1997 Declaration on

the Human Genome and Human Rights, which explicitly bans reproductive cloning in Article 11 – on the grounds that it is contrary to human dignity – as instigating the formation of customary law against reproductive cloning.

In the case of research cloning, it is difficult to identify a trend sufficient for formation of customary law due to the evidence of contrasting state practice. For "state practice to create a rule of customary law, it must be virtually uniform, both internally and collectively. 'Collective' uniformity means that different States must not have engaged in substantially different conduct, some doing one thing and some another."[1] While Belgium, China, Finland, India, Japan, Republic of Korea, Netherlands, Singapore, Sweden, and the UK have legislated to allow research cloning, Austria, Colombia, Costa Rica, Denmark, Germany, Iceland, Norway, Peru, Slovakia, Spain, South Africa, and Switzerland have enacted laws prohibiting research cloning. Any international declaration on therapeutic cloning will have a major effect in the formation of customary international law.

Pragmatism and ethics

Polarization of opinions on cloning led to a downgrading of the UN negotiations from proposals for an international convention to a Declaration on Human Cloning. Those countries that have promoted the idea of the need to "show respect for human life" are likely to raise the same issue within the framework of ongoing debates at UNESCO to develop a Universal Declaration on Bioethics. This will allow time for more considered debate than was possible under the tight timeline provided for resolution of negotiations on the Declaration on Human Cloning. It is possible that within the context of the UNESCO negotiations, efforts will be made to argue that definition of what amounts to human life, at least in so far as it applies to the issue of regulation of research cloning, should be decided at the national level.

Although the debates in the UN General Assembly ended on a less than satisfactory note, the UN and its agencies should explore other means to stay involved in developing a regulatory mechanism for cloning, with due attention to customary international law. A preliminary working draft of UNU-IAS research on the issue of international law and cloning was made available for participants in the meeting of the Working Group of the 6th Committee. The Institute is continuing its investigation in this area, and a policy report is due for release later in the year. The Biodiplomacy Initiative will continue its work in the area of bioethics, including through its participation at the UN Inter-agency Working Group on Bioethics and in the UNESCO debates to develop a Universal Declaration on Bioethics.

1 "Statement of Principles Applicable for the Formation of General Customary International Law", Final Report, International Conference, London 2000, International Law Association.

The Importance of Traditional Knowledge for Meeting Public Health Needs in Developing Countries

By Emilia Janska, Mihaela Serbulea, and Brendan Tobin

A large part of the world's population relies on traditional medicine as the primary source of health care. Though long dismissed by Western medicine as unscientific and unvalidated, traditional medicine is increasingly being recognized as providing sound, reliable, functional, and accessible health solutions for many ills.

Cultural and historical influence

Traditional knowledge plays an important role in meeting the health needs of a large proportion of the global population – a fact that is increasingly being recognized as relevant for national health planning and development policy-making. Traditional medicine is highly influenced by the culture and historical conditions within which it first evolved, and as such eludes precise definition, often containing diverse and sometimes conflicting characteristics and viewpoints. The World Health Organization (WHO) has adopted a very general definition that describes traditional medicine as knowledge based on the practices, beliefs, and experiences indigenous to different cultures, whether codified in writing or transmitted orally, used in the maintenance of health as well as the prevention, diagnosis, improvement, or treatment of physical and mental illness.[1]

In many developing countries, the majority of the population is dependent on traditional medicine to meet its primary health care needs.[2] The main reasons are affordability, accessibility, and acceptability – which are determined by a range of social, economic, geographical, and cultural factors as well as by the efficacy of the treatment. In some rural areas of Africa, for instance, the ratio of traditional healers to the population is 1:200 whereas the ratio of allopathic practitioners is 1:20,000 or less. Under such conditions, access to traditional medicine is of great importance.[3] Despite its importance, however, traditional health practitioners in many countries remain marginalized and often stigmatized by health authorities; awareness of the importance of their role in meeting public health needs is only recently being recognized.

Some countries, though (such as China, Democratic People's Republic of Korea, Republic of Korea, and Viet Nam), have fully integrated traditional health practices in their national health programmes, and are actively promoting traditional medicine both

domestically and abroad for health as well as commercial reasons. Others countries have adopted a different approach, promoting recognition of traditional medicine as complementary to the established medical system. Peru, for example, has recognized the Shipibo indigenous people's traditional medicinal practices as complementary to the national health system, while Thailand has adopted specific legislation to regulate traditional medicine, and Turkmenistan has established a system for licensing Tebib healers.

