Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization

Background and Analysis

BD Berne Declaration Déclaration de Berne Erklärung von Bern
Brot für die Welt
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About the publishers

The Berne Declaration is a Swiss non-governmental organization with 23,000 members. Through research, public education and advocacy work, it has promoted more equitable, sustainable and democratic North-South relations since 1968.

The Berne Declaration monitors the role of Swiss corporations, banks, and government agencies. It addresses the problems of unequal international trade and financial relations, unsustainable consumption patterns and cultural prejudices. It calls on all Swiss actors – the private sector and the state, citizens and consumers – to assume their responsibilities in resolving these problems.
www.evb.ch

Bread for the World – Protestant Development Service is the globally active relief and development agency of the Protestant Churches in Germany. In almost 100 countries all across the globe we empower the poor and marginalized to improve their living conditions by themselves. Key issues of our work are food security, the promotion of health and education, the respect for human rights as well as the integrity of creation. Through lobbying, public relations and education in Germany and Europe we seek to influence political decisions in favor of the poor and to raise awareness for the necessity of a sustainable way of life.
www.brot-fuer-die-welt.de

Tebtebba (Indigenous Peoples' International Centre for Policy Research and Education) was established in 1996 and is an indigenous peoples' organization born out of the need for heightened advocacy to have the rights of indigenous peoples respected, protected and fulfilled worldwide. It also advocates and works on the elaboration and operationalization of indigenous peoples' sustainable, self-determined development. Tebtebba actively engaged in the processes which led to the adoption of international human rights law and other international instruments, policies and agreements. These include the UN Declaration on the Rights of Indigenous Peoples (UNDRIP) and the establishment of spaces within the United Nations, such as the UN Permanent Forum on Indigenous Issues, among others.

Tebtebba seeks to promote and disseminate widely indigenous peoples worldviews, their perspectives on key issues such as individual and collective human rights, sustainable development, climate change, biodiversity, traditional knowledge, customary laws and governance, conflict transformation, gender, etc.

Tebtebba, a word used by the indigenous Kankana-ey Igorot of Northern Philippines, refers to a process of collectively discussing issues and presenting diverse views with the aim of reaching agreements, common positions, and concerted actions.
www.tebtebba.org

Third World Network is an independent non-profit international network of organisations and individuals involved in issues relating to sustainable development, developing countries and North-South affairs. (Its mission is to bring about a greater articulation of the needs and rights of peoples in the South, a fair distribution of world resources, and forms of development which are ecologically sustainable and fulfil human needs.

TWN's objectives are to deepen the understanding of the development dilemmas and challenges facing developing countries and to contribute to policy changes in pursuit of just, equitable and ecologically sustainable development.
www.twn.my

CHAPTER 1

INTRODUCTION

ARTICLES 1 and 15 of the Convention on Biological Diversity (CBD), contain the basic concepts of "fair and equitable sharing of the benefits arising out of the utilization of genetic resources", "sovereign rights of States over their natural resources", and both access and benefit sharing on mutually agreed terms. It was a long winding road, however, to the solidification of these concepts in the more specific Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation (Nagoya Protocol).

The important elements and steps on this road are addressed in the first part of this publication, forming the background of the analysis of the Nagoya Protocol. These give context, depth and understanding to the intricacies of wording, balances and imbalances of outcomes, unresolved or ambivalent interpretations of concepts, and unfinished business regarding implementation and compliance. Lastly comes an outlook on choices ahead, and recommendations for the continuation of the road towards Access and Benefit Sharing (ABS) regulations that are both effective and fair to all partners involved.

Many publications have been produced and will continue to be produced with similar purposes.

What is the specific context of this publication? It is a joint effort of civil society participants from both developing and industrialized countries who consistently attended and observed the negotiations ultimately addressing Articles 1, 8(j) and 15 of the CBD. These began at the 4th meeting of the Conference of the Parties (COP-4) of the CBD in 1998, and include the development of the Bonn Voluntary Guidelines on Access and Benefit Sharing, the negotiations following the 2002 Johannesburg political mandate aiming at an international regime on ABS, through to the last night of COP-10 in 2010, which established the text of the Nagoya Protocol.

Input into the negotiations was possible in oral and written form with a high level of participation in many phases of the negotiations, especially negotiations in the "Vienna Setting"[1] that was fully transparent for all participants whilst allowing focused negotiations by speakers representing Regional Groups through their respective self-

[1] During the negotiations of the Cartagena Protocol on Biosafety under the CBD, an innovative and transparent procedure was initiated by the chairman of the Working Group, then Minister Juan Mayr Maldonado of Colombia. Dubbed 'the Cartagena/Vienna setting' (since these procedures were first adopted in the Vienna preparatory meeting that followed the collapse of the negotiations in Cartagena). For more details see: http://www.twn.my/title/vienna.htm

selection. In the "Vienna Plus Setting" chosen for many days of the negotiations representatives of Indigenous Peoples, Academia, Civil Society and Business were also invited to directly contribute. The authors were involved in these formal negotiations as well as interacted actively with the government delegates.

Herein, the authors thus share their experiences. They also share some common basic views and perspectives. ABS negotiations and the Nagoya Protocol are situated not only at a crossroads of conflicting interpretations and attitudes regarding historical events, experiences and trends, but also of clashing cultural concepts, including knowledge systems, and, last but not least, dire asymmetries of political power, legal recognition and a widening economic gap between haves and have-nots. It is therefore not at all surprising that the negotiations were long and difficult. It is also not surprising that the Nagoya Protocol is seen as work in progress rather than the final word on the issue of ABS. Which paths will it take? That is the question now.

The answers will depend on difficult international compromises made at the meetings of the Ad Hoc Open Ended Intergovernmental Committee for the Nagoya Protocol, convened after its adoption in 2010[2], and subsequent Meetings of the Parties, held after the Nagoya Protocol's entry into force. The course will, however, by the very nature of the text of the Protocol, depend to a very large extent on the fine details of national ABS legislation. Our analysis and recommendations include both of these elements, but stress the irreplaceable role and even saving grace of the latter.

We now turn to some of the conflicts, unresolved concepts, frameworks and asymmetries mentioned above. They all have to do with justice, historical, current and future. ABS is about justice. We name a few of these issues that need to be addressed.

1.1 Genetic resources as colonial trophies

The atrocities of past colonialism are part of present realities, perceptions and positions. The accumulation of wealth in some countries at the expense of other countries is part of our history that still creates a huge divide between groups of countries. More specifically in the ABS context, colonialism – like other forms of domination – was and is associated with the collection and appropriation of cultural and natural heritage brought to the princely courts, the museums, the zoological and botanical gardens of the powerful intruders.

Biological collections of colonial trophies of the past have rarely been named and shamed as such. Admission of misappropriation would be an important step towards trust and cooperation. Unfortunately, these old collections set the stage for further collecting without respectfully asking permission to do so. Subjectively, many of the modern collectors feel justified, because they have the means of modern Western science

[2] The Committee is tasked with undertaking the preparations necessary for the first meeting of the Conference of the Parties to the Convention on Biological Diversity serving as the Meeting of the Parties to the Protocol (COP-MOP). At the time of writing, the Committee has met twice (6-10 June 2011 in Montreal and 2-6 July 2012 in New Delhi) and will meet again on 3-7 February 2014. The co-chairs are Mr. Fernando Casas (Colombia) and Ms. Janet Lowe (Canada).

to compare, give binary names and even barcode the DNA. They are part of the chain of added value. They feel that they are the givers of benefits, and do not understand the fuss some people make. The fuss is about respect, dignity, and sovereignty. And the fuss is about the fact that automatic "trickling down of benefits" does demonstrably not always work.

Who owns resources?

Whose permission do you have to ask for? The owner's permission, of course. But who is the owner of genetic resources? There are different modes of ownership at different levels, and the concepts and their relationships are often unclear, sometimes conflicting. Children in many countries and cultures when asked: "Who owns plants and animals?" gave the following three answers:

- "They belong to God, the Gods, Mother Earth."
- "They belong to themselves."
- "They belong to the people who take good care of them."

The answers of these children are a profound challenge to the concept of ownership of life forms. In many communities and peoples around the world plant, animals, and other biodiversity have intrinsic value and the character of "commons", safeguarded by customary rights and responsibilities, or at the level of national constitutions. In 1972, in the discussions and outcome of the UN Conference on the Human Environment in Stockholm, the concepts of "common heritage of humankind", "common concern of humanity" and the sovereign rights of States to exploit their resources were debated but made explicitly subject to their rational utilization for the present and future welfare of humankind. Rights and responsibilities at the international level, however, were neither explicitly formulated nor implemented. The establishment of an ombudsperson as an advisor and advocate for present and future welfare of mankind may have given it a better start. Consequently there were those that continued to appropriate, or rather misappropriate, the heritage and disregarded the concerns. They considered wild animals and plants as *res nullius* (property free for the taking), to be collected, used and appropriated.

The text of the CBD, opened for signature 20 years later at the 1992 Earth Summit (United Nations Conference on Environment and Development, UNCED) in Rio de Janeiro, while acknowledging biodiversity as a common concern, stresses "the sovereign rights of States over their natural resources". The common heritage concept was rejected. In any event, in relationships and situations marked by inequality and imbalance of power, "commons" are difficult to defend by the weaker actor and are extremely vulnerable to abuse and misappropriation. However, regardless of the concepts of common heritage, common concern or resource under the sovereign rights of a State, if biodiversity is unprotected and regarded as an open space ready for private enclosure the consequences will be dire. Nevertheless, the CBD objectives state a common concern and task for the international community – to establish and implement rules for

conservation, sustainable use and fair and equitable sharing of benefits of biological diversity.

The continued flow of biological resources from biodiversity rich developing countries to industrialized countries and their continuing, even increasing, misappropriation and privatization is further driven by the dramatic imposition of intellectual property claims on life forms through the 1994 Trade-related Aspects of Intellectual Property Rights Agreement (TRIPS) enforced by the World Trade Organization (WTO). TRIPS reshaped the international legal concepts and the balance between private privileges/monopoly and public and intergenerational interests.

Who owns knowledge?

Western "modern" science with its historical roots in the Enlightenment and the intellectual tradition of the university of olden times very often claims access to resources and associated knowledge as if these were a "commons". It claims that knowledge about genetic resources and traditional knowledge, once published, becomes "public domain". They typically do not like to make this dependent on whether there was biopiracy involved or traditional knowledge collected without the free prior informed consent of the peoples and communities holding it. Today, universities and other research institutions are seen as major factors in global economic competition. As they enter public private partnerships, the defining lines between basic research, applied research, development and commercialization become fuzzy. Modern science cannot have it both ways – claiming intellectual commons and applying for intellectual property rights (IPR) – but it often tries.

The elements described above give an indication of the huge challenge of clarifying ABS concepts. The strength of an agreement like the Nagoya Protocol which, by necessity addresses these concepts, relies on such clarification. Footnotes stating that there are diverging interpretations of concept are not good enough.

Whose ownership counts?

Beyond inconsistencies in Western science, there is a wider issue that needs to be addressed. The CBD in its Article 8(j) recognizes the importance of "knowledge, practices and innovations of indigenous and local communities". The Nagoya Protocol covers traditional knowledge associated with genetic resources. Traditional knowledge is more than an oddity waiting for exploitation. Recognition and respect for different knowledge systems and their particular forms and processes is a human rights issue.

Many of the successful systems of knowledge of indigenous peoples and local communities share common characteristics that differentiate those systems from the ones established by "modern" science. These differences could be an incentive for people from different cultures and backgrounds to discuss the history and philosophy of their respective knowledge cultures, and to learn from each other. Unfortunately, traditional knowledge keeps being appropriated by "modern" science rather than respected at both the national and international levels.

Two major achievements – the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP), adopted at the UN General Assembly in September 2007, and the Nagoya Protocol, adopted in October 2010 – can converge but remain underutilized and await countries that can create exemplary good precedents in this endeavour.

Governments, which are committed to delivering benefits to indigenous peoples and local communities arising from the Nagoya Protocol, are encouraged to enact national laws, policies and procedures consistent with Article 31 of UNDRIP in the course of national implementation:

1.2 Unfair and inequitable realities

ABS is about justice. Justice does not mean that the winner takes all. Justice means that asymmetries between actors are identified and rectified. So far asymmetries favour user countries against provider countries. They favour industrialized countries over developing countries. They favour "modern" science against other systems of knowledge. They favour investors and other commercially minded entities over holders of land, resources and knowledge, and the standing of the government against the resource and knowledge rights of indigenous peoples and local communities. They favour those with access to the best and most expensive legal advice on research and commercial contracts over those who must negotiate mutually agreed terms unassisted. The weaker actors cannot buy their successes, rather, they need rights and the ability to claim those rights successfully. This requires effective and reliable compliance with ABS regimes and other relevant regulations.

In legal affairs the devil is in the detail. This guide sets out many of the details of the Nagoya Protocol as it developed, as it stands, and as it could be, to become truly and reliably fair and equitable.

CHAPTER 2

BACKGROUND

2.1 Development of the ABS provisions of the CBD

THE roots of the Nagoya Protocol reach back into history – some of them only three decades old, others beginning many centuries in the past.

The exchange of seeds, plants, animals and microbial cultures for a wide range of uses, including production of food, medicines, fibers etc. – all of them can be characterised as genetic resources – between partners communicating or negotiating in mutual trust is a practice of humankind since time immemorial. This practice continues today, including in modern societies and their specialised sectors, such as pharmaceutical, industrial and environmental remediation uses.

During the time of colonialism, when entire countries and societies were treated as inferior or wholly without rights, a massive and systematic drain of genetic resources and associated traditional knowledge for research, development and commercialisation purposes was organised. This South to the North movement, specifically the creation of added value outside of the countries of origin, continues until today.

A new dimension was added to this exploitation when the methods of genetic engineering were developed in the 1970s and 1980s. From its beginning, many researchers from the public and private sector understood that through the application of these new technologies the traditional fields of breeding organisms might come to be redefined as engineering disciplines. Thus opened the prospect of the application of IPR, specifically patents, to organisms now regarded as technical inventions – if domestic law based on the Agreement on TRIPS Agreement of the WTO so allows.

In 1983, shortly after the first transgenic plant was "created", 150 governments under the auspices of the United Nations Food and Agriculture Organisation (FAO) signed a non-binding agreement under which they acknowledged some principles related to plant genetic resources for food and agriculture. The International Undertaking on Plant Genetic Resources for Food and Agriculture was "based on the universally accepted principle that plant genetic resources are a heritage of mankind and consequently should be available without restriction". This principle also applies to the exploitation of raw materials in extra-territorial areas, such as the Antarctic or the High Seas, especially the deep seabed. Later, the International Undertaking was amended by FAO Resolution 5/89 endorsing the concept of Farmers' Rights, which "allow farmers, their communities, and countries in all regions, to participate fully in the benefits derived, at present and in the future, from the improved use of plant genetic

resources, through plant breeding and other scientific methods." This concept of benefit sharing was taken up in the development of the Convention on Biological Diversity (CBD).

The codification of the concept of "heritage of mankind" in times of increasing industrialisation of the traditional breeding sectors was fiercely criticised by developing countries and many non-governmental organizations in the run-up to the 1992 United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro, Brazil. They argued that the system gave those with the financial and technological means implicit advantages over those who had little other than biodiversity. Furthermore, strengthening of the regulations to protect IPRs, including patents, which was taking place in the parallel negotiations of the TRIPS Agreement would support the privatisation of genetic resources by the industrial sector. Biological diversity, which is largely concentrated in the South, would then be transferred into the hands of North-based institutions and multinational companies via international patent law and become private property.

The question of ownership of genetic resources came to the political agenda exactly at the same time. While the FAO's International Undertaking finally recognised the sovereignty of States over their genetic resources in 1991, at the time of preparations for the Rio Summit, it also committed all FAO Member States to allow free access to plant genetic resources for food and agriculture. The CBD, signed in Rio in 1992, continues to consider the conservation of biodiversity as a common concern for humanity, but rather than emphasizing the contested concept of common heritage, the CBD reaffirms and emphasizes States' sovereignty over their natural resources and accordingly, their biological diversity.

Accordingly, the CBD gives its Parties the right to regulate access to genetic resources on their territory and to attach certain conditions in accordance with its provisions. Many developing countries were very concerned that the CBD would not cover plant genetic resources for food and agriculture collected before the entry into force of the CBD. Therefore, in adopting the agreed text of the CBD on 22 May 1992, governments also adopted Resolution 3 of the Nairobi Final Act[3] on "The Interrelationship Between the Convention on Biological Diversity and the Promotion of Sustainable Agriculture". This Act recognises the need to seek solutions to outstanding matters concerning plant genetic resources within the FAO Global System for the Conservation and Sustainable Use of Plant Genetic Resources for Food and Sustainable Agriculture, in particular: (a) access to *ex-situ* collections not acquired in accordance with the CBD, and (b) the question of Farmers' Rights. Ethiopia and Sweden took the lead in establishing this bridge between the CBD and the two crucial issues that would have otherwise been lost from the international legal regime on ABS.

In 1993, the FAO Conference then adopted Resolution 7/93 for the revision of the 1983 International Undertaking and requested FAO to provide a negotiation forum

[3] Nairobi Final Act of The Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity, May 1992.

in the Commission on Genetic Resources for Food and Agriculture for: a) the adaptation of the International Undertaking, in harmony with the CBD; b) consideration of the issue of access on mutually agreed terms to plant genetic resources, including *ex-situ* collections not addressed by the CBD; and c) the issue of the realization of Farmers' Rights.

The three objectives of the resulting International Treaty for Plant Genetic Resources for Food and Agriculture (ITPGRFA) concluded in 2001 (and entered into force in 2008) are in line with those of the CBD: "the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security".

The objectives of the CBD are: the conservation of biological diversity, its sustainable use and the fair and equitable sharing of the benefits arising from the utilisation of genetic resources. With its last objective, the CBD is the central instrument under international law for regulating access to genetic resources and fair and equitable benefit sharing. The wording of CBD Article 1 encapsulates the South-North dynamics with regard to biodiversity and genetic resources and offers a legal framework for its resolution (see Table 1).

Accordingly, Article 15 (Access to Genetic Resources) of the CBD lays down a framework for access to genetic resources and fair and equitable benefit sharing. First, it states generally that every State has the sovereign right to regulate access over its natural resources. In other words, every State can – but does not have to – adopt laws to regulate the removal of genetic resources from its territory. CBD Parties shall "endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses" by other Parties. But the CBD does not say that there is a right of access as such. Where access is facilitated under national legislation it is only for "environmentally sound" uses, the details of which need be negotiated, with the decision about what is "environmentally sound" being the responsibility of the authorities of the concerned Party.

With this premise, the CBD makes access dependent on "prior informed consent of the Contracting Party providing such resources". This means that a prospective user of a genetic resource who seeks access must provide information on what resources will be used, and for what purpose. This information alone, however, is not sufficient to obtain access, which may be granted only with the approval of the Contracting Party concerned. More precise details are to be regulated on the basis of mutually agreed terms.

Mutually agreed terms also apply to the determination of what constitutes fair and equitable benefit sharing, and Contracting Parties can take legislative, administrative and/or policy measures for this purpose. Article 15 (7) provides that "the results of research and development and the benefits arising from the commercial and other utilisation of genetic resources with the Contracting Party providing such resources" be shared "in a fair and equitable way".

