Moving towards fair and equitable benefit-sharing in research and development

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Moving towards fair and equitable benefit-sharing in research and development: the Nagoya Protocol on Access and Benefit-sharing to the Convention on Biological Diversity

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Catharanthus roseus, commonly known as the Madagascar periwinkle. The species has long been used in Indian and Chinese traditional medicine. It is also the source of the substances vinblastine and vincristine, widely used in chemotherapy to treat different types of cancer (Source: Wikipedia)

by Elsa Tsioumani

February 2015: The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention on Biological Diversity (CBD) is an innovative international instrument aiming to advance fair and equitable benefit-sharing in the field of biodiversity-based research and development.

The Nagoya Protocol entered into force on 12 October 2014 having been ratified by 54 countries at that time. The first meeting of its Parties (COP/MOP 1) was held from 13-17 October 2014, during the second week of the twelfth meeting of the Conference of the Parties (COP 12) to the CBD (See recent BENELEX blog post). After providing a short introduction to ABS and the Nagoya Protocol, this blog post highlights the main
developments that took place in October 2014 and ongoing work that is of relevance to the BENELEX project.

**Bioprospecting, ABS and the search for equity**

The evolution of modern bio-sciences has led to the rapid growth of scientific research on genes and chemical substances found in living organisms for use in different sectors, including agriculture, medicine, cosmetics and energy. In the field of medicine alone, terrestrial plants and microorganisms are important natural sources used in the development of new medicines, as illustrated by the case of the Madagascar or rosy periwinkle above.

Bioprospecting – the search for plants and animals from which commercially valuable compounds can be obtained, is often a transnational activity: it involves situations where genetic resources are found in one State but are used in another. Most of the world’s biodiversity is found in developing countries; whereas developed countries usually host research institutes and companies that make commercial use of this biodiversity. In light of the asymmetries between States providing and using genetic resources, as well as growing expectations concerning the commercial value of biodiversity, ABS was conceived as a tool for equity and as an opportunity for sustainable development. The idea behind it was quite simple: developing countries host most of the world’s biodiversity and thus genetic resources; commercial products developed on the basis of these genetic resources benefit mostly companies and consumers in developed countries; part of these benefits should flow back to the countries of origin of genetic resources.

Developing the international law and policies to put this idea into practice is however far from simple. In addition, the role of traditional knowledge in bioprospecting further complicates matters. On many occasions, it is traditional knowledge held by indigenous peoples and local communities that provides clues as to the potentially useful properties of a genetic resource. ABS was conceived as a tool to promote fairness and equity at the inter-state level, however, and traditional knowledge demands regulatory action at the intra-state level. Indigenous peoples and local communities reside within State boundaries, and their rights, subject to international human rights norms, are regulated by national law.

The asymmetries already highlighted in the context of genetic resources are exacerbated in the case of traditional knowledge. Historically, colonization, mandatory assimilation, relocation policies, and the forces of globalization have resulted in the marginalization of indigenous peoples and local communities, and the erosion of their cultures, governance and traditional knowledge systems. Furthermore, (ab)use of the intellectual property rights system has resulted in a series of famous biopiracy cases involving the misappropriation of traditional knowledge, including those related to turmeric, neem, ayahuasca and hoodia. Could ABS be used to address at least some of the challenges related to the struggle of indigenous peoples for justice and equity?

International law on ABS thus needs both to address the practical aspects of ABS transactions and to serve broader aims related to fairness, equity and justice. It needs to address the trans-jurisdictional aspects of regulating access to genetic resources and traditional knowledge in one country by users (often private entities) based in other
countries. It also needs to reward States holding biodiversity and thus genetic resources for conserving the raw material for the development of products that are eventually commercialized by actors in other countries. It needs to protect traditional knowledge and reward the indigenous peoples and local communities. In addition, international law needs to guide the development of domestic legislation on ABS, and ensure fairness in transnational ABS transactions in order to reduce asymmetries both among parties in each individual transaction, and among developed and developing States.[1]

ABS in international biodiversity law

The CBD subjected access to genetic resources to prior informed consent (PIC) of the State providing the resource, and included the fair and equitable sharing of the benefits arising out of the utilization of genetic resources among its objectives. Introducing the concept of inter-state benefit-sharing, it provided for sharing the results of research and development and the benefits arising from the utilization of genetic resources with the Party providing them.

However, few CBD Parties have translated the CBD provisions on ABS into national legislation. The CBD provides a set of basic principles on ABS, but gives little guidance on how to address complex ABS situations. Industrialized Parties in particular were very hesitant to adopt measures supporting effective benefit-sharing by their researchers and companies with provider countries. Interlinkages with other areas of international law, in particular intellectual property rights, and the potential conflict between the CBD ABS provisions and the WTO Agreement on Trade-related Intellectual Property Rights (TRIPS), introduced additional challenges and complications. Finally, the CBD was silent on the use of traditional knowledge for research and development purposes and did not provide for the sharing of benefits with indigenous peoples and local communities in such cases.