Enhancing traditional medicine for public health care

WHO's "Traditional Medicine Strategy for 2002–2005" focuses on four areas identified as requiring action if the potential of traditional medicine to play a role in public health is to be maximized: policy; safety, efficacy, and quality; access; and rational use. In recent years, most research on traditional medicine has focused on clinical and experimental medicine. There is now a need for research that considers the cultural, social, political, and economic aspects of traditional medicine in order to maximize its potential contribution to healthcare globally.[4]

It is ironic that while the majority of medical health research budgets is dedicated towards developing medicinal products for ailments of the rich, a significant number of leading drugs have been developed using the biological resources and traditional knowledge of developing countries whose populations cannot afford them. Considering the growing awareness of the value of traditional knowledge, and of its importance for public health needs, there is need for a significant investment of human and economic resources in the further enhancement of traditional medicine to ensure its efficacy and reliability and to improve delivery. Promoting awareness of the reality behind traditional medicine, its importance, the challenges for its promotion, and the need for protection of the populace against malpractice is a task that is being addressed by a number of national governments and international organizations.

To this end, the Biodiplomacy Initiative at UNU-IAS has initiated a research project on The Role of Traditional Knowledge in Public Health. This comparative research project looks at modalities for promoting recognition and respect for traditional medicine in public health policy-making and, where justified, its integration into health delivery systems in a respectful and culturally sensitive way. The project seeks to determine the manner in which national public health care will be enhanced by policies that encourage collaboration between traditional and modern health systems and their respective practitioners.

An initial set of case studies is being prepared with collaborators in Canada, Cote d'Ivoire, India, Mongolia, Peru, Trinidad and Tobago, and Japan. The study involves multiple triangulation (combining, in one investigation, multiple observers, theoretical perspectives, sources of data, and methodologies) to establish the credibility of qualitative analysis and provide clearer understanding of problems. It employs several methods of data collection, including questionnaires, observation, interviews, and analysis. The collaboration of national authorities, universities, local researchers, traditional healers, and indigenous health organizations is considered a vital part of the process and is invaluable for ensuring the quality of information for analysis.

A number of key challenges to incorporating traditional medicine into public health policy-making and delivery have already been identified:

- Traditional medicine has a different philosophical and cultural background than modern medicine. As a result, formal scientific methods have often failed to "prove" what centuries of continuous use have "demonstrated". There is a need for culturally appropriate research methodologies to investigate the scientific credibility of age-old therapeutics.
- Knowledge transfer must take place in a culturally sensitive manner. Education of community healers in the basics of nutrition and hygiene, of medical students and professionals in traditional practices, and of the general public will increase mutual understanding and access to safe and effective therapies
- A training and licensing system for traditional practitioners will enhance their authority and contribute to closing the gap between modern and traditional medicine. Such a system must be based on the customary law and practices of indigenous peoples and local communities, but must also ensure effective regulation of healers who serve the wider national or global community.
- Community and policy studies need to examine whether traditional medicine is a cost-effective and socially accepted complement to modern medicine, and vice versa.
- Investigating possibilities to build the capacity of traditional healers to utilize a certain range of Western medicinal practices may strengthen the healer's position and role in the community, and reduce resistance to the introduction of modern medicines. Similarly, training medical practitioners to understand and respect the value of traditional medicine by providing opportunities for patients to access their traditional healers while undergoing hospital and other treatment can ensure more effective long-term treatment of illnesses and reduce tensions between traditional healers and the medical establishment.

UNU-IAS research on the role of traditional knowledge in health delivery systems

Three field trips have been undertaken as part of this research. The first, in October 2004, involved visits to Cote d'Ivoire, Nigeria, and Senegal.[5] Meetings with traditional healers, national health authorities, academics, medical doctors, researchers, and others helped to identify the importance of traditional medicine and the most pressing problems facing it. Among the factors given for reliance on traditional medicine were the fact that traditional healers are generally accessible (they tend to live in the same community as their patients), speak the local language, and have good counselling skills. In addition to cultural beliefs, which lead many people to seek treatment first from a traditional healer, another important factor is the economic one; Western-style health care is routinely out of reach due to geographic access and financial limitations.

One of the main problems is charlatan healers. Population migration to urban areas has loosened community ties and alienated large numbers of people. In this context, the numbers of persons who claim to be "traditional" or "spiritual" healers are burgeoning, and their credentials are difficult to scrutinize. Anecdotal evidence claims that 70 per cent of healers in suburban areas in Africa are charlatans.

Amerindians in Trinidad and Tobago offer a traditional medicinal tonic of snakes, herbs and stones, 2004. (Photo: Emilia Janska)

Another category of healers are street vendors of medicinal plants; because the herbs they sell are often collected by others, the identification of species (and, thus, their curative properties) is difficult to guarantee.

Despite these difficulties, departments for the promotion of traditional medicine in the ministries of health of many African countries (including Cote d'Ivoire) are increasingly aware of the need to build on the traditional medicine assets existing in communities. Professional associations of traditional healers have been successfully established in a number of countries in Africa, providing a mechanism that can be utilized to differentiate authentic healers from charlatans.