In other words, a developing country is entitled to receive information about the intended use of its genetic resources before granting (or denying) approval for the

Table 1: Objectives of the CBD and their interpretation with regard to the South-North dynamics	
Objectives of the CBD (Article 1)	**Interpretation**
1) the conservation of biological diversity,	**Target:** In principle all States, but mostly developing countries that hold most of the biodiversity; communal/private owners or rights-holders over natural resources.
2) the sustainable use of its components, and	**Target:** All States; all users (public and private sectors, indigenous peoples and local communities).
3) the fair and equitable sharing of the benefits arising out of the utilization of genetic resources	**Target:** In principle all States, and in the North-South context, countries with industries and institutions holding technologies and collections of biological resources, i.e. mostly industrialised countries.
including by appropriate access to genetic resources and	**Mechanism:** The sovereignty over biological resources includes the right to determine access to genetic resources. What is "appropriate" is undefined under the CBD and thus to be determined by domestic law or negotiations under the CBD.
by appropriate transfer of relevant technologies	**Mechanism:** Owners of technologies relevant for the conservation and sustainable use of biodiversity, especially bio- and gene-technologies, make them accessible for biodiversity-rich countries. What is "appropriate" is undefined under the CBD and thus to be determined by domestic law or negotiations under the CBD.
taking into account all rights over those resources and to technologies, and	**Condition:** Recognition of the sovereignty of States over their biological resources, and the rights of indigenous peoples and local communities as well as relevant forms of private or user rights. Recognition of rights to technologies, including private rights such as IPRs, as determined by domestic law and relevant international law.
by appropriate funding.	**Condition:** Developed countries finance developing countries to implement the CBD in accordance with commitments

utilisation. Furthermore, it is entitled to be involved in the results of this research, which can mean, for example, receiving preferential conditions, such as access to technology related to genetic resources, e.g. for the licensed production of drugs or cosmetics. Moreover, the developing country should also be included in the benefits resulting from research and development. This means that in principle the developing country can claim a fair and equitable share of the profits arising, for example, from marketing of a drug that has been developed on the basis of genetic resources it made available. The technology, financial resources or other benefits the developing country ultimately receives is a matter for negotiation, as Article 15 (7) specifies that the sharing of the benefits be on mutually agreed terms.

The CBD therefore pursues a bilateral approach, subject to conditions and standards under national laws. This assumes that the negotiating partners – entities from the countries of origin/providers and users of a genetic resource – sit down around a table and work out the conditions. To meet the requirement of benefit-sharing "in a fair and equitable way" on the basis of negotiations, the balance of power between the partners must be more or less equal – which is not the case in general. Even where a fair and equitable agreement can be reached, enforcing this across borders is beyond the national law of the country of origin/provider country. These facts were among the main motivations for developing countries in calling for clear and effective international benefit-sharing rules and standards during the ABS negotiations.

2.2 Developing an ABS system under the CBD

Below is a short chronology of the ABS negotiations under the CBD from 1998 to 2004 when the mandate to negotiate the Nagoya Protocol was adopted by the CBD Parties, and the final days in October 2010 when it was adopted amidst controversy. Table 2 provides a chronology of the various meetings from 1998 to 2010.[4]

From Bratislava (1998) to Bonn (2001)

In view of the opposition by most developed country Parties to the CBD, to a legally binding benefit sharing protocol, work was undertaken instead to develop international guidelines on ABS. This took three and a half years of negotiations that started in May 1998 at the Fourth Conference of the Parties (COP-4) in Bratislava.

During COP-4, the German Federal Environment Ministry and the European Commission presented the results of a two-year discussion among selected participants on ABS rules that denied the existence of a need for internationally binding ABS rules. The study was conducted against the background of the needs of transnational pharmaceutical industries, whose main aim is the production of drugs with single active ingredients, and a turnover of over 100 million Euro per year.

[4] The webpage of the Nagoya Protocol provides a comprehensive overview about the topic: http://www.cbd.int/abs/

A parallel project by the Swiss government took up the needs of the Swiss industry and other researchers with regard to future ABS rules. It presented a code of conduct that suggested rules of a voluntary nature.

COP-4 decided to set up a group of experts to discuss the issues raised by the reports. Costa Rica declared its willingness to convene this group, and Switzerland offered its support. The group's final report addressed the important issues in the ABS discussion and reflected the spectrum of opinions.

In May 2000, COP-5 in Nairobi decided to hold another session of the group of experts and to convene an *ad hoc* working group open to all CBD Parties, charged with developing voluntary "guidelines and other approaches". The German Government invited the *ad hoc* working group to meet in Bonn.

The second meeting of experts that preceded the *ad hoc* working group took place in Canada in March 2001. Its agenda reflected a political compromise. Developing countries, such as Colombia and India, reported on their experience with national legislative activities, while industrialised countries made proposals as to how voluntary measures could be designed at an international level. A Swiss proposal articulated both rights and obligations for those who make genetic resources available, but only rights and no obligations for users of genetic resources. The proposal contained obligations for user states, but the controversial issue of IPR – specifically patents – was left out. For several years developing countries have been demanding that user states should reform their patent laws to be in conformity with the CBD, e.g. by requiring disclosure of country of origin and evidence of prior informed consent. Access in accordance with the rules of the CBD should be a prerequisite to receive a patent for the use of a genetic resource. This took place at the CBD and the WTO TRIPS Council.

From Bonn (2001) to The Hague (2002)

The first meeting of the CBD Ad Hoc Open-ended Working Group on ABS (WGABS-1) was held in Bonn in October 2001 and resulted in the draft Bonn Guidelines on Access and Benefit-sharing. The Guidelines apply to all genetic resources within the scope of the CBD.

Access to products of genetic resources, e.g. enzymes and other biochemical compounds, is not directly addressed by these Guidelines. Use of both the genetic and biochemical components of genetic resources can, however, be covered in benefit-sharing agreements. Representatives of the EU noted that this solution crossed their acceptable limit, as they would have preferred that the biochemical components (derivatives) be excluded from benefit-sharing. This position would have minimized benefit-sharing because the bulk of revenues from the utilisation of genetic resources accrues during the phase of commercialisation which, in many cases, relies on products made of or from derivatives. This is especially true for the pharmaceutical, cosmetic and nutraceutical sectors, which are classic examples of ABS-related industries.

Between Bratislava and The Hague, developing countries achieved success on several important points. In particular, all references to the WTO TRIPS Agreement were deleted, a link that would have made the Guidelines subject to WTO rules. For example, a proposal that the Guidelines must be "not inconsistent" with the WTO

TRIPS Agreement was simply deleted. A passage according to which the Guidelines were to be "non-discriminatory" also disappeared. The "non-discriminatory" wording originated in a Swiss submission to the 2001 meeting of experts in Montreal, and aimed to place foreign users of genetic resources in a given country on the same footing as national ones. In a world in which users of genetic resources have unequal capital, knowledge and technical resources, and appropriation via patents and other IPRs, this WTO concept would, in practice, have perpetuated the power and dominance of users from industrialized countries.

Further, the negotiating text at the 2001 Bonn meeting did not contain any far-reaching obligations for the CBD Parties with genetic resources users under their jurisdiction. Developing countries made clear that all states can be both users and providers of genetic resources, and added a list of detailed responsibilities of the providers in order to clarify their position relative to users. The role of the user was also more precisely defined.

Developing countries also achieved another important breakthrough: using a genetic resource for a purpose other than that originally intended, and agreed to, is not allowed. A new use requires new access negotiations. This clarification closed an important loophole, at least at the legal level. Further, the possibility to monitor the proper utilization of the genetic resources should be improved by the users who should provide information about the geographical origin of the genetic resources concerned, prior informed consent and the agreement on benefit-sharing.

In spite of these successes, developing countries did not achieve their main aim at Bonn: an international, legally binding protocol that would obligate the users to implement the CBD's objective of fair and equitable benefit sharing, and to penalise violations of these rules.

When it became clear that the resistance of the industrialised countries was such that it was impossible to achieve this aim in Bonn, major developing countries focused their efforts on COP-6, held at The Hague in April 2002. While they allowed the Bonn Guidelines negotiations to continue, twelve states that, according to their own information, are home to about 70% of the Earth's biodiversity, formed the "Group of Like-Minded Megadiverse Countries" (LMMC)[5]. In February 2002 the LMMC presented its position on future ABS rules in Cancun at a meeting convened by Mexico.

In April 2002 at COP-6 they succeeded in obtaining agreement of the CBD Parties to include in the Guidelines a decisive area that industrialized countries had thus far carefully kept out of the text: the role and obligation of CBD Parties with users of genetic resources under their jurisdiction.

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[5] The LMMC comprises Brazil, China, Colombia, Costa Rica, Democratic Republic of Congo, Ecuador, India, Indonesia, Kenya, Madagascar, Malaysia, Mexico, Peru, the Philippines, South Africa and Venezuela.

Finally, the Bonn Guidelines contained the specific recommendation for user measures by CBD Parties to actively monitor compliance with the provisions of the CBD by considering *inter alia*:

- Measures to encourage the disclosure of the country of origin of the genetic resources and of the origin of traditional knowledge, innovations and practices of indigenous and local communities in applications for intellectual property rights; and
- Measures aimed at preventing the use of genetic resources obtained without the prior informed consent of the Contracting Party providing such resources.

From Johannesburg (2002) to Kuala Lumpur (2004)

The LMMC obviously regarded the Bonn Guidelines negotiations as subordinate, and in addition to work at COP-6 in The Hague, directed their attention to the World Summit on Sustainable Development in Johannesburg in September 2002 (the "Rio+10" meeting to mark the 10th anniversary of the 1992 Rio Summit on Environment and Development). Seeking an internationally legally binding instrument on fair and equitable benefit sharing, if necessary outside the CBD, the LMMC achieved an important (if partial) success: The World Summit called for an international regime on benefit sharing to be developed under the umbrella of the CBD:

"… negotiate within the framework of the Convention on Biological Diversity, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources;"

The term "regime" reflected disagreement about the international legally binding effect of the ABS rules to be negotiated. Since the word "regime" is not defined in international law, it leaves the matter open. Nevertheless, the "Johannesburg Plan of Implementation" recognized a regulatory gap in the field of benefit sharing, and the need to close it with a new instrument.

The Johannesburg decision was strongly criticized by developed countries because it did not explicitly identify a need for international *access* standards (as opposed to benefit sharing standards). Thus the development of access provisions in ABS laws was left to each CBD Party in accordance with CBD Article 15(1). In March 2003, at the Open-Ended Inter-Sessional Meeting on the Multi-Year Programme of Work of the Conference of the Parties, the developed countries succeeded in changing this. The meeting decided that:

"[...] the international regime should respond to the different needs and priorities of Parties to the Convention and should address both access to genetic resources and benefit sharing".

In December 2003, the Ad Hoc Open Ended Working Group on ABS met in Montreal to prepare for discussions at COP-7 and to come up with a draft decision. Developed countries were of the view that before embarking on negotiations for an international ABS Regime, CBD Parties should review the experiences of implementation of the Bonn Guidelines. Developing countries replied that they were

unaware that any developed country would actually foster the implementation of these voluntary guidelines. Therefore, they argued, it would be a waste of time to wait for an analysis of the experiences, and a legally binding Nagoya Protocol[6] needed to be established as soon as possible.

At COP-7 in February 2004 in Kuala Lumpur, Malaysia, the same discussion was repeated. The developed countries objected saying that they noted that the Johannesburg Plan of Implementation did not refer to an internationally legally binding protocol and instead made reference to the Bonn Guidelines. The developing countries argued that the Johannesburg Plan could only sensibly be interpreted if the CBD Parties agreed on a new quality in the field of benefit sharing, in other words on a binding protocol. Further, they noted, the Bonn Guidelines were already voluntary, and there would be no need for another voluntary instrument.

The result of COP-7's Decision VII/19 did not resolve the dispute. The decision noted that a regime may contain elements that are binding under international law and elements that are not. For further clarification, it referred a list of issues to the Working Group on ABS.

In Kuala Lumpur, positions from previous negotiations resurfaced. While developed countries tried to introduce references to the WTO at various points, developing countries consistently rejected this. At the same time, developed countries blocked all attempts to include obligations for the users of genetic resources into the negotiation mandate.

Nevertheless, in Kuala Lumpur an outcome emerged with regard to disputed interpretations of CBD Article 15 (2). This understanding would be crucial for the future course of negotiations. It reads: "Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention."

The phrase "facilitate access" is the crux of the matter. The negotiations in Kuala Lumpur clarified understanding that there is no obligation to facilitate access and consequently the word "facilitate" was deleted from the terms of reference for the negotiations on the scope of the international regime. The CBD already requires that Parties "shall endeavour to create conditions to facilitate access". The clear emphasis was thus on securing benefit sharing. Decision VII/19 determined the scope of the future work of the Working Group as: "Access to genetic resources and promotion and safeguarding of fair and equitable sharing of the benefits arising out of the utilization of genetic resources in accordance with relevant provisions of the Convention on Biological Diversity".

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[6] A Protocol is a legally binding treaty negotiated and adopted under a "parent" treaty, in this case the CBD. In contrast, the regime advocated by developed countries was an attempt to avoid a dedicated legally binding treaty to deal with benefit-sharing.

From 2005 to 2010

The WGABS, armed with the negotiating mandate, and co-chaired by Fernando Casas of Dominica and Timothy Hodges of Canada, held 9 meetings between February 2005 and October 2016.

Developed countries continued to be averse to a legally binding ABS treaty, and considerable time was spent on reiterating positions and not allowing the process to produce a structured text that could be the basis of earnest negotiation. They argued that the mandate of COP-7 was for an international ABS regime that could contain legally binding and non-legally binding elements, and an analysis of gaps should first be done. Frustration was evident among many developing countries at the lack of progress after two WGABS meetings in February 2005 and January 2006. A group of developing countries, meanwhile, urged the AWSBG to consider an international certificate of origin, source or legal provenance as a tool to ensure compliance, including in applications for patents.

After some intense discussions, COP8 in March 2006 decided "to establish a group of technical experts to explore and elaborate possible options, without prejudging their desirability, for the form, intent and functioning of an internationally recognized certificate of origin/source/legal provenance and analyze its practicality, feasibility, costs and benefits, with a view to achieving the objectives of Article 15 and 8(j) of the Convention". A meeting was held in January 2007 and produced a valuable report that contributed to the WGABS work on an internationally recognized certificate of compliance.

To facilitate and catalyse the negotiations which, after another two WGABS meetings in October 2007 and January 2008, were still at snail's pace, COP9 in May 2008 decided to establish three distinct groups of technical and legal experts on: (i) compliance; (ii) concepts, terms, working definitions and sectoral approaches; and (iii) traditional knowledge associated with genetic resources.

The Group of Technical and Legal Experts (GTLE-1) on Concepts, Terms, Working Definitions and Sectoral Approaches met in December 2008; GTLE-2 on Compliance in January 2009, and GTLE-3 on Traditional Knowledge Associated with Genetic Resources in the Context of the International Regime on Access and Benefit-Sharing in June 2009.

There was active participation of experts from ILC, non-governmental organizations NGO), academia, industry and international organizations in all the four expert groups.

In between, WGABS met for the seventh time in April 2009, followed by the eighth meeting in November 2009. By this stage, there was growing anxiety among developing country delegates, the Co-chairs and observers that with only one more meeting mandated for the ABS protocol to be concluded, there was still no coherent text – the 57-page document that existed by this late stage of the proceedings was a compilation document of all the proposals of Parties, with stark divergence of positions and text related to the core issues, including scope, definitions, compliance, the treatment of traditional knowledge, and the relationship between the protocol and other international agreements.

The Co-chairs began to try innovative ways to break the impasse. With the consent of the WGABS, two informal meetings were held under the auspices of the Co-chairs. The first was a small group of 28 called "Friends of the Co-chairs" in January 2010 that had regional balance as well as one participant each from ILC, NGO, academia and industry. The Co-chairs submitted a paper on selected key issues for the discussion, aimed at seeking possible solutions to those issues. This discussion was open and frank. The second was a Co-Chairs' Informal Inter-regional Consultation in March 2010, with 54 of participants (including non-government participants); a Co-chairs' Guidance Note helped to facilitate discussion and Parties represented there requested the Co-chairs to produce a "streamlined text" for WGABS-9 that took place immediately afterwards. It was titled "Draft Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization".

When WGABS-9 convened, the Co-chairs' non-paper became the basis for negotiations. Since this was the moment when serious negotiations actually began, Parties needed more time. To get around the fact that they had only one last mandated meeting, the solution was to have WGABS convened in 3 parts (March, July and October 2010). Parties also created an Interregional Negotiating Group of WGABS-9 that met twice, in September 2010 and again in Nagoya during COP10.

WGABS-9 started on October 16 in the hope that an agreed protocol text would be achieved, but that was not to be. The COP10 President, the minister of Japan, established a COP10 Informal Consultative Group on October 18. With time running out, the pressure mounted on the delegates. The deep divisions between developing and developed countries over the key issues were starkly on the table, with a crisis point reached on October 25 as ministers descend upon Nagoya. The EU, after days (and many nights) of negotiation on the compliance provisions refused to proceed on one of the key components for compliance on that night, i.e. checkpoints in user countries to monitor potential biopiracy. It was agreed by then that compliance is at the heart of the protocol that is being forged. Therefore the most time had been allocated for this topic. By October 28, one day before the close of COP10, no consensus was in sight.

The final twists in Nagoya (2010)

In the early morning of October 29, 2010, at the COP 10 meeting in Nagoya, negotiation of the ABS Protocol came to a standstill. After almost six years of difficult and often contentious negotiations, a clear South-North divide remained over core issues that would determine the strength and effectiveness of the Protocol to address biopiracy and ensure benefit sharing. These included text on the scope of the Protocol (definition of "derivatives" and the inclusion, or not, of traditional knowledge that is publicly available but not attributable to an indigenous or local community), the compliance and monitoring system to be established, and the relationship between the Protocol and other processes that have an impact on ABS rules and standards.

The two co-chairs Fernando Casas (Colombia) and Timothy Hodges (Canada) abruptly stopped a negotiation mode called the "Vienna Setting", which was largely open and most of the time transparent. The stoppage came after delegations were unable

to find a consensus on central issues that had been debated at several informal sessions, over four preparatory meetings totalling 21 days, and during 11 days of COP-10 in 2010. The sum of these inconclusive efforts, a draft text in which 17 out of 26 core and operational articles contained many brackets, was passed to the Japanese Presidency of the COP for finalisation during the last day of the meeting. (See Annex I: Status of the last negotiated version of the draft Nagoya Protocol at the Ad Hoc Open Ended Working Group on Access and Benefit sharing (noon of October 27, 2010).)

What exactly happened behind closed doors during the night and last day in Nagoya is difficult to reconstruct in detail.[7] What seems certain is that the EU and Brazil – using its position as a coordinator of the Like Minded Megadiverse Countries (LMMC) – began secret negotiations with the blessing of the Japanese presidency on Wednesday, October 27. While the official process continued its struggle for consensus, behind closed doors, Brazil and the EU hammered out a deal that produced a compromise on the unresolved and contentious core issues mentioned above. This compromise could undermine the objective of the Protocol and CBD to make fair and equitable benefit sharing a reality.

Brazil appeared to have no mandate for the secret talks from the LMMC or GRULAC (i.e. the Group of Latin American and Caribbean Countries). There was no reporting and consultation process with the LMMC or other developing countries. With the exception of Brazil, the developing world appeared to be outside the negotiations. At the very last moment, Namibia (speaking for the African Group in the ABS negotiations) was invited – seemingly to ensure that the idea of the multilateral fund, which was strongly promoted by Namibia, would be included in the draft protocol in a way that Namibia, at least, could live with it. The Like Minded Asia Pacific Group (comprising developing countries of the region) that had remained vocal on key unresolved issues were not brought into this process.