The need for more detailed guidance on ABS led to the development of the non-binding Bonn Guidelines in April 2002. These guidelines aimed to steer governments in creating domestic measures on ABS. In line with the CBD, which provides that benefit-sharing arrangements in each ABS transaction are determined by mutually agreed terms (MAT), and thus a private contract, the Guidelines acknowledge that specific benefit-sharing arrangements may vary depending on the specific conditions of each individual case, emphasizing the role of contractual negotiations. The Bonn Guidelines also provide some guidance with regard to the types, timing and distribution of benefits, as well as mechanisms for benefit-sharing, in order to assist governments and stakeholders in the development of MAT. Notably, they provide a list of monetary and non-monetary benefits which is reproduced almost verbatim in the Annex to the Nagoya Protocol. This list, including monetary benefits ranging from access fees to joint intellectual property rights and non-monetary benefits such as sharing research results and technology transfer, represents a rare illustration in international law of what benefit-sharing may translate to in practical terms, and what mechanisms could be used. The Guidelines also recognize that traditional knowledge associated with genetic resources is often implicated in the ABS process, and call for the prior informed consent of the indigenous or local community concerned for access to such knowledge. Without providing much detail, indigenous and local communities are also identified among the potential beneficiaries of benefit-sharing arrangements.
Only a limited number of CBD Parties developed ABS legislation after the adoption of the Bonn Guidelines. In August 2002, the World Summit on Sustainable Development (WSSD) agreed to launch negotiations on an international regime on fair and equitable benefit-sharing. The WSSD mandate (WSSD report, para 44(o)) triggered the negotiations that eventually led to the adoption of the Nagoya Protocol.

The objective of the Nagoya Protocol is the fair and equitable sharing of benefits arising from the utilization of genetic resources, with a view to contributing to the conservation of biodiversity and the sustainable use of its components. Benefit-sharing is envisaged through appropriate access to genetic resources, the transfer of relevant technologies, and funding. Benefit-sharing obligations also arise from the use of traditional knowledge associated with such genetic resources (see also the BENELEX blog post on benefit-sharing and traditional knowledge, and genetic resources held by indigenous and local communities. In this regard, the Nagoya Protocol is particularly innovative: it is the first time that such obligations are triggered by the use of traditional knowledge for research and development purposes in an international legally binding instrument. The Protocol is also innovative in detailing measures to ensure compliance with ABS-related obligations – an aspect that was neglected under the CBD. It provides for the establishment of national focal points and competent national authorities, an ABS clearing-house, an internationally recognized certificate of compliance and national checkpoints, and calls for the creation of an international compliance mechanism. The Protocol also includes provisions on implementation support through capacity building, technology transfer and financial provisions.

According to the Protocol’s main provision on benefit-sharing, State Parties have three interrelated obligations: to share benefits with States providing genetic resources; to share benefits with indigenous and local communities within their territories when benefits derive from genetic resources held by these communities; and to share benefits arising from the utilization of traditional knowledge with the indigenous and local communities holding such knowledge. This provision is accompanied by an Annex outlining an indicative list of monetary and non-monetary benefits. While the Protocol obliges Parties to develop national measures to operationalize these provisions, it leaves them a significant margin of appreciation. In some cases, the Protocol also explicitly calls for continued multilateral negotiations to further develop the international legal framework. These issues, as well as all matters related to the Protocol’s implementation, are taken up by its meeting of Parties.

**COP/MOP 1: A key step towards implementation**

The major achievement of the first meeting of the Parties to the Protocol was the establishment of a compliance committee and agreement on procedures and mechanisms to promote compliance and address cases of non-compliance.

**Compliance**

The Protocol mandates COP/MOP 1 to establish multilateral procedures and mechanisms for monitoring compliance and addressing instances of non-compliance. Controversial issues mainly concerned the participation of representatives of indigenous and local communities in the compliance committee and the submission process, as well the
possibility for the committee to impose sanctions for non-compliance.

A compliance committee was established in line with experience gained under other multilateral environmental agreements, including the CBD Cartagena Protocol on Biosafety. The compliance procedures and mechanisms shall be non-adversarial, cooperative, simple, expeditious, advisory, facilitative, flexible and cost-effective. Their operation shall be guided by the principles of fairness, due process, rule of law, non-discrimination, transparency, accountability, predictability, and will pay particular attention to the needs of developing country Parties, especially the least developing countries and small island developing States, and Parties with economies in transition. An interesting provision aimed at promoting synergies says that, in performing its functions, the Committee may consult with the compliance committees of other agreements, to share experience on compliance issues and options for their resolution.