In December 2004, a second field trip was undertaken in Trinidad and Tobago – a multicultural and multiethnic society in which traditional medicine of two indigenous tribes, the Caribs and Arawaks, together with the traditional knowledge of Indians, Africans, Chinese, Mediterranean, and other nationalities, is still practiced. Traditional healing practices include herbal medicine, spiritual therapies, meditations, manual therapies, yoga, and various exercises. The high prevalence of use of medicinal herbs is significant; about 150 medicinal plants species are used traditionally as teas to treat colds, fevers, and other ailments.

A serious problem is that many people self-medicate without knowledge of proper dosages, which can be highly hazardous. The increasing availability of Western clinical services has led to a progressive loss of many important facts about usage of local herbs, plants, and trees. "Bush doctors" are dying out, and there is a great lack of documentation of their knowledge. Fortunately, this situation is now changing. A major step forward in documenting Caribbean herbals has been the production of a Caribbean herbal pharmacopoeia published by TRAMIL (Traditional Medicine in the Islands). TRAMIL's work is focused on validating the traditional Caribbean ethnomedicines, and the group works in direct contact with individual, low-income families who rely largely on home remedies.

A highly successful workshop in April 1998, at which traditional herbal practitioners met with the scientific community, led to the formation of the Caribbean Association of Researchers and Herbalists (CARAPA), which is gaining recognition and support from the government. CARAPA holds annual conferences with the aim of providing a scientific rationale for the traditional uses of plants; facilitating information exchange; educating local people on safe use of traditional medicines; and supporting the development of a sustainable herbal industry producing a range of safe and cost-effective herbal products. Last year, the medical school in Trinidad introduced herbal medicine into its curriculum; some students carried out research on acceptance and knowledge of medicinal herbs by physicians, which found a high acceptance level but very poor knowledge (which decreases their ability to adequately advise patients on the risks and benefits, and possible herb-drug interactions). The resurgence in use of medicinal herbs presents a unique challenge in a managed healthcare system.

In preparing the case studies for Trinidad and Tobago, meetings were held with the University of West Indies, University Hospital, CARAPA, and representatives of Public Health as well as with local and indigenous peoples of the Santa Rosa Carib Community. Ongoing collaboration with national researchers and experts will be a crucial element of the process for developing the UNU-IAS comparative report.

A third field trip to Mongolia was carried out in mid-January 2005. All field trips are reported on the UNU-IAS website[6] soon after completion.

The case studies highlight experiences, differing approaches, possible obstacles, and best practices in integrating traditional knowledge into national health policies or creating partnerships between traditional healers and medical doctors. The research also provides useful insights into the ethical aspects involved in evaluation, utilization, and sharing of traditional knowledge in different cultures. The results of this research will be presented at relevant international forums relating to traditional knowledge protection and to development of public health strategies.

UNU-IAS believes that drawing attention to successful experiences in promoting traditional medicine in a variety of differing cultural, political, and economic contexts will help to draw increased attention to the promise that it holds, and to the need for concerted efforts at the national and international level to build respect, protection, and incentives for use and development of traditional medicines.

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1 "WHO Traditional Medicine Strategy 2002–2005," WHO, Geneva: http://www.who.int/medicines/library/trm/trm_strat_eng.pdf.

2 Africa: 80 per cent; India: 67 per cent; China: 40 per cent; Chile: 71 per cent; Colombia: 40 per cent. Statistics from Geneva Foundation for Medical Education and Research: http://www.gfmer.ch/TMCAM/PGC_TMCAM_2004.htm.

3 In a conceptual framework on poverty and ecosystems, prepared by United Nations Environment Programme, access to traditional medicine is regarded as one of the ten constituents of well-being.

4 G. Bodeker and F. Kronenberg, 2002, "A Public Health Agenda for Complementary, Alternative and Traditional Medicine", *American Journal of Public Health,* 92, 10:1582-1591.

5 The field trip to Senegal was featured in early 2005 on the Development Gateway website: http://topics.developmentgateway.org/indigenous/highlights/viewHighlight.do~activeHighlightId=103240?intcmp=915.

6 See the UNU-IAS website at http://www.ias.unu.edu.

The Search for Effective Capacity Development on Access and Benefit-Sharing

By Haruko Okusu and Brendan Tobin

Effective global governance of access to genetic resources and benefit sharing is dependent upon the adoption and implementation of relevant law and policy by national governments. Capacity development is key to enabling developing countries to meet this challenge.

During the past 20 years, developing countries have found their global environmental commitments mushrooming under a host of multilateral environmental agreements (MEAs), each of which creates new obligations regarding national reporting, establishment of administrative and legal frameworks, and institution-building. Implementation of the Convention on Biological Diversity (CBD) is a case in point. While almost every decision of the CBD signifies a need for further capacity development, in-depth consideration of how to meet these needs is still in its infancy.

Parties to the CBD today face additional challenges posed by the Plan of Implementation of the 2002 World Summit on Sustainable Development (WSSD), which established commitments to the significant reduction of biodiversity loss by 2010; operationalization of the Cartagena Protocol on Biosafety; implementation of the Bonn Guidelines on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization; and negotiation of an international regime on access and benefit-sharing (ABS). Coordinated capacity development efforts are, therefore, vital to support the process of implementing MEAs.