According to various sources in Nagoya, the EU gave the final text to the Japanese presidency while continuing to have a hand in ensuring its acceptance. After the official negotiation process later collapsed, the result of the secret negotiation was tabled by the Japanese presidency as a compromise paper. Asian and Latin American countries agreed to the proposal with several amendments. These finally were reduced by Brazil to a single demand: The draft's Article 3, on scope, was changed to read "utilization of genetic resources" rather than "utilization of genetic material". The EU and other developed countries approved without further discussion.

The African Group (despite uneasiness among some Africa delegates and a firm ministerial level statement demanding a strong Protocol made at the Nagoya COP meeting) announced that it would support the draft as it stood, creating an apparent split among the developing world. Africa's unconditioned support of the Brazil-EU

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[7] An account by Gurdial Singh Nijar, one of the lead negotiators and coordinator of the Like Minded Asia Pacific Group at the ABS negotiations, is available at: http://biogov.uclouvain.be/multistakeholder/presentations/Gurdial-Nijar-NagoyaProtocolAnalysis-CEBLAW-Brief.pdf

proposal was seen by several observers as perhaps resulting from extensive EU-sponsored capacity building activities in African countries in the preceding years that may have created some misplaced trust in the EU. The idea of an ABS fund sought by the African Group ended up as a future consideration by the Protocol Parties of the "need for and modalities of a multilateral benefit-sharing *mechanism*". This is in Article 10 that was inserted at the last hours of the Nagoya COP meeting and never negotiated [Article 7bis in the version adopted on October 29. See Annex II: Synopsis of Article numbers in the adopted text (October 29, 2010) and the final official edition.]

The rest of the story is simple. Japan announced that it would present the draft to the plenary of COP-10 as a take-it-or-leave-it text. During these final hours of COP-10, the energy among developing countries was sapped. No country felt able to play the role of breaking the formal consensus achieved under considerable pressure. On the floor, some negotiators said that the EU-Brazil text was all they could get, others said they saw the text as a failure but were not in a position to oppose in the plenary session. Bolivia, Ecuador, Cuba and Venezuela, the members of ALBA (Alianza Bolivariana para los Pueblos de Nuestra América), voiced their disappointment in the plenary session. They said they disapproved of the protocol, because it would not be a useful instrument to fight biopiracy, however, they added that they would not oppose the other CBD Parties.

Whatever the details of what happened behind closed doors, who misled whom, and whose arms were twisted, one point is clear: the Nagoya Protocol is ultimately not the result of transparent and inclusive negotiations because of the peculiar, almost bizarre, way it was concluded. As a result, the document and its articles do not represent a true balance of interests of all CBD Parties. That is, the EU-Brazil draft upset normal negotiating balances, wherein specific articles had been agreed to subject to other articles being successfully resolved. Rather than following the practice of "nothing is agreed until everything is agreed", the Protocol is instead the result of power play and highly questionable tactics in the final days and nights of the Nagoya COP meeting.

It is not surprising, therefore, that when the Ad Hoc Open Ended Intergovernmental Committee for the Nagoya Protocol (ICNP) met subsequently in June 2011 and July 2012, the unresolved issues re-emerged as interpretation began of the uncomfortable compromise contained in core parts of the Protocol. The ICNP had been established in Nagoya to further clarify and interpret the Protocol and to set the foundations for its implementation

It is noteworthy that Namibia, on behalf of the African Group, expressed dissatisfaction over attempts to prolong a decision on the multilateral benefit sharing mechanism under Article 10. It stressed at the July 2012 meeting that the brackets that disappeared overnight in Nagoya (referring to the contested parts of the Protocol up until the final days) were key to the Protocol's adoption, that "we are willing to talk about our position, but it's absolutely unacceptable to the African Group that there's no need for a global mechanism". It said that Africa's flexibility on this was a key enabler for the adoption of Protocol in Nagoya, referring to the differences between Article 10 and the Group's original proposal.

(See Annex III for highlights of the ongoing work of the ICNP.)

Perhaps the biggest missing piece of the Protocol is the unilateral deletion, by the select few that produced the compromise, of Article 9(5) of the text of the draft Protocol as of October 27, 2010 noon. It reads as follows:

[5. Parties shall[, where appropriate,] [encourage][require] the users of [publicly available] traditional knowledge associated with genetic resources [which has been obtained by that user from a source other than an indigenous and local community] to take [all] reasonable measures[, including due diligence,] to enter into fair and equitable benefit sharing arrangements with the [rightful] holders of [that][such] knowledge [within their indigenous and local communities].]

This envisaged two situations. First, where the knowledge is publicly available and attributable to specific ILCs, and secondly, where the knowledge is no longer attributable to specific ILCs in which case the holder is the State that is custodian for the national heritage of knowledge.

China, India, Malaysia and Nepal especially argued strongly for benefit sharing from the use of such traditional knowledge. China, India and Nepal are among those particularly affected as they have ancient traditional knowledge that is widespread but well documented, relating especially to medicinal formulations and treatments.

Such knowledge continues to be freely accessed and the long available therapeutic formulations and consequential products are regularly patented in developed countries as "inventions" with "novelty" value. A final attempt by China in the final days of the Nagoya CBD COP meeting to offer compromise language of Article 9(5) was rejected by developed countries, and subsequently deleted in the "secret" negotiations of the select few.

However, paragraph 25 of the Preamble to the Protocol does recognize "the unique circumstances where traditional knowledge associated with genetic resources is held in countries, which may be oral, documented or in other forms, reflecting a rich cultural heritage relevant for conservation and sustainable use of biological diversity." This was a paragraph that had been earlier agreed to by all the negotiating Parties and it ironically remains in the Protocol with no accompanying operational provision.

Table 2: Overview of the ABS negotiations 1998-2010			
Meeting	**Date**	**Location**	**Reports & analyses**
COP-4	1998, May 04-15	Bratislava	Decision IV/8 http://www.cbd.int/doc?meeting=COP-04
EPABS-1	1999, Oct 04-08	San José	UNEP/CBD/COP/5/8 http://www.cbd.int/doc/?meeting=ABSEP-01
EPABS-2	2001, Mar 19-22	Montreal	UNEP/CBD/WG-ABS/1/2 http://www.cbd.int/doc/?meeting=ABSEP-02
WGABS-1	2001, Oct 22-26	Bonn	UNEP/CBD/COP/6/6 http://www.cbd.int/doc/?meeting=ABSWG-01
COP-6	2002, Apr 07-19	The Hague	Decision VI/24 http://www.cbd.int/doc/?meeting=COP-06
WSSD	2002, Aug 26 -Sep 04	Johannesburg	Plan of Implementation http://www.un.org/jsummit/
MYPOW-1	2003, Mar 17-20	Montreal	UNEP/CBD/COP/7/5 http://www.cbd.int/doc/?meeting=MYPOW-01
WGABS-2	2003, Dec 01-05	Montreal	UNEP/CBD/COP/7/6 http://www.cbd.int/doc/?meeting=ABSWG-02
COP-7	2004, Feb 09-20	Kuala Lumpur	Decision VII/19 http://www.cbd.int/doc/?meeting=COP-07
WGABS-3	2005, Feb 14-18	Bangkok	UNEP/CBD/COP/8/5 http://www.cbd.int/doc/?meeting=ABSWG-03
WGABS-4	2006, Jan 30- Feb 03	Granada	UNEP/CBD/COP/8/6 http://www.cbd.int/doc/?meeting=ABSWG-04
COP-8	2006, Mar 20-31	Curitiba	Decision VIII/4 http://www.cbd.int/meetings/cop8mop3/
GTE-1 on an Internationally Recognized Certificate of Origin/Source /Legal Provenance	2007, Jan 22-25	Lima	UNEP/CBD/WG-ABS/5/7 http://www.cbd.int/doc/?meeting=ABSGTE-01
WGABS-5	2007, Oct 08-12	Montreal	UNEP/CBD/COP/9/5 http://www.cbd.int/doc/?meeting=ABSWG-05
WGABS-6	2008, Jan 21-25	Geneva	UNEP/CBD/COP/9/6 http://www.cbd.int/doc/?meeting=ABSWG-06
COP-9	2008, May 19-30	Bonn	Decision IX/12 http://www.cbd.int/cop9/

GTLE-1 on Concepts, Terms, Working Definitions and Sectoral Approaches	2008, Dec 02-05	Windhoek	UNEP/CBD/ABSWG/7/2 http://www.cbd.int/doc/?meeting=ABSGTLE- 01
GTLE-2 on Compliance	2009, Jan 27-30	Tokyo	UNEP/CBD/WG-ABS/7/3 http://www.cbd.int/doc/?meeting=ABSGTLE-02
WGABS-7	2009, Apr 02 - 08	Paris	UNEP/CBD/WG-ABS/7/8 http://www.cbd.int/wgabs7/
GTLE-3 on Traditional Knowledge associated with Genetic Resources	2009, Jun 16-19	Hyderabad	UNEP/CBD/WG-ABS/8/2 http://www.cbd.int/doc/?meeting=ABSGTLE-03
WGABS-8	2009, Nov 09-15	Montreal	UNEP/CBD/WG-ABS/8/8 http://www.cbd.int/wgabs8/
Friends of the Co-Chairs (FOCC)	2010, Jan 26-29	Montreal	Paper on Selected Key Issues submitted by the Co-Chairs http://www.cbd.int/doc/?meeting=ABS-FOCC-01
Co-Chairs Informal Inter-regional Consultation (CIIC)	2010, Mar 16-18	Cali	Co-Chairs' Guidance Note http://www.cbd.int/doc/Informal?meeting=ABS-CIIC-01
WGABS-9/1	2010, Mar 22-28	Cali	UNEP/CBD/WG-ABS/9/3 http://www.cbd.intwgabs9/
WGABS-9/2	2010, Jul 10-16	Montreal	UNEP/CBD/COP/10/5/ADD4 http://www.cbd.int/wgabs9-resumed/
Interregional Negotiating Group (ING-1) of WGABS-9	2010, Sep 18-21	Montreal	UNEP/CBD/WG-ABS/9/ING/1 http://www.cbd.int/doc/?meeting=ABSWG-ING-01
Interregional Negotiating Group (ING-2) of WGABS-9	2010, Oct 13-16	Nagoya	UNEP/CBD/WG-ABS/9/ING/2 http://www.cbd.int/doc/?meeting=ABSWG-ING-02
WGABS-9 /3	2010, Oct 16	Nagoya 3RD	UNEP/CBD/COP/10/5/ADD5 http://www.cbd.int/doc/?meeting=ABSWG-09-
COP-10 Informal Consultative Group (ICG)	2010, Oct 18-28	Nagoya	negotiations in ICG, Small Groups (on specific topics, articles and paragraphs, some of the Small Group meetings were closed for observers), in-session documents only available in printed form

COP-10	2010, Oct 27	Nagoya	last negotiated version of theDraft ABS-ProtocolStatus as of 12 noon, 27 October 2010 http://www.cbd.int/cop10/insession/?tab=3
COP-10	2010, Oct 29	Nagoya	Closed door negotiations between some delegations resulted in Draft decision submitted for adoption UNEP/CBD/COP/10/L.43/Rev.1 http://www.cbd.int/cop10 insession?tab=0Decision X/1http://www.cbd.int/cop10/

CHAPTER 3

ANALYSIS OF THE NAGOYA PROTOCOL[8]

THIS Chapter traces the development of the specific Articles of the Nagoya Protocol by highlighting the relevant negotiation history and providing some analysis. We hope that this will contribute to an interpretation of the Articles that enables national and international implementation to meet the objectives of the Protocol and CBD.

In some instances, our discussion refers to the numbering of the Articles contained in the version adopted by COP-10 on October 29, 2010 in order to trace the evolution of those Articles – in these instances the reference is to "Draft Articles". For ease of comparison, see *Annex II: Synopsis of Article numbers in the adopted text (October 29, 2010) and the final official edition*. Some of the Articles that pertain to the standard provisions in an international treaty are not included in our analysis.

The core provisions can be summarised as follows:

1) The Nagoya Protocol covers genetic resources as defined in Article 2 of the Convention on Biological Diversity (CBD) and derivatives as defined in Article 2 of the Protocol.

- This means (i) any material of plant, animal, microbial or other origin containing functional units of heredity, which has actual or potential value, as well as (ii) naturally occurring biochemical compounds resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.

[8] The official title is "Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity".

2) The Nagoya Protocol requires fair and equitable sharing of benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization (Article 5).

- The Protocol defines "utilization of genetic resources"[9] that is the trigger for benefit sharing under Article 15 of the CBD (Access to Genetic Resources) and Article 5 of the Protocol (Fair and Equitable Benefit-sharing): this means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology. Derivatives are also included through the definition of "biotechnology".
- In addition to research and development benefit sharing, there is also an obligation to share benefits from subsequent applications and commercialization with the Party providing the genetic resource.
- With regard to benefit sharing with indigenous and local communities, however, only benefits from utilization of genetic resources are mentioned explicitly, apparently leaving it to national legislation to address benefits arising from subsequent applications and commercialization.
- Benefit sharing shall be on mutually agreed terms.

3) The Nagoya Protocol requires prior informed consent (PIC) for access to genetic resources accessed for their utilization (Article 6).

- PIC is required for genetic resources under the jurisdiction of a Party (including genetic resources in *ex situ* collections and when it is a country of origin. A Party can choose to not require PIC.
- Parties must ensure that the PIC or approval and involvement of ILCs is obtained for access to genetic resources over which the ILCs have established rights to grant access.

4) The Nagoya Protocol covers traditional knowledge associated with genetic resources held by ILCs (Articles 5 and 7)

- Parties to the Protocol must ensure that access to associated traditional knowledge is based on PIC or approval and involvement of the ILCs and that benefit sharing with the knowledge holders will take place (Traditional knowledge and its utilization is not defined.)

[9] Article 2 on Use of Terms states: "utilization of genetic resources" means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention.

5) The Nagoya Protocol establishes a compliance system for genetic resources and associated traditional knowledge (Articles 15 to 18, Article 30)

- Parties must ensure that genetic resources and associated traditional knowledge utilized under their jurisdiction have been accessed based on PIC and Mutually Agreed Terms (MAT) as required by the Party providing the genetic resource.
- Measures to monitor the utilization of genetic resources (Article 17), but not associated traditional knowledge, in order to support compliance, include:
  - One or more effective checkpoints relevant to the utilization of the genetic resource or to the collection of relevant information at any stage of research, development, innovation, pre-commercialization or commercialization;
  - The national access permit, providing information on PIC, MAT, and other items, is rendered into an internationally recognised certificate of compliance through its publication in the ABS clearing house.
- Parties need to support the compliance with MAT by providing opportunity to seek legal recourse and access to justice for the foreign party.

The following is a discussion of the individual Articles of the Nagoya Protocol and their development at the Ad Hoc Open-ended Working Group on ABS (WGABS) that was co-chaired by Fernando Casas of Colombia and Timothy Hodges of Canada.

Article 1 – OBJECTIVES

Article 1 sets the legal and political frame in which the Nagoya Protocol operates. In such an article, it is useful to name all critical issues in the objectives, although it is not necessarily detrimental if some of them are not, as long as they are comprehensively addressed in the operational articles themselves.

> Article 1 – OBJECTIVES
>
> The objective of this Protocol is the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components.

Development

During the negotiations, several controversial issues where raised, including if and how to reflect:

- The wording of CBD Article 15.2 “facilitate access” and “environmentally sound uses”
- Compliance with international and national rules;

- The prevention of misappropriation and misuse of genetic resources and associated traditional knowledge; and
- Other topics such as associated traditional knowledge, indigenous and local communities, specifically including the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP).

Article 1 sends two key messages for understanding and national implementation of the Nagoya Protocol. First, it clearly connects the three aims of the CBD and stipulates that all elements of benefit sharing need to contribute to the conservation and sustainable use of biological diversity. Second, it ended the long lasting dispute on the balance between access and benefit-sharing rules under international law. While the Nagoya Protocol defines benefit sharing as its objective, granting appropriate access is regarded as one of the elements of benefit sharing, but not as an objective of the treaty.

During the 7th meeting of the Ad Hoc Open-ended Working Group on ABS (WGABS-7) in 2009, Article 1 was discussed at length and all the different options incorporated in the draft text revealed the range of positions of Parties.

On facilitated access

The controversy related to the expression "facilitate access" is rooted in the language of Article 15(2) of the CBD itself.[10]

From the start of the ABS negotiations, developed countries used this language to justify making an objective of the Protocol to be to "facilitate access". Developing countries instead insisted on the phrase "regulating access", arguing that Article 15 of the CBD does not speak of "facilitated access" in isolation, rather in the context of environmentally sound uses. The authority for determining an answer to this question lies with national authorities.

Developing countries also argued that provisions and procedures of national ABS regulation need to be left to CBD Parties, and that the Protocol should not bind governments in how they set up national ABS systems. They argued that the CBD requires that a Party "shall endeavour to create conditions to facilitate access" and accordingly the existence of ABS regulation meets this obligation. On the other side, developed countries argued that international access rules that were too strict would be burdensome and fail to "facilitate access". They thus preferred non-binding guidelines. This issue was resolved at the second meeting of the 9th meeting of the Working Group (WGABS-9/2) in July 2010, where negotiators resorted to the wording of CBD Article 1, agreeing that the ABS Protocol would be legally binding and have an objective of enabling "appropriate access to genetic resources".

[10] Article 15(2) on Access to Genetic Resources states: "Each Contracting Party shall endeavour to **create conditions to facilitate access** to genetic resources for **environmentally sound uses** by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention" (Emphasis added).

On environmentally sound use

CBD Article 15(2) links access to the condition of environmentally sound use. While the wording "facilitate access" was consistently promoted by developed countries and is contained in all draft texts, "environmentally sound uses" lacked similarly enthusiastic backing, and moved in and out of the text. It was deleted in the draft text of WGABS-7, reintroduced during WGABS-8, and then deleted again in a Co-Chairs non-paper for WGABS-9/1 of March 2010. At the first meeting of the Inter-regional Negotiations Group (ING-1)[11] in September 2010 in Montreal, the concept was brought back, but in the context of draft Article 5 on access to genetic resources:

"[1 *ter*. In accordance with paragraph 2 of Article 15 of the Convention, all applications for access shall be channelled through the Competent National Authority of the Party where the applicant is domiciled and shall be accompanied by a full environmental impact assessment, conducted by an independent third party, certifying that the access requested is for environmentally sound uses as defined by the providing country.]"

While Article 15(2) does not define how environmentally sound uses are determined, this new text used Article 14 of the CBD and the related work on Environmental Impact Assessment (EIA) to specify how Article 15(2) could be implemented via the ABS Protocol as a measure to be taken by users.

At the CBD COP-10, the African Group supported this text while developed countries opposed linking the obligations of users of genetic resources to EIAs. Developed countries argued that the authorities of user countries are not involved in PIC negotiations and therefore cannot be responsible for channelling access applications including an EIA. They further argued that provider countries could conduct such EIA under their national ABS legislation. The African Group opposed burdening the provider country with the costs of the EIA. The issue remained unsolved and was finally deleted

[11] In order to facilitate the negotiations that were difficult and making very slow progress, the Ad Hoc Open-ended Working Group on ABS agreed to set up an Inter-regional Negotiations Group in July 2010. It was unique in its inclusiveness, consisting of five spokespersons self-selected from among the Parties from each of the five UN regions, two representatives each from Indigenous and Local Communities, Civil Society, Research Institutions and Private Sector, as well as then current (Germany) and incoming (Japan) COP Presidencies. These representatives could be replaced, as needed, by each grouping. All other Parties, non-Parties and observers were also in the room to ensure transparency of the proceedings. Observers at the table, including the authors of this book, could provide "guidance" on the items being negotiated while textual inputs are the prerogative of the Parties. (At the request of the International Indigenous Forum for Biodiversity it was decided that representatives of the Indigenous and Local Communities could also provide text proposals but these will then have to be supported by at least one Party to be considered in the negotiations. This was because the issue of traditional knowledge, prior informed consent and benefit sharing with these communities are integral parts of the Protocol. The outcome was taken back to the Ad Hoc Open-ended Working Group on ABS on the understanding that nothing was agreed until all had agreed.

from the text during the secret negotiations between the EU and Brazil in October 2010.