The Committee consists of 15 regional representatives nominated by the Parties. It will work on the basis of consensus, but majority voting is foreseen as a last resort. Parties may choose to nominate representatives of indigenous and local communities (ILCs). In addition, two ILC representatives nominated directly by ILCs, and with at least one from a developing country, shall serve as observers and participate in the deliberations of the committee, albeit not in decision-making. This provision on self-nominated ILC representatives is particularly innovative for an international environmental agreement, despite falling short of awarding full voting rights. It nevertheless gives the opportunity to representatives of ILCs to provide input to the Committee with regard to cases involving them, their genetic resources, and their traditional knowledge.

With regards to triggering the procedure, any Party with respect to itself, any Party with respect to another Party, and the COP/MOP may send submissions to the Committee. ILCs were not given triggering rights. They may however submit issues of concern on specific cases, either via the Secretariat or to the Committee directly. In another innovative provision reminiscent of human rights instruments, the Committee may also undertake information-gathering in the territory of the Party concerned, albeit only upon invitation of that Party.

The final decision did not include a provision on an ombudsman to assist developing countries and ILCs in identifying instances of non-compliance, despite extensive discussions on this issue. Instead, the Committee will consider, at a meeting to be held before COP/MOP 2, the need and modalities for a flexible mechanism to provide advice and assistance to developing country Parties and ILCs.

It remains to be seen whether the Committee will be instrumental in ensuring fairness and equity in benefit-sharing arrangements under the Protocol. This may seem doubtful at first sight, given its limited mandate to ensure compliance with the provisions of the Protocol, as well as current practice under other multilateral environmental agreements. Nevertheless, the provisions outlined above concerning the participation and input of ILC representatives can at least serve as a guarantee that the novel elements of the Protocol regarding the rights of ILCs to their genetic resources and traditional knowledge will remain a topic of deliberation and elaboration.
Global multilateral benefit-sharing mechanism

The first meeting of Parties did not actively consider a series of outstanding questions arising from Article 10 of the Protocol, calling instead for information-gathering and commissioning a study.

The Protocol provides for the possible establishment of a global multilateral benefit-sharing mechanism to cover transboundary situations or situations where it is not possible to grant or obtain PIC. Such a mechanism is envisaged to supplement the architecture of largely bilateral ABS transactions created by the Protocol. However, Parties are merely required to “consider the need for and modalities” of a global multilateral benefit-sharing mechanism; the Protocol does not necessarily call for its establishment.

Before reaching a decision as to whether or not to create such a global mechanism, the Parties are to address a series of complex questions, identified by an expert meeting and further deliberated within the framework of the Intergovernmental Committee for the Nagoya Protocol. Many of these questions concern the overall international legal framework on benefit-sharing and are therefore of great interest for the BENELEX project. Some are very practical, such as “Does the mere existence of the same species in more than one country constitute a transboundary situation?” Others have to do with unsettled issues related to the temporal scope of the Protocol, such as “How would a global multilateral benefit-sharing mechanism address collections made pre-Convention, post-Convention but pre-Nagoya Protocol, and post-Nagoya Protocol?” and “How would a global multilateral benefit-sharing mechanism address new uses of pre-Convention collections and continuing uses of pre-Convention collections?”

Other questions relate to the broader legal landscape of benefit-sharing. For instance, the question “Are there any existing international instruments or processes that could offer lessons learned for consideration in the context of a global multilateral benefit-sharing mechanism under the Nagoya Protocol?” refers to the Multilateral System of ABS operating under the International Treaty on Plant Genetic Resources for Food and Agriculture (see BENELEX blog post). Others point to the debatable geographic scope of the Nagoya Protocol and the possibility for a global mechanism to apply to marine genetic resources beyond natural jurisdictions, an issue which is currently under discussion in the framework of the UN General Assembly (see BENELEX blogposts on marine genetic resources Part I, and II).

Outlook

As CBD COP 12 has decided to hold the meetings of the Convention and its Protocols concurrently, a major opportunity to revisit the Convention processes and ensure synergistic operations in view of the three CBD objectives, conservation and sustainable use of biodiversity, and fair and equitable benefit-sharing, lies ahead. For the purposes of the BENELEX project, this may offer the chance to study the contribution of benefit-sharing to the provision of global public goods through biodiversity conservation more closely. In addition, intersessional developments related to the global multilateral benefit-sharing mechanism may provide opportunities to identify and assess the linkages among the

http://www.benelexblog.law.ed.ac.uk/2015/02/18/nagoya-protocol/
benefit-sharing architecture envisioned under the Nagoya Protocol, and structures of relevant international instruments and processes.


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