Trends and challenges in ABS and biosafety capacity development

ABS, which has been high on the CBD agenda since the Convention's inception, presents a classic case in which capacity development could play a significant role for the successful implementation of an MEA. Some countries have developed national ABS frameworks, relying mostly on national capacity and experiences in bioprospecting negotiations. The vast majority of countries, however, still lack ABS law and policy, and even where adopted, successful implementation has been difficult (frequently acting as a disincentive for access rather than working to facilitate good practice). Meanwhile, capacity to negotiate equitable ABS agreements has been hampered by a lack of human and financial resources as well as a major information gap.

The result is a piecemeal approach to developing ABS schemes at the national level, and an inefficient system of ABS governance. The adoption of the Bonn Guidelines, and the WSSD's call to negotiate a benefit-sharing regime under the CBD, has brought a new sense of urgency to the debate and focused attention on identifying potential means for consolidating existing experiences as well as on bringing countries "up to speed" through effective capacity development

Local community members participate in a UNU-IAS capacity development and planning workshop for indigenous peoples on the theme of traditional knowledge, Peru, 2005. (Photo: Brendan Tobin)

efforts. Based upon decisions taken at the Seventh Meeting of the Conference of the Parties to the Convention on Biological Diversity (COP 7), calls have been made for concerted efforts to build capacity on ABS – with a particular focus on developing countries – in order to ensure effective implementation of the Bonn Guidelines.

In meeting the significant challenge that this poses, an opportunity exists in the form of an already strong nucleus of institutions and individuals whose collective experience in the field can provide a wide range of experiences, options, and methodologies for developing national capacity. Achieving a practical level of synergy between capacity development efforts is an extremely difficult process, and the tendency towards competition for funds as well as for quick, concrete outcomes is often detrimental to effective global coverage. For this reason, there is a need for international development agencies and non-governmental organizations (NGOs) to work together to identify areas for synergy and consider options for improved coordination on ABS capacity development. Developing the confidence and trust necessary to secure such cooperation is a key challenge for all concerned.

Capacity development for biosafety

The Cartagena Protocol on Biosafety was adopted in 2000, after many years of tough negotiations and in the midst of rapidly increasing public concerns about the safety of genetically modified organisms (GMOs). Some organizations and governments developed their own biosafety capacity development initiatives without waiting for guidance from the Biosafety Protocol; others opted to wait until the Protocol set capacity development priorities. Attempts to network these capacity builders and synergize activities at regional/national levels through the development of coordinated action plans were relatively short-lived, due to insufficient enthusiasm and support. This is in contrast to networks that were initially conceived for negotiation purposes, and evolved into outreach activities through the provision of technical information to the general public.

With the entry into force of the Biosafety Protocol, a global capacity development project was initiated by the United Nations Environment Programme (UNEP). With funding from the Global Environment Facility (GEF), the programme is designed to assist over 100 countries to prepare their National Biosafety Frameworks to meet the requirements of the Cartagena Protocol. Using a country-driven process, the global project helps each participating country to set up a national framework for management of living modified organisms (LMOs) and promotes regional and sub-regional collaboration and exchange of experience on issues of relevance through convening of regional workshops.

The project so far has been successful in building a baseline capacity level on biosafety for the participating countries as well as in promoting networking among the countries to share lessons and experiences. The project has had less success, however, in addressing the issues of how to build on existing capacity development experiences, and how to collaborate with other agencies working at national and regional levels to enable a more effective development and use of national biosafety capacity.

This experience highlights the importance of securing effective collaboration amongst institutions and individuals with expertise in capacity development at the earliest possible stage of project development. In each case, it is necessary to consider whether collaboration and synergy are realistic and, if so, what practical options exist for working together. Building collaboration will not, per se, imply involvement in joint capacity development projects, but it may prove most effective in developing a creative and dynamic means to exchange information, pool existing expertise, and work towards a common purpose while balancing the needs and obligations of individual capacity builders and their institutional priorities. UNU-IAS has commenced a project to carry out a high-level evaluation of ongoing biosafety capacity development activities, the results of which will further inform work on ABS capacity development.

UNU-IAS contribution to ABS capacity development collaboration

During the past decade or so, a number of important and innovative efforts have been undertaken to develop national and regional ABS law and policy, as well as to build local community and indigenous peoples' capacity to regulate access to genetic resources and traditional knowledge. These experiences have generated a nucleus of expertise and a growing body of materials on ABS that may provide the basis for ABS capacity development. However, despite some informal collaboration between institutional programmes, and a measure of cross-fertilization through recourse to the same nucleus of experts, no formal effort has been made to develop a global response to capacity development needs or to harmonize and synergize efforts in order to ensure maximum outreach and the most effective use of resources. Materials are often hard to source, and there has been no comprehensive study of capacity development programmes and the effectiveness of the methodologies adopted. As a result, planning of capacity development programmes is carried out in less-than-optimal conditions.