On UNDRIP and ILC Rights over GR and Associated TK

In Article 1, representatives of indigenous and local communities (ILC) sought recognition of their rights under international law in conjunction with the 2007 United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP). ILCs wanted deletion of language that would subject their rights to national law, or that did not fully reflect or even contravened international and customary rights. ILCs looked for affirmation that ABS related to their genetic resources and associated traditional knowledge must respect their customary rights, as confirmed in UNDRIP.

At WGABS-8 in 2009, some negotiators proposed reference to the UNDRIP in Article 1. Delegates remained divided on how to reflect different national approaches to recognizing the status of indigenous peoples and their rights, and the reference to UNDRIP remained in brackets until the end. Some developing countries that do not follow the concept of "indigenous peoples" but of "local communities" instead, insisted on reference to national law, underlining the importance of national regulations to guide transactions with local communities.

The final compromise was one preambular paragraph that only "notes" the UNDRIP, which even then Canada resisted until the final days at COP-10 in 2010.

On Compliance

Developed countries rejected the request of developing countries that the objective of the Protocol should be to "secure" compliance with the ABS laws of provider countries. Developing countries stated that the core objective of the Protocol should be compliance with ABS rules in the user countries. Developed countries instead said that because national ABS laws govern access to genetic resources, an international treaty could not secure compliance with national rules.

On Misappropriation and Misuse

For developing countries, a critical goal of the ABS protocol was prevention of biopiracy. In the negotiation text, the terms misappropriation and misuse were used to describe this problem. Developed countries had reservations, and demanded definitions. The issue was discussed but not resolved at WGABS-7 in 2009, and deferred to future sessions, because at that stage the negotiators had not made any decisions on the need for definitions in the Protocol. During WGABS-8 in 2009, four options to describe the "International understanding of misappropriation/misuse" were developed for further negotiation later. This was reflected in a draft text on the objectives as a compilation of all options put on the table.

Finalization of Article 1

A non-paper by the Co-Chairs presented WGABS-9/1 in March 2010 tried to resolve disagreement on the text of Article 1 by replacing the different options (and attendant legal and political concepts) by referring to the CBD Objective[12]:

"The objective of this Protocol is to ensure the fair and equitable sharing of the benefits arising from the utilization of genetic resources, contributing to the conservation of biological diversity and the sustainable use of its components."

This approach proved frustrating for all because none of the more specific terms favoured by different groups could no longer be found in the objectives. During WGABS-9/2 in July 2010, a further effort to finalise Article 1 saw delegates bringing "their" issues back into the text. The meeting finally agreed on an amended version of that proposed by co-chairs, resolving the controversial issue of "facilitate access" with the compromise phrase "appropriate access":

"The objective of this Protocol is the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components."

Misappropriation and misuse, compliance, and the rights of ILCs did not return to the objectives. Article 1 wound up as one of the two most controversial articles of those that were finalized in the formal negotiations.

Article 2 – USE OF TERMS

Article 2 on "use of terms" addresses the need to clarify the meaning of terms of central importance in a legally binding text.

[12] Article 1 of the CBD states: "The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and **the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding**." (Emphasis added)

Article 2 – USE OF TERMS

The terms defined in Article 2 of the Convention shall apply to this Protocol. In addition, for the purposes of this Protocol:
(a) "Conference of the Parties" means the Conference of the Parties to the Convention;
(b) "Convention" means the Convention on Biological Diversity;
(c) "Utilization of genetic resources" means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention.
(d) "Biotechnology" as defined in Article 2 of the Convention means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.
(e) "Derivative" means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.

Development

The definition and use of terms occupied CBD Parties' attention even before the 2004 mandate by COP-7 to negotiate the Nagoya Protocol at the Ad Hoc Open-ended Working Group on Access and Benefit-sharing. This was triggered by the CBD definitions of the terms "genetic resources" and "genetic material" that incorporates the notion of "functional units of heredity".[13]

There are few if any new drugs and cosmetics in development or on the market that are directly based on the utilization of "functional units of heredity" from genetic resources; the interest of the industries lies in biochemical compounds. A narrow interpretation of the CBD definitions (that only elements of heredity have value and that "derivatives" are not within the CBD scope) would result in severely narrowing the scope of benefit sharing.

When CBD Parties finalised the voluntary Bonn Guidelines on ABS at COP6 in 2002, time constraints prevented thorough discussion on definitions and the use of certain terms. In Decision VI/24A of COP 6, Parties decided "to reconvene the Ad Hoc Open-ended Working Group on Access and Benefit-sharing to advise the Conference of the Parties on: (a) Use of terms, definitions and/or glossary, as appropriate".

When WGABS-2 in 2003 discussed the issue, delegates felt that more information was needed, and called for submissions from Parties and observers. At WGABS-3 in February 2005, several suggestions for definitions were presented. While developing countries called for a definition of "derivatives" from the beginning, the crucial issue

[13] Article 2 of the CBD states: "Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity; "Genetic resources" means genetic material of actual or potential value.

of the exact understanding of "genetic resources" in the context of ABS was only raised later in the governmental submissions. At WGABS-3, several NGOs stressed the importance of a sound definition of "genetic resources" to include derivatives and showed that some limited interpretations would lead to the exclusion of many typical ABS cases from a future ABS Protocol. Canada, the European Commission and EU Member States, however, rejected further discussion on definitions and use of terms. WGABS-3 decided to continue collecting views. WGABS-4 further postponed the discussion, and WGABS-5 did not discuss it at all. At the centre of these years of jostling were two opposing views: developing countries argued for definitions that would maximise the scope of the benefit sharing under the CBD (and later the Protocol) while developed countries preferred to narrow the scope through definitional constructs.

As can be seen below, the negotiations of the definition of "utilization of genetic resources" and "derivative" were central to the scope and thus effectiveness of the Protocol to ensure benefit sharing. The understanding of the CBD definitions of "genetic resources" and "genetic material" with regard to functional units of heredity was part of this struggle.

Defining the Concept of Utilization

At WGABS-6 in 2008, Peru suggested convening a workshop to discuss the definition of derivatives. COP 9 decided positively on the idea, and the first meeting of a Group of Technical and Legal Experts (GTLE-1) took place in December 2008 in Windhoek, Namibia. The GTLE conducted the first in-depth discussion on the meaning of "genetic resources" and "derivatives" in the ABS context since 2002. The growing importance of a meaningful interpretation of the term "genetic resources" was stressed in the submission of Colombia for the Windhoek meeting:

"What is not possible is the interpretation whereby Genetic Resources are exclusively units of functional heredity. This reductionist interpretation raises a number of problems. Scientifically speaking, it could reduce the scope to nucleic acids. Such a view is contradicted by practical experience, which shows that genetic resources have been isolated and manipulated from time immemorial, independently from the isolation and direct manipulation of said nucleic acids. Although nucleic acids are a *sine qua non* condition, they are not sufficient to obtain genetic material. Furthermore, this reductionist interpretation would mean that most genetic material, or biological material containing genetic resources usually provided as the basis for are the basis of making use of any genetic trait or property specific to biodiversity, would be excluded from the fair and equitable sharing remuneration of benefits arising from access to said materials and their use. This would prevent the implementation of the CBD's objectives."

The European Commission and EU Member States argued against this understanding, instead favouring limiting the scope of the future ABS Protocol as much as possible. In its submission, the CBD was interpreted as suggesting that the actual value of a genetic resource refers only to the elements of heredity – nucleic acids – and not to the genetic material as such:

"The actual or potential value of genetic resources is therefore determined by the potential for utilization, i.e. it is the use of the functional units of heredity which will distinguish them from genetic material of biological resources."

The CBD itself states, however, that: "'*genetic resources*' means genetic material of actual or potential value". Genetic material is characterized by "containing" the units of functional heredity, but the CBD does not state that the value lies exclusively in the use of the units of functional heredity.

Thus the EU's position aimed to dramatically reduce the scope of the ABS Protocol. By excluding the utilization of biochemical substances from the scope of the ABS Protocol would mean, as Colombia observed, that many typical uses would not be covered by international ABS rules. Paradoxically, the examples for utilization of genetic resources in the EU submission includes exactly those cases which the EU wanted to exclude:

"Pharmaceutical industry [...] Main forms of utilization of genetic resources: [...] To meet an increasing demand for new products to address a range of illnesses, the pharmaceutical industry is one of the most research intensive industries in the world. Genetic resources have been an important component of that research work.

"Fragrance and cosmetics [...] Main forms of utilization of genetic resources: [...] Genetic resources are used in relation to extraction, identification and synthesis of new compounds."

A stance similar to the EU's was taken by the International Chamber of Commerce (ICC) in preparation for GTLE-1:

"The IR (international regime on ABS) should also only regulate the relationship between the provider and party gaining access to genetic resources and not seek to regulate downstream activities and/or derivatives or products being developed from them. [...] any IR which tries to regulate downstream activities and products will be unworkable, unenforceable and extremely costly to implement."

The ICC describes these sorts of products as including bread, wine and wood products – which very well might be regulated through private contracts. Yet, contradictorily, industry representatives conceded that other types of "downstream products", such as drugs derived from genetic resources, are typical examples in which ABS rules could be applied under the Protocol, as indicated by the compilation of case studies distributed at GTLE-1. As we observed at the beginning of this discussion, biochemical compounds are what interest industry. There are few if any new drugs and cosmetics that are directly based on the utilization of "functional units of heredity" from genetic resources.

The main conclusion of the expert group was that it is neither useful nor appropriate to redefine or interpret the definitions of genetic resources in the CBD, and that the ABS Protocol would be better based on the concept of "utilization of genetic resources". The group came up with a list of typical uses, based on the understanding that genetic material contains units of heredity and other substances. The utilization of all components of genetic material is intrinsic to the ABS Protocol and should thus be subject to ABS rules.

This consensus at the technical level was not taken up by WGABS-8 in 2009 because definitions were still under dispute due to their implications for the scope of the Protocol. It was decided to accept further submissions. At WGABS-9/1 in March 2010, all Parties supported the creation of a legally binding treaty that would include an article on use of terms. WGABS-9/2 in July 2010 developed a footnote text on "Utilization of genetic resources" based on the understanding developed at GTLE-1:

"Utilization of genetic resources includes/means the conduct of research and development, on the genetic and biochemical makeup/composition of genetic material/biological resources, including through the application of biotechnology as defined in Article 2 of the Convention, as well as subsequent applications and commercialization."

ING-1 in September 2010 integrated this footnote into Article 2, adding a definition on "derivatives" that was bracketed indicating lack of consensus:

"[(c) "Utilization of genetic resources" means to conduct research and development on the genetic and biochemical composition of genetic material/biological resources/genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention.

"Derivative" means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if they do not contain functional units of heredity.

Article 2 of CBD: "Biotechnology" means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.]"

While on the one hand this text was a breakthrough in a broad understanding of utilization of genetic resources, on the other it closed the door for regulating use of genetic resources in industrial processes under international ABS rules through deletion of the phrase "subsequent applications and commercialization" (from the WGABS-9/2 text). Article 2 thus now focused on the utilization of genetic resources for research and development purposes. This decision reflected the debate under Article 1 (on the Protocol Objective), where developed countries demanded exclusion of "commodities in trade" from the Protocol's scope.

During COP-10 on October 28, a final was made attempt by the EU with Brazil's support to revert the understanding developed by GTLE-1 by proposing a definition that would only include the utilization of units of heredity (genes) and the products of their expression (proteins). This EU-Brazil text was rejected by other negotiators.

Due to the insistence of many developing countries, "subsequent application and commercialization" was ultimately included in Article 5 of the Nagoya Protocol that sets out the benefit sharing obligations.

Defining Derivatives

The final text of the Nagoya Protocol also contains a definition of derivatives, as sought by developing countries since 2002. Since the operational articles do not explicitly refer to derivatives, the value of this definition is not apparent at first sight. Read together with the other definitions, it becomes clear that the term "utilization of genetic resources" includes "utilization of derivatives", namely of naturally occurring

biochemical compound contained in materials of biological origin. Thus, all provisions of the Nagoya Protocol related to "utilization of genetic resources" also apply to derivatives, specifically the obligations on benefit sharing. While this outcome of the Nagoya Protocol confirms the approach taken beginning in the 2002 voluntary Bonn Guidelines, the main controversy is not settled by the adoption of the Nagoya Protocol, that is, whether access to derivatives which are already extracted from genetic resources are covered by the access rules of the treaty. Expert opinions are divided on this matter. Currently, many national ABS laws include such cases into their scope. It remains to be seen how Parties to the Protocol will deal with this issue in the future.

Article 3 – SCOPE

Article 3 determines which utilization rules do and do not apply to types of genetic resources. It thus should be read together with the definitions (Article 2 of Use of Terms), and CBD Articles 2 (Use of Terms), 4 (Jurisdictional Scope) and 15 (Access to Genetic Resources). The scope of the Nagoya Protocol is narrower than that of the CBD in excluding territories beyond national jurisdiction yet including all types of genetic resources per CBD Article 15. Areas of national jurisdiction are determined by the borders of a country. If a country has a coast, this includes the Exclusive Economic Zone of a country, which can stretch as far as 200 nautical miles (370.4 km) offshore, including the water column and the seabed. Under specific circumstances, the seabed (but not the water column) as far as 350 nautical miles (648.2 km) from the coast can be declared to be under national jurisdiction. In terms of ABS implications, probably all coral reefs lie within the jurisdiction of a state, whereas biodiversity around hot springs in the deep seabed generally lies in areas beyond national jurisdiction. Access to the latter genetic resources is not regulated by the Nagoya Protocol but may be discussed in the context of the UN Convention on the Law of the Sea (UNCLOS).

> Article 3 – SCOPE
>
> 1. This Protocol shall apply to genetic resources within the scope of Article 15 of the Convention and to the benefits arising from the utilization of such resources. This Protocol shall also apply to traditional knowledge associated with genetic resources within the scope of the Convention and to the benefits arising from the utilization of such knowledge.

Development

Discussions on Article 3 were intense and characterised by deep divisions between groups of countries. Arguments raised were based on two positions:

- To include all genetic resources in the scope of the Protocol (with the option perhaps for specific rules under other articles); or
- To exclude as many genetic resources as possible from ABS rules even though the CBD covers all genetic resources.

The first approach was chosen previously in the Cartagena Protocol on Biosafety, which includes all genetically modified organisms (GMOs) within its scope, with exclusions for specific GMOs created via specific rules in separate articles.

The initial negotiations revealed a degree of common understanding that certain types of genetic resources might fall out of the scope of the ABS Protocol, including:

- Plant genetic resources for food and agriculture listed in Annex I of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and covered by its Multilateral System. The ITPGRFA is recognised as a specialized ABS agreement by its Parties, although its 127 Parties are fewer than the 193 of the CBD.
- Human genetic resources, based on COP-2 Decision II/11: Access to Genetic Resources, stating, "that human genetic resources are not included within the framework of the Convention". In the course of the negotiations, however, there was discussion that this COP decision could be changed by a new one if CBD Parties choose to reverse that decision.

At WGABS-6 in 2008, the Co-chairs Fernando Casas and Timothy Hodges suggested a rather short and simple text for scope:

"All genetic resources, and associated traditional knowledge, covered under the Convention on Biological Diversity and the benefits resulting from their use."

WGABS-6 started with six options for scope that varied with regard to the legal nature of the text, but appeared to be reasonably consistent with regard to the three central elements of the objectives of the draft text: access, benefit sharing and inclusion of associated traditional knowledge. During the meeting it became obvious that the simple suggestion of the Co-chairs would not lead to a clarification of controversial issues raised when several developed countries started to exclude more and more genetic resources from the scope. The draft text on scope was ultimately assembled from seven options ranging from coverage of all genetic resources to various exclusions.

The discussions also revealed profound differences on the temporal scope of the draft agreement. Developing countries sought coverage of utilization of genetic resources accessed prior to the entry into force of the CBD or, at least, from entry into force of the CBD (December 29, 1993) through benefit sharing on the "continuing uses". Developed countries argued that the Protocol could not cover the utilization of genetic resources accessed before its entry into force.

The proposed exclusion of genetic resources under the Antarctic Treaty System launched the debate on the geographical scope.

In addition some delegations started to discuss special treatment for all genetic resources covered by the ITPGRFA and the International Convention for the Protection of New Plant Varieties (UPOV), and/or for animal and other genetic resources for food and agriculture under the remit of the FAO Commission on Genetic Resources for Food and Agriculture, or for genetic resources and traditional knowledge associated with genetic resources as dealt with by the WIPO. Such options were characterized as the political scope of the ABS Protocol, again aimed at carving out application of the Protocol's ABS rules.

During WGABS-7 in 2009, the controversy on scope peaked, yet it remained unresolved until the end of the discussion at COP-10 in 2010.

The developed countries' proposal that the date of entry into force of the ABS Protocol determine its temporal scope constituted a further restriction of the draft agreement's scope beyond the options in the draft text. It followed from this suggestion that benefit sharing on the continuing use of genetic resources would be excluded.

The debate on the political scope was broadened by the suggestion that genetic resources as "commodities in trade" should not fall under the ABS Protocol. This idea was to exclude the application of ABS rules, for example, on pharmaceutical companies using plant material that needed to be collected or harvested as a source of phytopharmaceuticals. But developing countries feared that such an exclusion would incentivise researchers and industry to access commodities marketed for a different purpose, for example as food, and utilize them to develop new products rather than accessing them under agreed ABS procedures. This scenario was supported by contributions at the first meeting of the Group of Technical and Legal Experts (GTLE-1) in 2008 when industry delegates stated that they access most R&D materials in the commodity marketplace so as to circumvent ABS negotiations with countries of origin.

Another element was added with the provision that the exchange of genetic resources and associated traditional knowledge by indigenous and local communities "for their own consumption based on their customary practices" should not be restricted by international ABS rules.

The negotiations on scope that were already fraught with difficulties were brought to a standstill when the EU demanded exclusion of "specific uses of pathogens" from the scope. The debate over this demand developed into one of the major points of conflict between developing and developed countries and is discussed in detail under Article 8 below.

Finally, negotiators from developed countries introduced language on the relationship to other international treaties as well as negotiations and developments under Article 3 (of the draft text, that is now Article 4 of the Nagoya Protocol). These parts of the negotiations are discussed under Articles 4 and 8 below.

In their non-paper for WGABS-9/2 the Co-chairs again suggested a simple scope article:

"This Protocol shall apply to genetic resources within the scope of the Convention on Biological Diversity and to the benefits arising from the utilization of such resources. This Protocol shall also apply to traditional knowledge associated with genetic resources and to the benefits arising from the utilization of such knowledge."

This formulation on the scope of the Nagoya Protocol clearly states its coverage of both genetic resources and associated traditional knowledge within the scope of the CBD, but also separates and distinguishes the subject matter of genetic resources from that of traditional knowledge associated with genetic resources.

Clarifying the inter-relationship between genetic resources and associated traditional knowledge was an important issue in the negotiations, and the subject of a meeting of technical and legal experts on traditional knowledge associated with genetic resources in the context of the international regime on access and benefit sharing held 16-19 June, 2009 in Hyderabad, India (see the accompanying Box).

CONCLUSIONS FROM MEETING OF LEGAL AND TECHNICAL EXPERTS ON TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES, 16-19 JUNE, HYDERABAD, INDIA

ALTHOUGH in most cases genetic resources seem to have associated traditional knowledge it was also recognized that not all genetic resources have associated traditional knowledge.In situations where traditional knowledge is associated to genetic resources however it was highlighted by many experts that traditional knowledge and genetic resources are inseparable.Another point raised is the fact that there is not always a relationship between the owners of genetic resources accessed and the holders of traditional knowledge. In some instances genetic resources may be owned by the government or a private landowner or indigenous and local communities and the traditional knowledge (is) held by indigenous and local communities. It was noted that the relationship between access and use might vary depending on the nature of State sovereignty. It was highlighted that biological resources is an umbrella term used by some countries and communities in addressing access and benefit sharing in order to encompass not only genetic resources but also biochemical properties organic extracts and others.There is also a need to address not only traditional knowledge associated with genetic resources that is accessed *in situ* but also traditional knowledge and genetic resources accessed *ex situ* including in databases or libraries and the potential sharing of benefits. It was also suggested that the International Regime should address the situation of traditional knowledge found in the public domain. In this respect it was stated that intellectual property rights couldn't be granted on traditional knowledge found in the public domain. Some suggested that traditional knowledge found in the public domain remains the property of indigenous and local communities and therefore should require prior informed consent before being used. The distinction between public availability and the public domain was stressed. Indigenous peoples and local communities hold rights to traditional knowledge associated with genetic resources and that their agreement should be obtained before such knowledge is accessed. As mentioned such decisions as well as terms for granting access will often be guided by the indigenous peoples or local communities customary laws and community level procedures.Given the nature of traditional knowledge innovations and practices which are collective and intergenerationalit was highlighted that any conflict with other systems relating to the same issues need to be addressed by the International Regime.It was noted that there may be different levels of law relevant to the development of the International Regime incorporating international regional national sub-national and customary laws and the relationship between and obligations arising from these different levels of laws may need to be clarified in the International Regime. National laws should provide for respecting customary laws and community protocols – whether codified or not – to regulate the process to obtain prior informed consent and for best practice codes of conduct to be observed by applicants for access. Protocols and codes of conduct should fully reflect the rights/decisions of indigenous peoples and local communities concerned.

(Extracted from the meeting report)

This formal legal separation between genetic resources and associated traditional knowledge in the scope of the Nagoya Protocol is difficult to reconcile with indigenous customary law and indigenous perspectives, which emphasize inextricable relationships between biological resources and traditional knowledge. The distinction also paves the way for distinct treatment of the two, and potential inconsistencies between them within the Protocol as well as in national policies and laws on traditional knowledge associated with genetic resources, as can be seen in the discussion of the relevant Articles below.

During subsequent meetings, the delegations of developed countries reintroduced their list of exemptions, a move that was always countered by a list of corresponding inclusions put forward by developing countries. At COP-10, it was again suggested that the negotiation go back to the simple version of scope, as presented in the report of WGABS-9/3 in October 2010.

The EU and Canada argued that the scope of the ABS Protocol should fit within the scope of CBD Article 15. The implication of this suggestion is that genetic resources from outside national territories would be excluded because CBD Article 15 refers to territories under national jurisdiction. Developing countries and Norway preferred that the scope of the ABS Protocol be matched to the broader scope of the CBD, thereby including territories outside of national jurisdiction:

CBD Article 4. Jurisdictional Scope: Subject to the rights of other States, and except as otherwise expressly provided in this Convention, the provisions of this Convention apply, in relation to each Contracting Party: [...] (b) In the case of processes and activities, regardless of where their effects occur, carried out under its jurisdiction or control, within the area of its national jurisdiction or beyond the limits of national jurisdiction.

Some developing countries and Australia stressed that the scope of the ABS Protocol needed to be within the scope of CBD Article 8(j) on traditional knowledge associated with genetic resources.

With regard to the temporal scope, Japan suggested that draft Article 3 be silent, in which case Article 4 of the Vienna Convention on the Law of Treaties would apply, which does not allow the retroactive application of treaties.

Developing countries did not argue that the ABS Protocol should be applied retroactively on past accesses and utilization but that the benefit sharing obligations be applied to ongoing and new utilization. Brazil suggested that the scope should – after its entry into force – cover the utilization of all genetic resources whether access happened with or without PIC and MAT. The EU proposed to accept this proposal if (a) benefit sharing is restricted to the utilization of genetic resources acquired after the entry into force of the Protocol, and (b) the EU's proposal on the restriction of the geographical scope is accepted.

Because of the long but fruitless discussion on lists of exemptions and inclusions, delegations could not reach an agreement on the issue of scope. The closed-door process of October 29, 2010 led by the EU and Brazil finally put in place a short version of the scope.

The proposed restriction on temporal scope was shifted to draft Article 4(1) on benefit sharing (now Article 5 of the Nagoya Protocol) as discussed later.

The conflicts around the temporal, geographic or political topics were resolved in following ways:

On Temporal Scope

Article 3 does not explicitly deal with the temporal scope of the Nagoya Protocol. Articles 5 (Fair and Equitable Benefit-sharing) and 6 (Access to Genetic Resources) deal indirectly with this issue but do not resolve it. The language of Article 3, however, has room for additional interpretations. It states that the Protocol shall apply to genetic resources and associated traditional knowledge within the scope of Article 15 of the CBD. Article 15(7) of the CBD obliges Parties (from the entry into force of the CBD in December 1993) to "take legislative, administrative or policy measures, as appropriate, [...] with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources".

Additionally, Article 4(4) on Relationship with International Agreements and Instruments states: "This Protocol is the instrument for the implementation of the access and benefit sharing provisions of the Convention". It could thus be considered obvious that benefit sharing for continuous use starting from the entry into force of the Convention falls within the Nagoya Protocol's scope. On the other hand, there is no operational text for this, making national implementation an important step to fulfil the objective of the Protocol.

On Geographic Scope

The decision to base the Nagoya Protocol on the scope of CBD Article 15 means its provisions do not apply to genetic resources and associated traditional knowledge that exist outside of the area of jurisdiction of its Parties. Article 4(2) opens the possibility to negotiate specialized ABS agreements for extra-territorial areas such as Antarctica or the high seas. Developed countries, however, introduced these geographic exemptions in order to prevent the application of ABS rules in those areas. Developed countries noted that ABS for the excluded areas should be dealt with in other fora, but it cannot be expected that these countries would actually support such negotiations there. It thus seems very unlikely that specific ABS agreements under the Antarctic Treaty or UNCLOS will be achieved in the near future.

Another entry point for negotiations on expanding the geographic scope might be offered by Article 10 (Global multilateral benefit sharing mechanism), provided that Parties of the Protocol agree that situations "for which it is not possible to grant or obtain prior informed consent" may refer to such areas. The wording of Article 10 does not give any ground for being optimistic, however, because it obliges Parties to first consider the need for such a mechanism, again suggesting that it is unlikely that the geographic scope of the Protocol could be expanded soon.

On Political Scope

Article 3 does not directly address issues of political scope. The issue was partially resolved through the definitions in Article 2, which while these clarify the types of biological substances falling under the ABS provisions; they exclude commodities from the access provisions of the treaty. The relationship to other relevant agreements is clarified in general terms in Article 4, where specialised ABS agreements could be negotiated on basis of Article 4(1).

Article 8 indirectly deals with the political scope because it provides for special considerations in national ABS legislation concerning non-commercial research, cases of present or imminent health emergencies, and genetic resources for food and agriculture, without exempting them from ABS rules.

Article 2 that explicitly links the utilization of genetic resources to research and development activities could be interpreted to exclude trade and commercialization. Experts' views are divided on this, but in any event the benefit sharing obligations under the Protocol clearly extend to benefits arising from subsequent applications and commercialization (as explained later).

While the restrictions in geographical scope obviously cannot be directly addressed in national access rules, the utilization of genetic resources accessed in extraterritorial or non-Party areas could be covered. This approach, including the use of benefits for national biodiversity conservation purposes is recommended because the establishment of a multilateral mechanism under Article 10 that includes access in areas beyond national jurisdiction seems unlikely in the near future.

Article 4 – RELATIONSHIP WITH INTERNATIONAL AGREEMENTS AND INSTRUMENTS

The purpose of Article 4 of the Nagoya Protocol (draft Nagoya Article 3bis) is to state the relationship of the Protocol with other international agreements and instruments.

A "relationship clause" is common in most international treaties to clarify the status and relative priorities of provisions of international treaties that could address similar or related fields or that might create conflicting or synergistic obligations for the Parties concerned.

The applicable general rule of international law is found in the 1969 Vienna Convention in Article 30 (3) (Application of successive treaties relating to the same subject-matter): "When all the parties to the earlier treaty are parties also to the later treaty, … the earlier treaty applies only to the extent that its provisions are compatible with those of the latter treaty."

Therefore the later or newer treaty prevails over an earlier treaty that is still in force. When a State is not party to the later treaty, then the earlier treaty governs the relationship. This rule sets up a hierarchy between treaties adopted at different times. Accordingly, a more specific provision in one treaty prevails over a more general in another treaty when both relate to the same subject matter.

Article 4(1) states that the Nagoya Protocol is not intended to create a hierarchy between itself and other international instruments in relation to the rights and obligations

of a Party under any existing international agreement, "except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity". We submit, however, that for purposes of interpretation of the treaties concerned, the general rule discussed above would still apply.

Article 4(2) allows for other relevant international agreements, including other specialised ABS agreements as long as "they are supportive of and do not run counter to the objectives of the Convention and (the) Protocol".

However, Article 4.3 introduces complications by deviating from the conventional international law practice for relationship clauses. It states that, "Due regard should be paid to **useful and relevant ongoing work or practices under such international instruments (relevant to the Protocol) and relevant international organizations** provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol" (emphasis added). This is discussed below.

ARTICLE 4 – RELATIONSHIP WITH INTERNATIONAL AGREEMENTS AND INSTRUMENTS

1. The provisions of this Protocol shall not affect the rights and obligations of any Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity. This paragraph is not intended to create a hierarchy between this Protocol and other international instruments.
2. Nothing in this Protocol shall prevent the Parties from developing and implementing other relevant international agreements, including other specialised access and benefit-sharing agreements, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.
3. This Protocol shall be implemented in a mutually supportive manner with other international instruments relevant to this Protocol. Due regard should be paid to useful and relevant ongoing work or practices under such international instruments and relevant international organizations, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.
4. This Protocol is the instrument for the implementation of the access and benefit-sharing provisions of the Convention. Where a specialized international access and benefit-sharing instrument applies that is consistent with, and does not run counter to the objectives of the Convention and this Protocol, this Protocol does not apply for the Party or Parties to the specialised instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument.

Development

A central issue in the relationship between international agreements is that of the trade and environment interface.

Since the TRIPS Agreement entered into force in 1995, an international debate has been ongoing over the relationship between this WTO agreement and the CBD. On the one hand, the CBD reaffirms a State's sovereignty to regulate access to its

genetic resources and obligates users to share benefits. On the other hand, the TRIPS Agreement obligates its members to allow for patenting of microorganisms, non-biological and microbiological processes, and allows them to offer patenting of plants and animals. With the phrase "non-biological and microbiological processes" genetic engineering breeding methods such as a "gene-gun" or transformation via *Agrobacterium tumefaciens* became patentable.

Article 16(5) of the CBD explicitly states that "patents and other intellectual property rights may have an influence on the implementation of this Convention" and accordingly Parties shall cooperate "to ensure that such rights are supportive of and do not run counter to" the CBD objectives (fair and equitable benefit sharing being the third objective).

A central objective of developing countries, therefore, is that international and national patent law should contribute to the compliance with Prior Informed Consent, as it is used in ABS, and related contracts between providers and users of genetic resources and associated traditional knowledge. In practice, this objective means that applications for IPR, especially patents, on genetic resources, and/or associated traditional knowledge, would be required to be accompanied by disclosure of origin and documentation of PIC and MAT. These disclosures would prove that the genetic resource and, as applicable, associated traditional knowledge, had been obtained in accordance with the CBD and national ABS legislation. Since 2001, such anti-biopiracy provisions in patent law have been a hot topic at the WTO TRIPS Council, which is mandated to address the relationship between the TRIPS Agreement and the CBD. Despite the efforts of developing countries during this decade-long process, disclosure of origin has yet to be enshrined in international intellectual property law. It has been the developed countries, notably the USA, which have prevented progress in this regard.

At WGABS-3 in 2005, the first extended exchange of views on the relationship between the TRIPS Agreement and the CBD ABS regime took place. The position of developing countries was mirrored in the intervention of the UNEP representative as it was noted in the meeting's report:

"12. While many biotechnologies were already in the public domain, intellectual property rights (IPRs) had become a key feature in biotechnological development, which meant for many developing countries the introduction of new or revised intellectual property protection (IPP) regimes which allowed for the patenting of life forms. It was important for the present meeting to examine the relationships between the Convention and international biotechnology transfer, particularly as they exercised an impact on developing countries and in light of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). There were real contradictions in essential points between TRIPS and the Convention that had to be resolved. Intellectual Property Rights applied to life forms under TRIPS ran counter to and did not support the objectives of the Convention.

13. Furthermore, the private property regime established by the TRIPS Agreement would undermine implementation of the access and benefit sharing provisions of the Convention. Private monopoly could begin only where national or community sovereignty had been effectively suspended. Therefore, under TRIPS the very genetic resources to which nations and communities were supposed to control access would

be under the control of IPR holders. Governments and communities would have no means of regulating access or demanding a share of benefits because they would be subject to private ownership, and that was contrary to the objectives of the Convention."

This clear understanding of the position of developing countries was well received by the African Group and Brazil but triggered immediate protest by developed countries. It was later declared that the intervention did not represent the position of the Executive Director of UNEP and UNEP itself.

In the course of the negotiations, Parties requested more information and studies dealing with the relationship between IPRs and ABS. Some studies were made available at WGABS-7 in 2009, and covered the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), the WTO, the World Intellectual Property Rights Organization (WIPO), and the International Union for the Protection of New Varieties of Plants (UPOV), as well as the Antarctic Treaty System and UNCLOS.

The relationship between the ITPGRFA, more specifically its Multilateral System of Access and Benefit-sharing and the future ABS Protocol was considered to be among the less problematic items. The ITPGRFA recognizes the CBD's ABS provisions and Parties to the ITPGRFA agree that its objectives are in harmony with the CBD (as it was the mandate of the FAO members to harmonise the ITPGRFA with the CBD objectives), although the benefit sharing system under the ITPGRFA is not yet effectively implemented.

"Ongoing work or practices" under other international instruments and "relevant international organizations"

At the first part of the 9th meeting of the Ad Hoc Open Ended Working Group on ABS (WGABS-9/1) in 2010 in Cali, Colombia many delegations pointed out that provisions on relationships with other agreements will be a key issue of the future ABS Protocol, and the EU suggested a stand-alone provision. The co-chairs' non-paper for the Cali meeting did not contain a provision on relationships. While there was agreement on the importance of the issue there were deep divisions on the content. The EU suggested that:

"The provisions of this Protocol are without prejudice to ongoing work or practices under relevant international organizations and conventions."

This wording could have undermined the effectiveness of the ABS Protocol. The idea behind the EU proposal was that if an ABS Protocol were adopted in the future, its Parties would not be obliged to adhere to its provisions when negotiating or implementing any other ABS relevant treaty. It was at the WGABS-9/2 meeting in 2010 when Article 4 was finally introduced (then numbered as Article 3bis). While paragraphs 2 and 4 of the draft article stood without brackets from the beginning, paragraphs 1 and 3 were only resolved at the final closed-door process in Nagoya among a selected few.

In Nagoya the discussion centred on the EU suggestion to specify the ABS Protocol's relationship not only with other legally binding treaties but also with "ongoing work or practices" in other fora. Developing countries replied the latter link would create a new concept in UN treaties, because "ongoing work or practices" elsewhere

might be unlinked from Parties' obligations Parties under the ABS Protocol. Developing countries were concerned that the EU suggestion would undermine treaty relationships under international law. (The EU's insistence was directly due to the parallel negotiations at the World Health Organization over access to pandemic influenza viruses and benefit sharing of vaccines: see accompanying Box.)

As a compromise the African Group suggested adding "provided that they are supportive of and do not run counter to the objectives of this Convention and this Protocol."

Pathogens

The fierce debate on the exclusion of pathogens from the ABS Protocol that started at WGABS-7 in 2009 overshadowed the discussion on the relationship clause of Article 4. One strand of the debate dealt with developed countries' desire to impose specific provisions exempting pathogens from the ABS Protocol's scope or, at least, to oblige Parties to grant simplified or "immediate" access to pathogens under certain circumstances. As a compromise, the co-chairs' non-paper developed for WGABS-9/1 in 2010 suggested the issue be addressed under the "emergency situations" article, but without naming specific genetic resources. During COP-10 a merger of the relationship and emergency situations articles (Articles 4 and 8, respectively, in the final text) was discussed but did not yield an acceptable result. The final language for Article 8 requires that:

"In the development and implementation of its access and benefit-sharing legislation or regulatory requirements, each Party shall:

… (b) Pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally. Parties may take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need, especially in developing countries".

The relationship clause in Article 4(3) retains the requirement to pay due regard "to useful and relevant ongoing work or practices under such international instruments (relevant to the Protocol) and relevant international organizations". The EU's insistence on this text was predominantly motivated by the pathogens debate at the World Health Organization, and its final inclusion despite consistent strong objections by developing countries makes Article 4(3) one of the controversial provisions that is not the result of full negotiation. Furthermore, developing countries had earlier agreed in principle to Article 8 subject to the removal of Article 4(3) to which they had objections.

Pertinent discussions are further described in the section below on Article 8(b), on the outcome of the World Health Organization's negotiations on the Framework on Pandemic Influenza Preparedness.

The EU further insisted that relationships with the WTO should not be addressed in the ABS Protocol because neither it nor the CBD are trade agreements. The EU's intent was clear: The ABS Protocol should not touch IPR issues. Developing countries opposed this and pointed out that developed countries had introduced trade language in Article 5 on access to genetic resources. In the final draft text of 26 October, delegations agreed on language that took up the new concept but at the same time reduced its legal implications to a minimum:

"3. This Protocol shall be implemented in a mutually supportive manner with other international instruments relevant to this Protocol. Due regard should be paid to useful and relevant ongoing work or practices under such international instruments [and international organizations], provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol."

The remaining bracket indicating that developing countries still did not accept the link to international organizations was removed during the closed-door process on 29 October 2010, and the word "relevant" was added to qualify the words "ongoing work or practices" in Article 4(3).

From the above discussion, it can be said that the Nagoya Protocol's Article 4(3) is an aberration of general international law relating to a relationship clause in a treaty, and could result in problems during the implementation stage.

Relationship and hierarchy in international law is a subject of scholarship. This includes (a) the general relationship between different sources of international legal obligations, in particular between treaty and customary international law; (b) the relationship between different subject matter areas of international law (for example, trade and environment; development and human rights); and (c) where a treaty obligation in one field interfaces with a customary norm in another. The basis of the scholarship and practice is the sources of international law that provide the principles, norms and rules for the international community.

The widely recognized authoritative statement on the sources of international law is Article 38 of the Statute of the International Court of Justice (ICJ) that provides that in deciding disputes, the Court shall apply:

- International conventions, whether general or particular, establishing rules expressly recognized by the contesting states;
- International custom, as evidence of a general practice accepted as law;
- The general principles of law recognized by civilized nations;
- Judicial decisions and the teachings of the most highly qualified publicists of the various nations, as subsidiary means for the determination of rules of law.