The UNU-IAS Biodiplomacy Initiative seeks to change this scenario and help catalyse a heightened level of collaboration, planning, and information dissemination with a view to promoting greater local-level self-sufficiency. To this end, work is ongoing to promote what is termed "capacity development mapping," the intention being to provide facilitated access to information on the status of ABS law and policy worldwide and on capacity development programmes, needs, expertise, materials, methodologies, and funding. This information will serve to provide developing countries with a menu of experts, materials, and methodologies from which to devise national and regional capacity development programmes that respond to their own needs, priorities, and social, cultural, and economic reality.

The information will also serve the interests of local and indigenous communities seeking to develop their own capacity development programmes. The resulting map of capacity development needs, expertise, ongoing projects, and funding priorities of aid agencies will provide international organizations and other donors and aid agencies with a clear picture of who is funding what, and where. This will help highlight "orphan" countries and regions where funding for ABS is not available, with a view to promoting more effective use of resources and providing more complete global coverage.

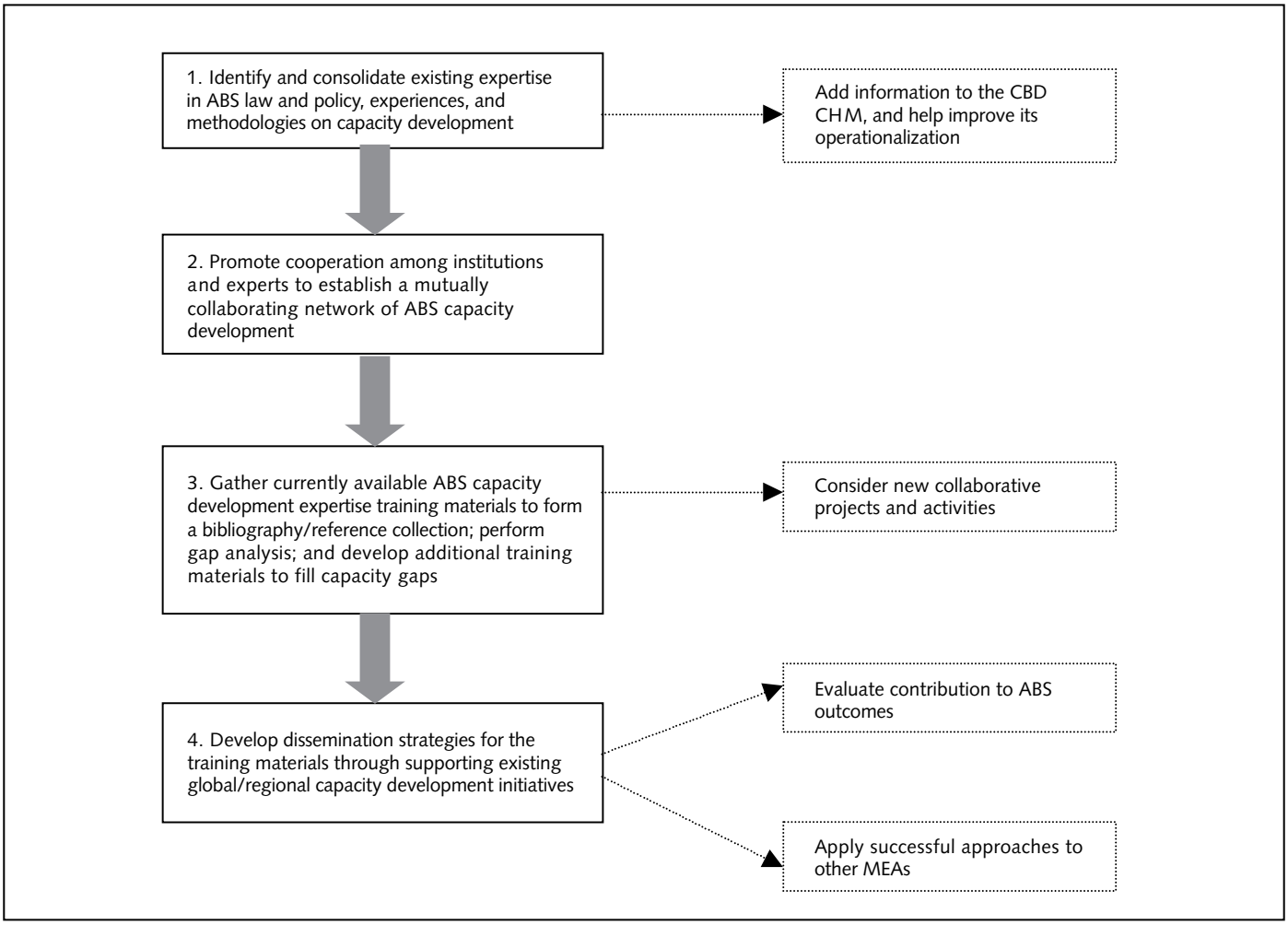
Some information of this nature is available on the CBD Clearing-House Mechanism (CHM), but it needs to be made more easily accessible and digestible. This work, therefore, will not duplicate but rather complement and strengthen the CHM. To that end, UNU-IAS will maintain close consultation with the CBD Secretariat in order to ensure that the expertise and information identified through this collaboration will be available through the CHM.