The first three categories (treaties, custom, and principles of law) are referred to in some jurisdictions as "primary sources" of international law. The last two (judicial decisions and the teachings of publicists) are sometimes referred to as "secondary sources" or evidence of international law rules.

In recent times the growing role of international organizations is recognised, including the resolutions and other acts of international governmental organizations, such as the United Nations, as potential sources or evidence of international law.

It is clear, however, that there is a hierarchy of the sources of international law. To ensure legal certainty when States take on legally binding obligations in a treaty, the relationship clause must be crafted carefully. As such, it is unfortunate that Article 4(3) has introduced legal uncertainty.

First, a relationship clause deals with other international instruments. As argued by many developing countries up until the final hours of the negotiations in Nagoya, reference to international organizations is inappropriate as these are not of the same status as international instruments. Secondly, the reference to "any ongoing work or practices under such organizations" is even weaker and thus also inappropriate. There is legal uncertainty as 'ongoing work' is always in a state of flux and reflects work that has not been concluded. Furthermore, 'practices' have no status in international law as a source of law. Practices of international organizations may be 'created' in all kinds of ways: through use, custom, decisions, and such like. To equate these to the obligations and commitments of a legally binding treaty would have an adverse effect on the force of international law.

However, it is important to note that Article 4(3) is worded in a permissive, and not mandatory, manner: Parties "should" and not "shall" or "must". Furthermore, the requirement is to "pay due regard" and even this is subject to the proviso that the work or practices concerned are "supportive of and does not run counter to the objectives of the CBD and the Protocol".

Nevertheless, it is hoped that Article 4(3) will not be a precedent for future treaties.

Ongoing WIPO-IGC negotiations

The work of the WIPO Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore (IGC) will need to ensure consistency with the provisions of Article 4(2) of the Nagoya Protocol. During negotiation of the Protocol, CBD Parties agreed that the WIPO IGC work should not prejudice or pre-empt the outcome of the ABS negotiations. At the time of writing the WIPO IGC has begun text based negotiations on an "international legal instrument" on genetic resources and associated traditional knowledge. In a linked process, the IGC is also considering traditional knowledge in other areas, such as traditional cultural expressions including music and art.)At the IGC, developing countries have placed a strong focus on creating an international requirement to disclose the origin of genetic resources and associated traditional knowledge in intellectual property applications. Such a mandatory requirement is strongly opposed by the United States, Japan, Canada, and South Korea, and it is unclear if an agreement including a disclosure requirement will eventually be reached.In these negotiations, CBD Parties need to ensure that any resulting WIPO agreement is compliant with and supportive of the objectives and provisions of the CBD and the Nagoya Protocol, and that a mandatory disclosure requirement, if created, be strong enough so as to discourage and prevent biopiracy.

Article 5 – FAIR AND EQUITABLE BENEFIT SHARING

Article 5 of the Nagoya Protocol (draft Article 4) on fair and equitable benefit sharing is certainly its core article. It builds upon a key provision of the CBD, Article 15(7)[14], which developing countries have emphasized since the CBD came into force

To date no developed country, apart from Norway in its 2009 Act relating to the management of biological, geological and landscape diversity, has implemented this obligation by introducing "user measures" requiring national users to comply with benefit sharing obligations under national and international law.

The importance of CBD Article 15(7) was recognized at the World Summit for Sustainable Development in 2002 in Johannesburg when the Heads of States and Governments agreed to:

"… negotiate within the framework of the Convention on Biological Diversity, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources;"

Based on the COP 7 Decision VII/19, the ABS Protocol was also mandated to include utilization of traditional knowledge associated with genetic resources in its benefit sharing provisions.

Article 5 defines which Parties are eligible for benefit sharing, and creates an obligation for Parties to set up legislative, administrative and policy measures to share the benefits that arise from the utilization of:

- Genetic resources;
- Genetic resources of ILC; and
- Traditional knowledge of ILC associated with genetic resources.

One of major achievements of the Nagoya Protocol is to clarify that the negotiation of access to genetic resources and associated traditional knowledge is not the trigger for benefit sharing obligations. Rather, it is the utilization of genetic resources or associated traditional knowledge that triggers this requirement. This concept was born out of the understanding among developing countries that past and present biopiracy must not be rewarded by delaying the establishment and implementation of international benefit sharing rules.

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[14] [Parties] "shall take legislative, administrative or policy measures, as appropriate, [...] with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms."

Article 5 – FAIR AND EQUITABLE BENEFIT-SHARING

1. In accordance with Article 15, paragraphs 3 and 7 of the Convention, benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention. Such sharing shall be upon mutually agreed terms.
2. Each Party shall take legislative, administrative or policy measures, as appropriate, with the aim of ensuring that benefits arising from the utilization of genetic resources that are held by indigenous and local communities, in accordance with domestic legislation regarding the established rights of these indigenous and local communities over these genetic resources, are shared in a fair and equitable way with the communities concerned, based on mutually agreed terms.
3. To implement paragraph 1, each Party shall take legislative, administrative or policy measures, as appropriate.
4. Benefits may include monetary and non monetary benefits, including but not limited to those listed in the Annex.
5. Each Party shall take legislative, administrative or policy measures as appropriate, in order that the benefits arising from the utilization of traditional knowledge associated with genetic resources are shared in a fair and equitable way with indigenous and local communities holding such knowledge. Such sharing shall be upon mutually agreed terms.

Development

Article 5 does not only formulate international standards for benefit sharing, it also contains wording that aims at resolving some of the most contentious issues of the ABS discussions as for example the utilization of products derived from genetic resources and the utilization of derivatives in the context of traditional knowledge associated with genetic resources. The various WGABS-meetings produced a large body of paragraphs and language on benefit sharing obligations that were finally condensed in one article in the co-chairs non-paper for ABSWG-9/1 in 2010 in Cali:

"1. Parties shall take legislative, administrative or policy measures, as appropriate, with the aim of ensuring the fair and equitable sharing of the benefits arising from the utilization of genetic resources with the country providing such resources.

2. Benefits shall be shared on mutually agreed terms. Benefits may include monetary and non-monetary benefits provided for by the Convention in Articles 15, 16 and 19 including but not limited to those listed in the Annex.

3. Parties shall take legislative, administrative or policy measures, as appropriate, to ensure the fair and equitable sharing of benefits arising from the utilization of traditional knowledge associated with genetic resources with the holders of such knowledge pursuant to mutually agreed terms, taking into consideration the provisions of Article 9."

During the WGABS-9/1 and -9/2 meetings this concept was broadened to capture the mentioned critical aspects, the ING-Meeting in 2010 in Montreal developed a draft Article 5 that came close to the final version.

On Legal Nature

The Co-chairs' non-paper tried to accommodate the two positions with regard to the legal nature of the benefit sharing provisions.

Parties to the Protocol must be pro-active in taking benefit sharing measures but can choose among 3 options "as appropriate" – legislative, administrative or policy measures – each with different legal force. Most developing countries favour this flexibility throughout the Protocol because of various difficulties encountered in formulating ABS laws, including limited capacity to develop and implement such laws. That is also one of the main reasons for these countries to seek strong legislative measures from developed country Parties to enforce benefit sharing.

On the other hand, the long-standing refusal of the developed countries to agree on any binding ABS rules is reflected in the words "with the aim of ensuring". There is a distinct difference between this and "to ensure". With the former, Parties would have a low standard to meet as to whether their measures comply with their Protocol obligations, and benefit sharing need not be guaranteed. This wording is in support of the consistent parallel attempts of developed countries to weaken the provisions on compliance as far as possible. Not surprising, the EU supported this wording in the non-paper at WGABS-9/1 in 2010.

At WGABS-9/1 delegations finally deleted the language on "aim of ensuring" from draft Article 4(1) and included traditional knowledge associated with genetic resources, thus building further on the provisions of the CBD. In addition a new Article 4(2) was drafted that dealt with sharing the benefits of the utilization of products, which used the weaker language of the non-paper. The ING-Meeting in 2010 finally decided to deal with the utilization of genetic resources and their products, which are under the control of the State in draft Article 4(1), establishing a strong and explicit obligation in the context of benefit sharing. The specific conditions that would make benefit sharing "fair and equitable" would eventually be negotiated between the partners of an ABS contract. The elements and criteria of such ABS negotiations and conditions could be further guided by national regulation.

On Genetic Resources and Associated Traditional Knowledge of ILC

The ING meeting in 2010 decided to use the CBD language "with the aim of ensuring" in draft Article 4(1)bis on benefit sharing from the utilization of genetic resources that are held by ILC in accordance with national legislation:

"[… Parties shall take legislative, administrative or policy measures, as appropriate, with the aim of ensuring that benefits arising from the utilization of genetic resources and/or traditional knowledge associated with genetic resources that are held by indigenous and local communities, in accordance with national legislation regarding the established rights of these indigenous and local communities over these genetic

resources, are shared in a fair and equitable way with the communities concerned, based on mutually agreed terms.]"

Draft article 4(1)bis was strongly opposed by Canada that only gave up its resistance to this new international obligation with regard to genetic resources of ILC on 27 October after the reference to traditional knowledge associated with genetic resources was deleted. Negotiators agreed to consider access to associated traditional knowledge in a separate draft Article 4(4). While draft article 4(4) simply speaks of ILC that are holders of the associated traditional knowledge – without explaining what constitutes "holders" – draft article 4(1)bis had referred to the established rights of ILC over their genetic resources "in accordance with domestic legislation".

The UNDRIP adopted by the UN General Assembly in 2007, recognizes international norms regarding the rights of indigenous peoples and of relevance to the Nagoya Protocol is Article 31, which states:

"1. Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts. They also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions.

2. In conjunction with indigenous peoples, States shall take effective measures to recognize and protect the exercise of these rights."

Governments, which are committed to delivering benefits to indigenous peoples and local communities arising from the Nagoya Protocol, are enjoined to enact national laws, policies and procedures consistent with Article 31 of UNDRIP in the course of national implementation.

The reference to domestic legislation in the Nagoya Protocol cannot be interpreted to mean that governments have absolute flexibility with regards the content of national laws and policy, but rather, that domestic legislation shall give effect to international obligations and that established rights – including the rights of indigenous peoples – shall be recognized and enshrined in national law. Such an interpretation of the Nagoya Protocol will enable equitable benefit sharing for ILCs.

The Protocol now requires Parties to take appropriate measures "with the aim of ensuring" benefit sharing with ILCs from the utilization of genetic resources that are held by them under established rights in accordance with domestic legislation in Article 5(2). In contrast Parties shall take appropriate measures "in order that" there is benefit sharing from the utilization of traditional knowledge associated with GR, with the ILC holders of such knowledge. The words "as well as subsequent applications and commercialization" are also missing from Article 5(2).

On Subsequent Applications and Commercialization

The utilization of genetic resources can be divided into three phases: research, development and commercialization. During the Protocol negotiations delegations agreed that in the context of access provisions the use of genetic resources for certain purposes such as manufacturing (e.g. wood for furniture production) or human consumption (e.g. oranges for juice production) should not be included. For that purpose the definition of utilization of genetic resources only covers the two first stages of research and development. It was argued by some delegations that since marginal (monetary) benefits will accrue at that stage, draft Article 4 (now Article 5 in the Protocol) should ensure that benefits arising in the phase of commercialization should also be shared.

While the Co-chairs' non-paper did not take this up, some delegations at WBGABS-9/2 introduced a new Article 4(2) to address this issue. The ING-Meeting in 2010 decided to merge draft Articles 4(1) and 4(2) and introduced the term "benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization" to capture benefits from the commercialization phase of products derived from genetic resources. This term stems from deliberations of a small group during WGABS-9/2 in 2010 at the discussion of the definition of "utilization of genetic resources" and reads as follows:

"Utilization of genetic resources includes/means the conduct of research and development, on the genetic and biochemical makeup/composition of genetic material/ biological resources, including through the application of biotechnology as defined in Article 2 of the Convention, as well as subsequent applications and commercialization."

At the ING-Meeting, delegations decided to shift the last words to the draft Article 4(1) on benefit sharing where it was kept in brackets until the end of the negotiations. Developed countries knew that without these words, no substantial benefits would ever reach the provider. They thus bracketed the words as bargaining chip in their negotiations with developing countries.

At the same time, developed countries also bracketed the word "utilization" in the draft Article 4 – as well as everywhere else in the draft text – until the outcome of the separate discussion on the use of terms was clear. It was only during the closed door process on 29 October 2010 that it was decided that the Protocol would contain a benefit sharing provision that can ensure the inclusion of the main portion of benefits arising from the utilization of genetic resources. This appears to be part of the trade-off that the EU and Brazil crafted to offset a much weakened compliance system and the removal of publicly available traditional knowledge, among other things.

While the inclusion of the sharing of benefits arising from the commercialization of genetic resources and their derivatives appeared to be an option preferred by a large majority of the delegations, wording leading to this similar effect was deleted from draft Article 4(1)bis on genetic resources of ILC at the ING meeting in Nagoya in October 2010. Thus, Parties to the Protocol are only obliged to "aim at ensuring" the sharing of benefits arising from the utilization of genetic resources with the ILCs concerned. The words "as well subsequent applications and commercialization" do not appear in the final Article 5(2).

The Nagoya Protocol seemingly does not establish an international obligation for its Parties to share the benefits arising from the most lucrative phase of commercialization of genetic resources of ILC. A similar reference to the benefits arising from the commercialization phase of associated traditional knowledge in draft Article 4(4) was finally deleted in the closed-door process at the last day of COP-10. The exact effect of this deletion is not clear because the Nagoya Protocol does not define "utilization of traditional knowledge". Currently, definitions for traditional knowledge and their rightful holders are negotiated at the WIPO. It would be very important for Parties to the CBD and Nagoya Protocol to ensure that the outcome of this negotiation is supportive of the Nagoya Protocol and augments its implementation at the national level.

On Temporal Scope and Benefit Sharing with the Country of Origin

During WGABS-7 and -8 the applicability of the Protocol to genetic resources accessed before the entry into force of the CBD or the Protocol itself was under debate. The Co-chairs' draft Article 3 on scope in their non-paper for WGABS-9/1 in 2010 was based on the understanding that there cannot be a retrospective application of the Protocol; its draft Article 4(1) proposed "ensuring the fair and equitable sharing of the benefits arising from the utilization of genetic resources with the country providing such resources".

At this meeting, the Like-minded Asian and Pacific Group and the Group of Like-minded Megadiverse Countries changed this wording of draft Article 4(1) into "Party providing such resources" to read as follows:

"Users of genetic resources, their derivatives and associated traditional knowledge, as appropriate, must share benefits arising from every utilization of such resources, their derivatives and associated traditional knowledge in a fair and equitable way with the Contracting Party providing the genetic resource, their derivatives and associated traditional knowledge, that is the country of origin of such resources or by Parties that have acquired the said resources in accordance with the Convention on Biological Diversity."

The crucial question of the temporal scope of the Nagoya Protocol is not resolved by explicit provisions in Article 3 (Scope) nor Article 5 (Benefit-Sharing). Several articles of the Protocol, however, indicate that the scope of the Nagoya Protocol should be the same as the scope of the CBD, such as Article 4(4), which states, "This Protocol is the instrument for the implementation of the access and benefit-sharing provisions of the Convention" or Art. 5(1) "In accordance with Article 15, paragraphs 3 and 7 of the Convention, […]." Therefore the scope of the Nagoya Protocol should not be narrower than the scope of the Convention.

Some have argued that the Protocol cannot have any retroactive effect. As there is no explicit provision relating to this question, Article 28, on retroactivity, of the Vienna Convention on the Law of Treaties applies: "Unless a different intention appears from the treaty or is otherwise established, its provisions do not bind a party in relation to any act or fact which took place or any situation which ceased to exist before the date of the entry into force of the treaty with respect to that party." In applying the

Vienna Convention it is evident that there is no obligation to share benefits from utilization that took place or which ceased to exist before the entry into force of the Protocol. But – taking up the same argument – there would be an obligation to share the benefits of new or ongoing utilizations, even if access has taken place before the Protocol's entry into force because the trigger for the benefit sharing obligations is the act of utilization and not the act of access.

The way in which this issue will be resolved in national laws implementing the Nagoya Protocol will decide on the impact and usefulness of the Protocol. Sharing only benefits arising from the utilization of genetic resources which were acquired after the entry into force of the Protocol may mean refusing to share the largest part of the benefits arising from the use of genetic resources.

Before the Nagoya Protocol was agreed upon, several stakeholders had already taken a decision on the question of temporal scope. The principles of Botanic Gardens Conservation International state: "Share benefits arising from the use of genetic resources acquired prior to the entry into force of the CBD, as far as possible, in the same manner as for those acquired thereafter."

Moreover, botanical gardens working together in the International Plant Exchange Network (IPEN) have agreed to use a material transfer agreement which includes the following provision: "By signing this Agreement the recipients commit themselves to act in compliance with the CBD and its agreed provisions on Access and Benefit-Sharing. This includes a new Prior Informed Consent (PIC) of the country of origin for any uses not covered by terms under which it has been acquired (such as commercialization)."

The International Treaty (ITPGRFA) also does not differentiate between genetic resources accessed by CGIAR Centers (or other seed banks) before or after the coming into force of the CBD. This is the currently widely adopted practice of public *ex-situ* collections.

Article 6 – ACCESS TO GENETIC RESOURCES

While developing countries wanted a legally binding benefit sharing treaty under the CBD, developed countries did not. When it was evident that there would be intergovernmental negotiations launched on a benefit sharing international regime resulting from the political direction of Heads of Stated and Governments at the 2002 Johannesburg Summit on Sustainable Development, developed countries tried to establish international access rules on at least an equal footing with any benefit sharing outcome. The negotiated mandate for the Protocol included access, but developing countries argued that access is a matter of national sovereignty and the principle of prior informed consent (PIC) included the right to allow or deny access. On the other hand, the thrust and objective of the negotiations were to secure benefit sharing.

To understand the long-drawn controversy over the access provisions of Article 6 and the debates on "international access standards" and "facilitated access", it is important to remember that the CBD in Article 15(1) recognizes:

"the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation."

Developing countries argued that the ABS Protocol should contain no or at least no substantive provisions on national access rules going beyond CBD Article 15(2), which states:

"Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention."

Developed countries argued that the Protocol should set international access standards if not to harmonise national access rules, then at least to ensure better compliance across jurisdictions.

The final Article 6 imposes additional obligations on Parties that provide genetic resources.

First, Article 6(1) sets out the conditions under which access to a genetic resource is granted by a Party the Protocol and requires domestic ABS legislation or regulatory requirements to be in place for prior informed consent.

Article 15(5) of the CBD, however, creates a clear obligation for those seeking access to genetic resources to first obtain prior informed consent but does not specifically require national ABS regulations as a pre-condition to consent being granted. It states: "access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party."

This raises a concern that in the absence of a national law, some may argue that PIC is not required. Another concern is that without specific access regulation, a Party may not be able to require other Parties to undertake user measures or ensure compliance with the rights of providers (Parties or ILCs) even though these are in the CBD and Nagoya Protocol.

Secondly, the Protocol in Article 6(3) goes further than the CBD by requiring additional obligations that will need to be incorporated into national legislative, administrative or policy measures. Despite the reaffirmation of national sovereignty, Article 6(3) describes in strong language the elements and procedures to be adopted in national access measures, considerably reducing the national autonomy under the CBD.

It would be necessary now for countries to formulate national ABS legislation or regulatory requirements as a matter of priority if it decides to be Party to the Protocol.

Based on the COP-7 mandate for the negotiations, the Nagoya Protocol also covers access to traditional knowledge associated with genetic resources. It sets up rules for access to genetic resources of ILC in Article 6(2), and access to traditional knowledge associated to genetic resources in the separate Article 7.

Article 6 – ACCESS TO GENETIC RESOURCES

1. In the exercise of sovereign rights over natural resources, and subject to its domestic access and benefit-sharing legislation or regulatory requirements, access to genetic resources for their utilization, shall be subject to the prior informed consent of the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention, unless otherwise determined by that Party.

2. In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that the prior informed consent or approval and involvement of indigenous and local communities is obtained for access to genetic resources where they have the established right to grant access to such resources.

3. Pursuant to paragraph 1 above, each Party requiring prior informed consent, shall take the necessary legislative, administrative or policy measures, as appropriate, to:

(a) Provide for legal certainty, clarity and transparency of their domestic access and benefit-sharing legislation or regulatory requirements;

(b) Provide for fair and non-arbitrary rules and procedures on accessing genetic resources;

(c) Provide information on how to apply for prior informed consent;

(d) Provide for a clear and transparent written decision by a competent national authority, in a cost-effective manner and within a reasonable period of time;

(e) Provide for the issuance at the time of access of a permit or its equivalent as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms, and notify the Access and Benefit-sharing Clearing-House accordingly;

(f) Where applicable, and subject to domestic legislation, set out criteria and/or processes for obtaining prior informed consent or approval and involvement of indigenous and local communities for access to genetic resources; and

(g) Establish clear rules and procedures for requiring and establishing mutually agreed terms. Such terms shall be set out in writing and may include, *inter alia*:

(i) A dispute settlement clause;

(ii) Terms on benefit-sharing, including in relation to intellectual property rights;

(iii) Terms on subsequent third-party use, if any; and

(iv) Terms on changes of intent, where applicable.

Development

As with the development of Article 5, Article 6 prompted contentious discussions, for example, on temporal and political scope of the Protocol, access to derivatives or products derived from genetic resources, the option for a Party to not require PIC as well as the inclusion of traditional knowledge associated with genetic resources. Lengthy debates related to Article 6 also included discussion of "international access standards" and "non-discriminatory access rules".

The attempt by the EU and Canada to introduce the trade notions of "non-discrimination" and "national treatment" so that foreign and domestic requesters for access should be treated the same, sparked intense debate over several meetings of the negotiations.

It is important to be clear that "non-discrimination" in certain WTO agreements and bilateral free trade agreements generally means "most favoured nation" (MFN) and "national treatment". Countries cannot normally discriminate between their trading partners under these two notions. However, in each WTO agreement the principle is handled slightly differently. Some exceptions are allowed under specific conditions.

National treatment in trade law means that foreigners and locals are to be treated equally. So, for example, imported and locally produced goods should be treated equally after the foreign goods have entered the market. The same should apply to foreign and domestic services, and to foreign and local trademarks, copyrights and patents. It is important to note that national treatment only applies once a product, service or item of intellectual property has entered the market. Therefore, charging customs duty on an import is not a violation of national treatment even if locally produced products are not charged an equivalent tax.

Thus, there is a substantive legal difference between "non-discrimination" or "non-discriminatory way" and "fair and non-arbitrary".

The Co-chairs' non-paper for WGABS-9/1 brought together the debates on these various items in the following text:

"1. In the exercise of their sovereign rights over their natural resources, Parties shall take the necessary legislative, administrative or policy measures, as appropriate, to provide for legal certainty, clarity and transparency of their national access and benefit-sharing requirements. Such measures shall *inter alia*:

(a) Set-out clear and fair rules and procedures on accessing genetic resources that do not arbitrarily distinguish between national and foreign users;

(b) Provide for accessible information on domestic access and benefit-sharing requirements, in particular, on how to apply for prior informed consent;

(c) Establish clear criteria against which applications for prior informed consent are judged and for a written decision by a competent national authority to be notified to the applicant within a reasonable period of time;

(d) Provide for the issuance of a permit or certificate as evidence of the decision to grant prior informed consent;

(e) Establish clear rules and procedures for requiring and establishing mutually agreed terms at the time of access. Such terms shall be set out in writing and include: (i) a dispute settlement clause; (ii) terms on benefit-sharing; (iii) terms on subsequent third-party use; and (iv) terms on changes of intent.

2. Parties shall inform the Access and Benefit-sharing Clearing-House established under Article 11 of their decisions to grant prior informed consent.

3. A Party that determines that access to its genetic resources will not be subject to prior informed consent shall inform the Access and Benefit-sharing Clearing-House accordingly.

4. Subject to national legislation, access to traditional knowledge associated with

genetic resources shall be subject to the prior informed consent of the holders of such knowledge and based on mutually agreed terms, taking into consideration the provisions of Article 9. Mutually agreed terms shall provide for the fair and equitable sharing of benefits arising from the utilization of such knowledge with the holders."

This draft was accepted as a template for further negotiations and is still recognizable in the final Article 6 of the Nagoya Protocol. At WGABS-9/1 in March 2010, delegations decided to use draft Article 5(1) to define the conditions for access to genetic resources, while access standards would be dealt with in a separate paragraph.

In line with the guidance of the Group of Technical and Legal Experts from its 2008 meeting in Windhoek, the Nagoya Protocol does not regulate access to genetic resources as such. GTLE-1 suggested that rather than renegotiating the imprecise definitions of the CBD, a more practical approach should be taken: the Nagoya Protocol should regulate distinct categories of "typical" utilization of genetic resources, based on a more deductive approach. Article 6 in combination with Article 2 covers utilization of genetic resources for research and development, which would also cover changes in utilization of genetic resources that had been originally acquired outside of the scope of the Nagoya Protocol, e.g. as commodities.

On Derivatives

While CBD Article 15 does not provide for the application of its ABS rules on derivatives, the Bonn Guidelines adopted in 2002 recognised that there could be benefit sharing with respect to the utilization of derivatives. While for example the inclusion of traditional knowledge associated to genetic resources – which is also not dealt with under CBD Article 15 – was incorporated in the mandate to negotiate the Nagoya Protocol, CBD Parties could never agree on broadening the scope of the access rules of the Nagoya Protocol to include derivatives. Developing countries have always included respective wording in the different versions of the draft text, developed countries have put it in brackets. The co-chairs non-paper for WGABS-9/1 in March 2010 in Cali tried to accommodate the position of developing countries through its wording for draft Article 5.1 when it used the expression "natural resources" that could include derivatives:

"In the exercise of their sovereign rights over their natural resources, Parties shall take the necessary legislative, administrative or policy measures, as appropriate, to provide for legal certainty, clarity and transparency of their national access and benefit-sharing requirements."

WGABS-9/1 using the expression "genetic resources" changed this text. Reacting on this change, developing countries at WGABS-9/2 brought back the word "derivatives", but already at ING-1 in September 2010 in Montreal it ultimately disappeared from the text of draft Article 5.1. At the same meeting, a definition for the term "derivatives" was for the first time included in the draft text but negotiators could never agree on using the term in the definition of utilization. Thus, it was essentially

decided that the access rules of Article 5 of the Nagoya Protocol do not mention derivatives as such, which would leave this topic to be regulated under national legislation - as it is the case in many countries already. In combination with the definitions provided by Article 2, some experts argue that access to derivatives could still fall under the rules of the Nagoya Protocol, while other experts reject this interpretation.

One of the prominent examples of establishing an ABS system on the basis of access to derivatives is the InBIO case of Costa Rica. The extracts, which InBIO makes available to its clients, are due to the applied extraction methods free of functional units of heredity, namely DNA and RNA. Although this case has meanwhile reached worldwide recognition as a pioneering ABS case implementing the CBD it actually has always been outside of the scope of the CBD and probably also the Nagoya Protocol. At the same time it shows the importance to capture access to derivatives under national ABS regimes in order to benefit from increased national capacities in research and development and moving beyond the state of merely providing raw materials for the industries of developing countries.

On Genetic Resources and Associated Traditional Knowledge of ILC

Based on the COP 7 mandate, access to traditional knowledge associated with genetic resources was an element in the draft provisions on access from the beginning. The WGABS-9/1 Co-chairs' non-paper suggested a specific paragraph on the issue in the benefit sharing draft:

> "4. Subject to national legislation, access to traditional knowledge associated with genetic resources shall be subject to the prior informed consent of the holders of such knowledge and based on mutually agreed terms, taking into consideration the provisions of Article 9. Mutually agreed terms shall provide for the fair and equitable sharing of benefits arising from the utilization of such knowledge with the holders."

This formulation did not recognize a right of ILCs to PIC if a user wants to access their traditional knowledge associated with genetic resources as such. Rather, it subjected ILCs' PIC rights to provisions of national legislation. Representatives of ILCs said the wording was inconsistent with UNDRIP, and a similar discussion ensued under draft Article 5bis (now Article 7 of the Nagoya Protocol: Access to traditional knowledge associated with genetic resources).

WGABS-9/1 included the issue under "access standards," and WGABS-9/2 finally linked access to traditional knowledge associated with genetic resources with access to genetic resources under draft Article 5.1. When the delegations informally agreed to comparably treat genetic resources and associated traditional knowledge, ING 1 created a new draft Article 5.1bis, with three options, as an attempt to better capture the different legal and customary c law oncepts with regard to the ownership of genetic resources, and associated traditional knowledge.

These three options included reference to genetic resources owned by ILC, a new concept not previously contained in the CBD or the Bonn Guidelines. This concept is a logical application of the principle of sovereignty over natural resources as confirmed in the CBD. With the adoption of UNDRIP, indigenous peoples have the right at the international level to determine over their genetic resources and traditional knowledge. Consequently, governments should formally recognize these customary rights in national legislation, including the right to PIC in cases where access to ILC genetic resources or traditional knowledge is sought.

While the Nagoya Protocol fails to fully acknowledge the customary rights of ILC and obliges the Parties to formalize them in positive law, its preamble states that, "nothing in this Protocol shall be construed as diminishing or extinguishing the existing rights of indigenous and local communities".

The three options mentioned above reflected different governmental approaches to recognizing traditional knowledge associated with genetic resources, and for the legal rights of ILCs under their jurisdiction. During COP-10, delegates debated how to approach the integration of traditional knowledge associated with genetic resources into access and benefit sharing provisions in the context of draft Article 4.1bis (see comments in the earlier section on Article 5 of the Nagoya Protocol). It was thought that when a solution was found for Article 5 (on benefit sharing) that Article 6 (on access) could be resolved on the same basis.

On Access to Genetic Resources Limited to Country of Origin

As noted before, at the WGABS-9/1 the Like-minded Asia and Pacific Group and the Group of Like-minded Megadiverse Countries linked access provisions to the country of origin in draft Article 5.1 (now Article 6.1 of the Nagoya Protocol):

> "Every access shall be with the prior informed consent of the Contracting Party providing the genetic resources, and their derivatives that is the country of origin of such resources, or by a Party that has acquired the genetic resource and their derivatives, unless a Party otherwise determines under Article 15(5) of the Convention on Biological Diversity and taking into account Article 5(3) of this Protocol."

This proposal builds upon three definitions from the CBD itself.[15]

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[15] CBD Article 2 on Use of Terms: "*Country providing genetic resources* means the country supplying genetic resources collected from *in-situ* sources, including populations of both wild and domesticated species, or taken from *ex-situ* sources, which may or may not have originated in that country."
"*In-situ conditions"* means conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties."
"*Country of origin of genetic resources* means the country which possesses those genetic resources in *in-situ* conditions."

Consequently, genetic resources provided by a Party to the Protocol would encompass wild and agricultural genetic resources that were developed or bred in that country, as well as genetic resources from *ex-situ* collections. The implication of the combined application of all three definitions is that a Party to the Protocol could not give access to genetic resources from other countries which itself keeps in *ex-situ* collections – unless they were acquired in accordance with the CBD.

The intention of the like-minded groups was that this complements an accompanying submission on draft Article 4.1 on benefit sharing. This addition invoked CBD Article 15(3) limiting the application of ABS provisions to genetic resources accessed in the country of origin. While the submission for draft Article 4.1 took up accepted CBD text and concepts, the submission for draft Article 5.1 had strong implications for access to genetic resources worldwide. The submission implied that Parties that are not the country of origin for a specific genetic resource would be unable to grant a PIC to users requesting access to that genetic resource.

The effect of the proposal would be, to take an example, that if Country A held, in a genebank, microbial cultures originating in Country B, Country A could not provide PIC and access to those cultures to a requester from a third country. Instead, Country A would refer such requests to Country B, the origin of the genetic resource.

While this wording is in line with CBD Article 15.3, given the far-ranging consequences of such a provision for *ex situ collections* (seed banks, botanical gardens, culture collections, and others), the wording on "countries of origin" remained in brackets until the negotiations were stalled on October 29. The issue was only resolved during the closed-door process on October 29.

A second issue was some countries' announcement that they would not require PIC for access to genetic resources already included in the draft provisions at WGABS-7 in 2009. This was carried along in the various text versions. This underscored that the Nagoya Protocol was not to set substantive access standards, as developing countries at WGABS-9/2 included the wording that they be "subject to national law". This addition was bracketed by developed countries and also was only to be resolved during the closed-door process on October 29.

The final version of draft Article 5(1), before October 29, recognized all positions and aimed to prevent overly prescriptive language on access via the proviso "unless otherwise determined by that Party," which applies to all provisions of draft Article 5(1) (Now Article 6 of the Nagoya Protocol).

On Ex-situ Collections

A further topic presenting difficulty for ABS rules are the many *ex-situ* collections of plant, microbial and animal genetic resources, such as botanical gardens, microbial collections, and zoos. A vast number of the accessions in *ex-situ* collections stem from pre-CBD times and, to further complicate matters, some were acquired after the CBD entered into force but without respecting the treaty's ABS requirements.

As a result of the unresolved status of these collections and the inactivity of most national governments (especially those that house these collections) to set ABS norms, the institutions that manage many *ex-situ* collections started developing their own ABS

guidelines at an early stage. Prominent examples are the International Plant Exchange Network (IPEN), Botanical Gardens Conservation International (BGCI) and the Micro-Organisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC) guidelines. The 147 members of IPEN and the 28 botanical gardens and institutes that have endorsed the BGCI "Principles on Access to Genetic Resources and Benefit-Sharing" declare that any new accessions will be acquired on the basis of PIC and that they will develop policies on how to deal with accessions present in their collections that were not.

IPEN members agree to seek a new PIC when accessions are sold for commercial purposes, however, members of BGCI consider themselves free to sell their accessions without PIC, provided they have a clear policy on commercialization. The MOSAICC guidelines, first published in 2000, also advise *ex-situ* collections to acquire new resources with PIC and MAT and to clarify utilization and IPR issues. In cases were no PIC is available, MOSAICC recommends that the country of origin be determined, and *ex-situ* collections are cautioned to only exchange samples with PIC or an identified country of origin.

Interestingly, the topic of *ex-situ* collections never took on a prominent role in the ABS negotiations. At the ING meeting in October 2012, the question how to address them was marked as outstanding issue in a footnote. *Ex-situ* collections then disappeared altogether during the final closed-door process. Based on the provisions of Articles 5 and 6 of he Nagoya Protocol it can be concluded that *ex-situ* collections are to be regarded as like any other source of genetic resources in a Party of the Protocol. Access to those genetic resources is possible when the provider country is the country of origin or has acquired them in accordance with the CBD.

On International Access Standards

At WGABS-6 in 2008, the EU launched a debate on international access standards which was met by strong opposition from developing countries. It was eventually agreed that such standards should be regarded as "tools to encourage compliance". WGABS-7 and 8 elaborated extensively on the topic with the understanding of the need for a balance between access and compliance standards in order to offer legal certainty to both users and providers. The Co-chairs' non-paper based its draft Articles on this debate. WGABS-9/1 put all the access standards under draft Article 5(2) [Now Article 6(3) of the Nagoya Protocol]. Many substantive issues were resolved at WGABS-9/2.

Two issues, however, remained highly controversial: "non-discriminatory access rules" in draft Article 5(2)(a)bis and "appeals procedures" in draft Article 5.2 (g).

On "fair and non-arbitrary" Access Rules and Procedures

Whether and under which circumstances access rules could differentiate between users, for example between domestic and foreign requests for access, was a matter of debate from WGABS-1 in 2001 when the Bonn Guidelines were drafted. Developed countries worked to include "trade language" in the text, for example introducing the

concept of "non-discriminatory" access. In Bonn, they argued that all potential users, domestic or from other Parties, should enjoy the same status ("rights and duties") in access to genetic resources and associated traditional knowledge.

During WGABS-2 in 2003, developed countries revived "non-discriminatory" access and by the time of WGABS-3 in 2005 linked it to the issue of "facilitated" access in the draft text for scope:

> "Facilitate access to genetic resources in a non-discriminatory fashion."

At WGABS-6 in 2007, the EU proposed that Parties ensure that national access rules apply in a non-discriminatory way. Canada became a vocal proponent of this at WGABS-7, arguing that foreign applicants for access should be treated in the same way as nationals, and that nationals of one foreign country always be accorded the same treatment as those of another. Developing countries considered the introduction of a concept used in trade negotiations to be inappropriate, and consistently stressed its inconsistency with the sovereign right of States to determine access conditions.

A group of developing countries made a counter proposal to use the term "non-arbitrary". This reflected the recognition by many delegations that there are many reasons to treat requesters differently, for example national research institutions versus foreign multinational companies, yet there was also broad agreement that rules should be implemented in a non-arbitrary manner:

> "[(g) [Appropriate] administrative or judicial appeals procedures in respect of prior informed consent[, including for failure to act and [arbitrary and unjustifiably] discriminatory access practices];]"

In an attempt to resolve the controversy the WGABS-9/1 Co-chairs' non-paper did not use either term. Canada, however, insisted on adding the trade language to the provisions on access standards. Developing countries strongly opposed Canada's proposal. When it became clear that Canada was not willing to change its position, the negotiations on this issue broke down and little subsequent progress was made until Nagoya.

For the debate at COP-10, a third option was added:

> "[Provide for fair and non-arbitrary rules and procedures on accessing genetic resources]"

An intense debate over this option ensued when some developing country delegates opposed it, prompting the EU to ask if they would instead prefer "unfair and arbitrary rules". Developing countries made it clear that they did not reject the concept of "fair and non-arbitrary" but the context. They observed that while the EU demanded non-arbitrariness in national access rules, it rejected the same concepts in the context of compliance, leading to an unbalanced Protocol at the expense of providers. Many developing countries opposed the paragraph as such and preferred to see it as an element

of the preamble. No compromise could be reached, and the closed-door process on 29 October ultimately selected option 3 mentioned above.

It is noteworthy that in the final hours of negotiations at Nagoya in October 2010, the EU confirmed that this requirement as worded in option 3 is all about procedural justice. This means that it does not interfere with the prerogative of States to make the substantive decision on whether or not to grant access. Therefore a provider Party is entitled in its national law to establish different classes of applicants, such as local researchers, foreign researchers, public research institutions or foreign research institutions. The rules and procedures for dealing procedurally with applications for access may differ according to any such classification. This would be consistent with Article 8 of the Nagoya Protocol on Special Considerations where paragraph (a) distinguishes simplified measures on access for "non-commercial research purposes".

Article 7 – ACCESS TO TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

While the CBD did not link access and benefit sharing in Article 15 to traditional knowledge associated with genetic resources, the COP-7 negotiating mandate regarded genetic resources and associated traditional knowledge together, stating in Decision VII/19:

> "... to elaborate and negotiate an international regime on access to genetic resources and benefit sharing with the aim of adopting an instrument\instruments to effectively implement the provisions in Article 15 and Article 8(j) of the Convention and the three objectives of the Convention;"

Delegations judged it essential to articulate the link with a separate article (Article 7 of the Nagoya Protocol, or draft Article 5bis) to address international and national obligations for Parties related to traditional knowledge associated with genetic resources. The implications of this article for national ABS regulations also depend on the results of ongoing WIPO negotiations on traditional knowledge and genetic resources of ILCs.[16]

The Nagoya Protocol has introduced new obligations for governments to respect and support the rights of ILCs, as expressed in UNDRIP, but does not offer any related definitions and concepts, thereby placing the WIPO negotiations in the spotlight.