Development of a collaborative capacity development communication effort would include the steps set out in the figure on this page.

In ABS, there is a relatively small core of experts who, despite a significant amount of collaboration amongst certain institutions and individuals, still operate in a relatively independent manner. Efforts to build closer collaboration have taken place with discussions in Davis (October 2003), Montreal (December 2003), and Kuala Lumpur (February 2004), and strong interest in collaboration has been expressed among the stakeholder organizations.[1] Some participants suggested that UNU-IAS take on an active role in developing coordination opportunities for creating and utilizing capacity development tools. UNU-IAS has thus commenced the collection of information on the capacity development efforts of a number of key organizations; this has been circulated for comment and will be submitted to the CHM in the near future.

The effectiveness of a capacity development strategy may be determined by the extent to which reliance on external capacity builders is reduced. Historically, capacity development programmes have tended to rely on structured capacity development workshops held among mid-level government and NGO personnel. This has proven to be ineffective, as personnel can quickly change, so there is a need to adopt new strategies that can ensure the maintenance of a core of national and regional expertise in ABS issues to facilitate ongoing training. UNU-IAS has adopted a policy of capacity development that targets not only government officials and NGOs but also includes selective training of trainers and promotion of collective learning opportunities for indigenous peoples and local communities.

To complement hands-on training, information dissemination will play a crucial role in ensuring the long-term effectiveness of capacity development efforts. This will require a bibliography of existing materials and of training methodologies, as well information about their accessibility. From this, a gap analysis will serve to focus future research activities and preparation of new materials by appropriate experts. The challenge will be to make these materials and the content, implementation, and outcomes of future capacity development programmes available to the widest possible audience. UNU-IAS envisages the use of online education tools as a potential means to most effectively provide ongoing ABS capacity



Steps in the ABS collaborative capacity development effort, and other possible contributions

development support to the global community.

The Biodiplomacy Initiative is currently collaborating with UNDP and UNEP in the development of a number of regional ABS capacity development projects. These include potential projects in ASEAN countries, Central Asia and Mongolia, East Africa, Latin America, and the Pacific region that are envisaged as the initial phase of a more comprehensive global programme on ABS capacity development. Effective monitoring and evaluation of this work will serve to ensure an iterative process, the results of which will more effectively lay the basis for future capacity development activity.

In its efforts to support this programme, the UNU-IAS Biodiplomacy Initiative team aims to continue in its efforts to build a network of ABS expertise, and also aims to promote collaboration within the UNU family by working closely with the UNU-IAS Education for Sustainable Development Programme. In addition, in recognition of the growing importance of new technologies to transmit information online to the public, the Biodiplomacy Initiative intends to work with the UNU Online Learning Programme (Media Studio) to use the Internet as a means to enhance outreach.

The efforts being taken to develop collaborative working strategies and mechanisms to help secure continuity of ABS capacity development should serve as a useful precedent for designing more effective responses to capacity development needs that may arise under MEAs in the future.

1 Among the key stakeholders in ABS that have expressed interest in collaboration are the Center for International Environmental Law (CIEL); Centre for International Sustainable Development Law (CISDL); Foundation for International Environmental Law and Development (FIELD); International Development Research Centre (IDRC); International Plant Genetic Resources Institute (IPGRI); IUCN-The World Conservation Union; Peruvian Environmental Law Society (SPDA); Secretariat of the Convention on Biological Diversity (SCBD); South Pacific Regional Environment Programme (SPREP); United Nations Development Programme (UNDP); United Nations Environment Programme (UNEP); and World Intellectual Property Organization (WIPO).

ABS Capacity Development and the Central Asia and Mongolia Bioresources and Biosecurity Network

By Kirsten Neumann and Giulio Quaggiotto

Central Asia and Mongolia – amongst the world's 14 centres of crop diversity – are rich in traditional knowledge. Extreme environments make the region a valuable source of genetic diversity. UNU-IAS is working with countries of the region to develop access and benefit-sharing programmes that respond to local priorities.

The world-renowned Silk Road trade route in Central Asia stretches for over 4,000 miles through some of the world's highest mountain ranges and most treacherous deserts. Silk, jade, and precious metals were transported and traded along this route, as well as natural products such as nuts, flowers, spices, dyes, incense, and oils. Though long-since replaced by more cost-effective transport systems, the Silk Road remains a testament to the important role the region once played in international trade. However, with the significant exception of the Republic of Kazakhstan, which is on its way to joining the world's foremost oil economies, the countries of Central Asia and Mongolia now find themselves amongst some of the world's weakest economies.

Biodiversity under threat

While the cultural and historical wealth of the Republic of Kazakhstan, Kyrgyz Republic, Tajikistan, Turkmenistan, Uzbekistan, and Mongolia is widely recognized, less well known is the region's important biodiversity, and its recognition as one of the world's 14 so-called Vavilov centres of crop diversity.[1] These countries are an extremely rich and important repository of biodiversity, including many endemic species adapted to harsh, fragile, and often extreme environments, and they share a history as centres of origin for many domesticated plant species (such as the wild cultivars of apricots and walnuts) and endemic medicinal plants (such as liquorice and Trans-Caspian thyme).

They are also rich in traditional knowledge. In Tajikistan, for example, 1,700 different herbs are used in traditional medicine, and in Turkmenistan over 200 recognized traditional Tebib healers continue to carry out their healing activities (which range from treating fractures and dislocations to herbal treatment of skin, internal or other diseases).

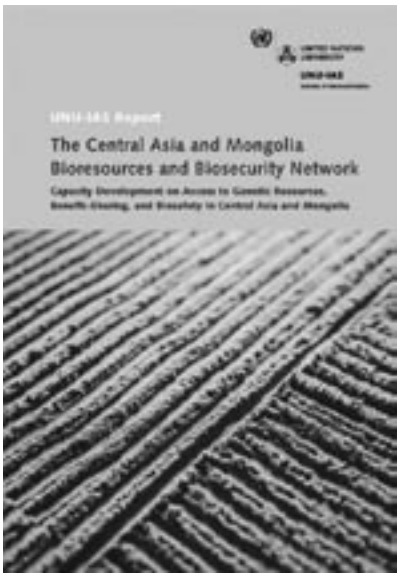
The countries of the region share, in varying proportions, a common geography that includes arid and semi-arid and mountainous ecosystems and a strong continental climate. Half of Tajikistan is located at altitudes of above 3,000 metres; 80 per cent of Uzbekistan and Turkmenistan are covered by deserts; and 94 per cent of Kyrgyzstan lies above an altitude of 1,000 meters.

The extreme environments and diverse ecosystems of the region present interesting opportunities for bioprospecting and discovery of new species or genes with unique properties. Mongolia, for instance, is characterized by permafrost areas, saline lakes, and the large Gobi desert in the south (with less than one per cent arable land). These conditions have formed a nomadic, tribal culture that, over centuries, has accumulated detailed knowledge of pasture usage, climate, vegetation and soil conditions, and terrain, which form the basis of modern animal husbandry.

Despite this important diversity, the region is among the most

environmentally vulnerable in the world, threatened by land degradation, desertification, deforestation, salinization and erosion of soil, overuse of biological resources, and soil, water, and air pollution. These problems are exacerbated by growing pressures of economic development in areas such as mining, hydro-electric power projects, and agricultural development. In addition, the countries of the region face diplomatic challenges over the need to cooperate in matters of cross-border management of ecosystems and water resources.

Generally, living standards have decreased since the end of Soviet rule. While the Republic of Kazakhstan, rich in oil and gas, is experiencing economic growth and increased wealth for some parts of its population, other countries in the region are now ranked among the poorest in the world in terms of gross domestic product, with large parts of their populations surviving on an average income of less than two US dollars a day. One consequence is increased pressure on genetic resources. In Tajikistan, Mongolia, and Kyrgyzstan, medicinal plants, which are mainly used in traditional Chinese medicine, are often sold for a price far below their market value. Lack of adequate legal regimes to regulate access to genetic resources and benefit-sharing (ABS), protection of traditional knowledge, and the safe handling of genetically modified organisms further reduces the capacity of countries of the region to respond to challenges of the moment.



This report is available for download from http://www.ias.unu.edu/binaries/UNUIAS_CentralAsia2ndEd.pdf

A further issue of concern for the countries in the region is that during the Soviet era, large collections of their biological and genetic resources were made, many of which are still held in the Vavilov Centre in St. Petersburg (the third-largest gene bank in the world). This poses a threefold problem:

- the countries of the region cannot exercise their sovereign rights over their genetic resources;
- their scientists' research activities are inhibited by lack of access to the collection; and
- the collection is threatened by inadequate funding, which is particularly worrisome as one-third of the collection can no longer be found in the wild.

Central Asia and Mongolia have a highly educated and extensive base of sound local scientific capacity and knowledge of their national environments. Unfortunately, this capacity is being over-looked and threatened by a lack of funding to maintain and update existing databases and collections or to maintain scientific institutions.

Developing capacity to protect and conserve biodiversity

To date, relatively little international attention has been given to providing support for the conservation and sustainable use of the biological diversity of this region. Conscious of these needs, UNU-IAS – at the request of concerned scientists from the region – has embarked upon a capacity development programme in the region. The programme focuses primarily on building regional capacity to respond to a number of pressing biodiversity-related issues, including ABS, protection of traditional knowledge, and biosafety.

Two regional workshops have been held: the first in 2002 in Mongolia, which provided an introduction to relevant Multilateral Environmental Agreements for policy makers and scientific experts from the region, and the second in 2003 in the Kyrgyz Republic, which brought together representatives of government, academia, and non-governmental organizations (NGOs) to discuss capacity development needs and identify priority actions. UNU-IAS staff prepared a policy report based on national case studies and the outcomes of the two workshops.

These workshops led to the establishment of a Central Asia and Mongolia Bioresources and Biosecurity Network. The principal aim of this network is to assist Central Asian countries and Mongolia to conserve and sustainably use their biological diversity through the exchange of scientific, technical, environmental, and legal information; case studies; best practices and experiences on issues related to biodiversity and biosecurity; regional cooperation; and continued capacity development activities. A national workshop was held in Uzbekistan, in July 2004, in cooperation with the national Academy of Science, to raise awareness of ABS issues among different representatives of the government, academic and research institutions, and civil society.

Experts in the region identified the need to strengthen the legislative base in their respective countries. Although all the countries have legislation in place to protect biodiversity, action is only just commencing for the development of law and policy on ABS, protection of traditional knowledge, and biosafety. To support this process, UNU-IAS, together with the Central Asia and Mongolia Bioresources and Biosecurity Network, organized a regional meeting of legal experts in Kazakhstan, in July 2004, to discuss ABS legislation and enhance regional and national capacity in this area. Country representatives attending the workshop agreed to form a working group on legal issues and to prepare case studies to analyse the legislative framework in each country and identify gaps.

One of the key difficulties for the region has been a lack of adequate information and limited access to information to promote institutional coordination within governments and between governments and stakeholders. To address this, UNU-IAS has worked with the Central Asia and Mongolia Bioresources and Biosecurity Network to develop a model bilingual Russian-English website, including a series of communication tools. It is intended that the website, once operational, will be hosted by the Mongolian Academy of Sciences. Plans to launch the website have been postponed, however, due to a shortage of committed funding.

Traditional knowledge is viewed as an integral part of the region's history and culture, and as a source for renewal and sustainable development. To ensure local communities' rights over traditional

knowledge, workshop participants recommended the establishment of regulations for ABS and regional networks to promote dialogue between government bodies and local communities. In response, UNU-IAS is working with the Uzbek Patent Office and the World Intellectual Property Organization to organize a regional workshop for local communities and traditional healers in October 2006.

The Network

Over the next two years, formal establishment and implementation of the Central Asia and Mongolia Bioresources and Biosecurity Network will take place. The priorities of the Network for this biennium are to build awareness of the relevant international context, facilitate the exchange of information, educate about and raise awareness of the issues, and strengthen the legislative basis. This work will be promoted by an interim secretariat located in the Kyrgyz Republic, with the support of an international advisory council and UNU-IAS.

The Network has already established a working group of legal experts on ABS issues. Additional working groups are expected to be set up in the areas of traditional knowledge, biosafety, and inventory of genetic resources. The group has begun work on the preparation of national case studies of existing ABS law and policy as a first step towards promoting enhanced national regulation on ABS. UNU-IAS is providing support to the working group in its research activities.

In cooperation with the International Science and Technology Centre (based in Russia) and UNU-IAS, the Central Asia and Mongolia Bioresources and Biosecurity Network is looking at convening a meeting to elaborate the possibility of and ways to develop a regional database of genetic resources that would integrate and standardize currently scattered information. Together with national and international NGOs in the region, UNU-IAS is working in collaboration with the recently established legal experts working group and the Network to develop national case studies on information dissemination and public participation in environmental decision-making. This information will feed into a third regional biosecurity workshop ("Biosecurity III") planned for 2005, which will focus on ABS legislation, information dissemination, and public participation.

UNU-IAS continues to provide technical support to the secretariat of the Network and organize capacity development activities in the region. The success to date in building awareness of the needs for regional collaboration has been enhanced by the collaboration and support of a number of international and regional partners.[2] Continuing this collaboration will offer the possibility for long-term sustainability of the nascent regional cooperation through building of local capacity to assume responsibility for the design of functional programmes that respond to local needs and challenges, and to bring a common voice to the international negotiation process.

At the request of government agencies, NGOs, and international institutions, UNU-IAS is supporting the Network in the development of a comprehensive capacity development programme on ABS for the region. The experience gained in this region will, it is hoped, be replicable in other regions, such as the Caucasus.

1 The Vavilov centres of crop diversity are named after Russian biologist and geneticist Nikolai Vavilov (1887–1943), whose research led to the identification of 14 areas of high diversity of crops worldwide.

2 These include IUCN-The World Conservation Union, UNESCO, United Nations Environment Programme, International Union for the Protection of New Varieties of Plants (UPOV), Japan Bioindustry Association (JBA), and Showa-Shell Foundation.

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Work in Progress *A Review of Research Activities of the United Nations University*

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