In the WIPO negotiations, however, governments tend to view their objective not as that of enshrining new rights for ILCs but rather to guide patent offices to ensure that they do not permit theft of ILCs' traditional knowledge. Developing countries argue for mandatory rules requiring full disclosure of the origin of genetic resources and associated TK in intellectual property applications. These countries say that this will serve to identify and prevent misappropriation of traditional knowledge (and genetic resources). On the other hand, developed countries favor weaker measures for

[16] See Box related to "Ongoing WIPO-IGC negotiations" in the discussion on Article 4 (Relationship with International Agreements and Instruments).

protection, with some, including the United States and Japan, opposing any new rules at all. This discussion remains unresolved.

A priority for ILCs is to address intellectual property claims on traditional knowledge that has been disseminated in scientific and other publications, for example, ethnobotanical journals. Under current intellectual property law, this knowledge is regarded as freely accessible, even if it was published without ILCs' consent. ILCs understandably do not accept such free appropriation of their knowledge, especially when it was made public without their agreement.

Attempts to deal with this contentious topic under the Nagoya Protocol ended inconclusively. At WIPO, indigenous and local communities insist that PIC and MAT should be required if intellectual property claims are made that include appropriation of published traditional knowledge. Some governments oppose this idea and say that published traditional knowledge may be freely utilized in patent claims, even if it was disseminated without the consent of its developers.

Related to this is an unresolved debate in WIPO over the meaning of "associated traditional knowledge". ILCs and many developing countries, especially African countries, view genetic resources that have evolved under the influence of breeding, selection, and other activities by ILCs as being inherently intertwined, that the material and knowledge are conceptually inseparable. Some others, however, especially developed country governments and industry, wish to draw black and white distinctions between the physical material of genetic resources and knowledge about them. This conceptual difference in the understanding of associated traditional knowledge is unresolved.

While developed countries are likely to continue to resist large scale change to the existing intellectual property legal framework to accommodate concern over misappropriation of traditional knowledge, including published traditional knowledge, the adoption of strong measures for the disclosure of origin of genetic resources claimed in patent applications may at least help facilitate identification of these types of biopiracy cases.

Article 7 – ACCESS TO TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that traditional knowledge associated with genetic resources that is held by indigenous and local communities is accessed with the prior and informed consent or approval and involvement of these indigenous and local communities, and that mutually agreed terms have been established.

Development

The debate on ABS rules for associated traditional knowledge started during WGABS-8 in 2009. Suggested options treated PIC from ILCs as analogous to the government PIC under CBD Article 15, raising questions about how governments would comply with this obligation. There was strong support for representatives of

ILCs who called for the establishment of international standards for ABS involving associated traditional knowledge. Also at this meeting, contentious options for language emerged that placed such rules as either "subject to" or "in accordance with" national legislation.

Parties on one side supported the establishment of general international standards, while on the other (depending on wording of Article 8(j) of the CBD) others insisted that any detailed provision need to be based on practices, decisions, and laws at national and community level. The representatives of ILCs opposed the wording "subject to national law", as they felt the Protocol must acknowledge universal rights expressed in UNDRIP, and set rules beneficial for ILCs, including situations where no national law applies. ILCs felt this would be better captured in the wording "according to national law" rather than "subject to national law".

When the Co-chairs' non-paper was distributed at WGABS-9/1 in 2010, the draft Article 1 on Objective of the Protocol was devoid of reference to associated traditional knowledge and the rights of ILCs. In Article 5.4 on access to genetic resources, the non-paper chose a more restrictive wording, "subject to":

> "4. Subject to national legislation, access to traditional knowledge associated with genetic resources shall be subject to the prior informed consent of the holders of such knowledge and based on mutually agreed terms, taking into consideration the provisions of Article 9. Mutually agreed terms shall provide for the fair and equitable sharing of benefits arising from the utilization of such knowledge with the holders."

WGABS-9/1 decided to deal with the issue in a self-standing Article 5bis (now Article 7 of the Nagoya Protocol on "Access to traditional knowledge associated with genetic resources") that more closely reflected the position of ILCs:

> "Parties shall take legislative, administrative, or policy measures, as appropriate, with the aim of ensuring that traditional knowledge associated with genetic resources held by indigenous and local communities is accessed with the prior and informed consent/approval and involvement of indigenous and local communities, and is based on mutually agreed terms."

A second severe crisis of the WGABS9/1 meeting (following that regarding the "non-discriminatory" debate) was started when New Zealand declared it could not accept the term prior informed consent in the context of associated traditional knowledge due to national legislation and debates the New Zealand government had with Maori people. Delegations eventually agreed to insert the wording "approval and involvement" suggested by New Zealand and contained in CBD Article 8(j), with the understanding that there is essentially no different meaning between that and PIC.

WGABS-9/2 in 2010 amended the draft text with three new paragraphs dealing with compliance in the context associated traditional knowledge. At the meeting of the ING in 2010, New Zealand presented a compromise text reading "in accordance with domestic law". In a last attempt to weaken a new obligation for ABS rules covering

associated traditional knowledge, at COP-10, the EU said it could not support the treatment of genetic resources and associated traditional knowledge at the same legal level. The EU claimed that negotiations could not go forward until WIPO defined traditional knowledge associated with genetic resources.

Canada used the opportunity opened by the EU to support the wording "subject to domestic law," then also demanding the deletion of the word "measures" in order to keep the text as general as possible. After additional negotiations, the delegations agreed on a compromise text and to create a separate draft Article 12bis (now Article 16 of the Nagoya Protocol) on compliance with national rules on ABS for traditional knowledge associated with genetic resources.

Article 8 – SPECIAL CONSIDERATIONS

Article 8 (draft Nagoya Article 6) was introduced to find a compromise on the following highly controversial issues:

a. Simplified procedures for access to genetic resources and traditional knowledge associated with genetic resources for non-commercial research;
b. Simplified access to pathogens and specifically viruses; and
c. Address the issue of access to genetic resources for food and agriculture.

Delegates decided that these topics that had been discussed under exemptions from the scope, sectoral approaches and international access standards should be kept as issues in the Nagoya Protocol. Nevertheless, the measures and procedures and how to address them have to be developed at national level.

Article 8 – SPECIAL CONSIDERATIONS

In the development and implementation of its access and benefit-sharing legislation or regulatory requirements, each Party shall:

(a) Create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including through simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research.

(b) Pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally. Parties may take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need, especially in developing countries.

(c) Consider the importance of genetic resources for food and agriculture and their special role for food security.

Development

On Non-commercial Research

Simplified access rules for non-commercial research were proposed at WGABS-6 in 2008 by several developed countries supported by some developing countries while many others argued that the distinction between commercial and non-commercial research is artificial at worst and blurred as best. With so many contentious and difficult issues confronting the negotiators, and all options could be tabled and compiled, the next meeting proceeded to discuss how to integrate potential simplified access procedures, with the general access obligations applicable to other circumstances. This caused discussion of non-commercial research, and the potential creation of different access rules for it, to become entangled with the question of how to address the language of CBD Article 15, which says that "Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources".

While developed countries insisted that the ABS Protocol must "facilitate" access, developing countries said such decisions should be left to national regulations and not be specifically addressed at the international level. Addressing the disagreement, the Co-chairs' non-paper for WGABS-9/1 in 2010 supported the position of developing countries by suggesting the issue be placed under national regulations and by omitting the word "facilitate". The paper also suggested that any kind of research – non-commercial and commercial – should be dealt with equally and proposed the wording "biodiversity-related research":

> "In the development and implementation of their national legislation on access and benefit-sharing, Parties shall pay due regard to:
> (a) Avoiding or minimizing impediments to biodiversity-related research, important for the conservation of biological diversity and the sustainable use of its components;"

During WGABS-9/1 two delegations reintroduced both the concept of "facilitating" access and "non-commercial" research. The controversy was not resolved until the 2010 ING in Nagoya, when it was decided that the ABS Protocol should not "facilitate" access but rather provide for "appropriate" access. While delegations agreed that Parties should promote and encourage biodiversity-related research, they linked the issue of simplified access measures to non-commercial research specifically.

On Emergency Situations

As discussed under Articles 3 and 4 above, there was a debate on the exclusion of pathogens, including viruses, from the scope of the ABS Protocol. This underlaid a second discussion on simplified access rules for genetic resources, in this case in the context of preventing or dealing with emergency situations. Developed countries took the position that ABS rules should be relaxed or waived for genetic resources that might be needed in order to respond to emergency situations, for example, the

appearance of a new strain of a dangerous infectious disease. WGABS-8 in 2009 introduced a preambular paragraph as follows:

> "Stressing the importance of facilitating access to genetic resources in emergency situations when public health, food security or the biological diversity are seriously threatened …"

The Co-chairs' non-paper for ABSWG-9/1 in 2010 included chapeau language on emergencies in its draft Article 6 [now Article 8(b) of the Nagoya Protocol]:

> "In the development and implementation of their national legislation on access and benefit-sharing, Parties shall pay due regard to:
> (b) Emergency situations including serious threats to public health, food security or biological diversity."

This issue was fueled by a contentious debate at the World Health Organization (WHO) that began in 2007. At WHO, a number of developing country Member States sought changes to WHO's system to collect and share influenza viruses, which was collecting viruses and then giving them to industry (for research and vaccine production) without any benefit sharing to the countries of origin. Reformers to the WHO system insisted that the WHO influenza network needed a benefit sharing framework consistent with the objectives and principles of the CBD.

Developed countries were resistant to applying CBD principles to the collection and sharing of influenza viruses. They advanced an oversimplified argument holding that because pathogens are "bad" biodiversity that the rules for them should be different. Until 2007, exchange of influenza viruses in effect took place based on an antiquated (pre-CBD) understanding of viruses as a "common heritage"-type genetic resource to which state sovereignty should not be asserted.

Although they resisted application of CBD ideas to influenza, industry and wealthy governments were also very worried that developing countries might pull out of WHO's system, cutting off access to influenza viruses, particularly potentially pandemic H5N1-type strains. Although a compromise to implement CBD principles at WHO was eventually reached (see "*CBD principles shape WHO pandemic influenza framework"* below), during negotiation of the Nagoya Protocol and in the WHO negotiation, the EU took the position that access procedures under the CBD should not be applicable to pathogens.

Delegations debated the issue intensively. Developing countries stressed that the concept of emergency situations was unclear, noting that users might use this vague concept to pressure countries to simplify access to a very wide range of genetic resources. Further, they underlined that all Parties to the CBD are bound to the benefit sharing obligations regardless of specific circumstances of emergency. At WGABS-9/2 the controversy heightened when developed countries demanded "immediate access", thereby linking the pathogen debate to the concept of sectoral approaches discussed under scope. The report of WGABS-9/3 reflected the disagreement, and contained two options for draft Article 6(b).

During the negotiations at COP-10, delegations again discussed that would define emergency situations and which other fora draft Article 6(b) might relate to. Developed countries such as New Zealand, suggested replacing the term "emergency situation" with "serious and immediate threat" another broad and ill-defined phrase. Switzerland mentioned that genetic resources for biological control purposes and all kind of pest organisms would fall under the provisions of draft Article 6(b). Both countries stressed that the ABS Protocol must look beyond the narrow case of specific rules for pathogens.

Developing countries argued that the provisions of the ABS Protocol needed to be applicable in emergency situations. Japan supported their call to define which emergency situations would fall under draft Article 6(b). The EU suggested that while the ABS Protocol would be on "global goods" there was a need for a specific article on "global bads", the discussion on immediate access to pathogens should not be linked with the issue of emergency cases. To complicate matters, the EU and Canada suggested dealing with food security and pathogens together:

> "…establish to provide continuing and facilitated access for appropriate genetic resources for food and agriculture for the purpose of contribution to the reestablishment of agricultural systems, in emergency disaster situations as identified by appropriate intergovernmental organizations, in coordination with disaster relief coordination;"

Developing countries questioned whether there are officially recognized emergency situations for all kind of pathogens and warned to mix draft Article 6(b) with issues of food security.

During negotiations at COP-10, developing countries were able to secure agreement that draft Article 6(b) would address access rules and benefit sharing rules on an equal level, and that the language of facilitated access – which had been deleted from Article 1 since WGABS-9/2 – would be replaced. For the time being, then, the conclusion was that draft Article 6(b) would address four issues: emergency situations, public health, expeditious access, benefit sharing:

> "Pay due regard to public concern health emergencies according to the applicable international and national law which threaten or damage the health of humans or animals or that would cause a serious damage or threat to biological diversity. In these situations take into consideration, as appropriate, the need for expeditious/ simplified measures on access provided that there is fair and equitable of benefits including by means of access to the distribution of affordable treatments to this in need especially in developing countries."

The next round of negotiations resulted in a shorter version of this text, into which the EU inserted the additional issue of plant health. Further, Australia, Canada, and the EU wanted the scope of draft Article 6(b) to refer not only to emergency but also "pre-emergency" situations. Developing countries countered that "pre-emergency" situations would apply to all situations in any normal day and that this was an unacceptably vague concept. The negotiations at COP 10 ended with two bracketed

alternatives for draft Article 6(b) of which the following version led to the final text decided upon in the closed-door process:

> [(b) Pay due regard to cases of [present or imminent] emergencies[, including those of international concern,] that threaten or damage human, animal or plant health, as determined in accordance with applicable national and international law [including under relevant international organizations]. Parties may take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need, especially in developing countries.]

Article 8(b) of the Nagoya Protocol, after the long and intense debate, was ultimately not agreed to in a full negotiation mode and instead became part of the "take-it-or-leave-it" package.

CBD principles shape WHO pandemic influenza framework

The CBD and ABS Protocol negotiations were meanwhile asserting influence over a parallel track at the WHO, where developing countries were engaged in an intense and contentious debate, from 2007 to 2011, over biopiracy of pandemic influenza viruses by developed country research centres and multinational pharmaceutical and vaccine corporations. The negotiation sought to overcome the weaknesses of the WHO global influenza surveillance and response system, which includes National Influenza Centres, WHO Collaborating Centres on Influenza, and a number of other regulatory and reference labs. A group of developing countries, in accordance with their CBD obligations, insisted on a new system to govern the WHO system that was consistent with the CBD's 3rd objective and ABS provisions. The experience of the International Treaty on Plant Genetic Resources for Food and Agriculture also provided guidance to the WHO negotiations.

On 24 May 2011 the World Health Assembly adopted the Pandemic Influenza Preparedness (PIP) Framework containing terms and conditions that now govern the sharing of influenza viruses (sourced mostly from developing countries), and the sharing of resulting public health benefits including vaccines and diagnostic kits. The Framework is:

> ... to improve pandemic influenza preparedness and response, and strengthen the protection against the pandemic influenza by improving and strengthening the WHO global influenza surveillance and response system, with the objective of a fair, transparent, equitable, efficient, effective system for, on an equal footing:
> (i) The sharing of H5N1 and other influenza viruses with human pandemic potential; and
> (ii) Access to vaccines and sharing of other benefits.

The agreement is a milestone as it puts in place for the first time in the WHO a Framework and two accompanying contractual instruments in the form of "Standard Material Transfer Agreements" (SMTAs) to govern the sharing of influenza viruses and benefits. The agreement is also precedent setting as it obligates the pharmaceutical industry and other entities that benefit from the WHO virus-sharing scheme to share benefits as a condition of access to influenza viruses of pandemic potential. The first SMTA is to be used when sharing PIP biological materials within the WHO GISRS, while a second SMTA is to be used when the WHO GISRS shares biological materials with entities outside the WHO GISRS (e.g. a vaccine company).

Despite being a significant agreement, the PIP Framework and the accompanying SMTAs have shortcomings that can inform the implementation of the Nagoya Protocol. The Framework does not go far enough to secure a reasonable level of benefits from industry and other entities. The $25-30 million annual monetary contribution required of manufacturers plus a 10% set-aside of vaccines and anti-viral medicines are a first step that is unprecedented, but remains far too little to meet the needs of developing countries (which account for 80% of world population) in the event of a pandemic outbreak. These benefits should have been set at higher levels.

Furthermore, because users of influenza viruses under SMTA-2 can choose between different benefit sharing options, the granting of non-exclusive licenses at affordable royalties or royalty-free to developing countries for the production of patented vaccines and other products to respond to influenza outbreaks is only a voluntary benefit sharing option. This should instead have been listed as a stand-alone mandatory benefit to facilitate the sharing of knowledge, technology, and know-how, which developing countries need in order to counter an influenza pandemic.

During the negotiations, developing countries sought greater benefits. The outcome was disappointing, however, due to the resistance by developed countries, in particular the United States. This significantly diluted the benefit sharing obligations and protected industry's profits and intellectual property. As the final outcome is based on many compromises, there is an inbuilt review that will take place by 2016 with a view to proposing revisions reflecting developments as appropriate, to the World Health Assembly in 2017.

The PIP Framework also establishes an oversight mechanism that includes the World Health Assembly, the WHO Director-General and an independent 18-member Advisory Group of internationally recognized policy makers, public health experts and technical experts in the field of influenza, selected from the WHO regions. Broadly, the Advisory Group will assist the Director-General in monitoring the implementation of the Framework in accordance with its agreed terms of reference. The Advisory Group will also present an annual report to the Director-General on its evaluation of the implementation of this Framework.

The first SMTA-2 was signed in December 2012 with one of the three largest manufacturers of influenza vaccines, GlaxoSmithKline. It legally binds the company to give WHO access to 10% of its total production of pandemic vaccines as they are produced. In addition, six companies have together made financial contributions, called "partnership contributions", of more than $18 million. These funds will be invested to

strengthen pandemic preparedness and response capacities, in line with recommendations from the Advisory Group, according to the WHO Director-General.

This is regarded as a first step and questions remain over the transparency of the negotiations with the users (mainly industry) and the adequacy of the benefit sharing, in the sense of whether it meets the criteria of being "fair and equitable".

With regard to Article 8(b) of the Nagoya Protocol, where national legislation or regulatory requirements provide for expeditious access, these must also be based on "expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need especially in developing countries".

On Food Security

Representatives of the UN Food and Agriculture Organization (FAO), agricultural research institutions and agriculture ministries were always present at the ABS negotiations. They stressed the importance of the ITPGRFA in guaranteeing facilitated access to genetic resources, therefore contributing to food security, and at WGABS-2 in 2003 it was noted that the work of the FAO Commission on Genetic Resources and the CBD ABS negotiations needed to stay in harmony. While most delegates seemed to agree that the Multilateral System of the ITPGRFA is the appropriate specialized ABS system, for access to those genetic resources described in the treaty's Annex 1, there was some disagreement on how to treat plant genetic resources for food and agriculture that are not contained in Annex 1. Representatives from agricultural institutions present at the meeting were of the opinion that it would best be dealt with outside of an ABS protocol. Many of them also sought to exclude animal and microbial genetic resources for food and agriculture from the scope of the ABS protocol, although for these genetic resources there is no specialized ABS system harmonized with the CBD and equivalent to the ITPGRFA.

WGABS-8 in 2009 mentioned the issue of food security in the preamble:

"Stressing the importance of facilitating access to genetic resources in emergency situations when public health, food security or the biological diversity are seriously threatened".

It also linked the issue of facilitated access to emergency situations with regard to food security.

The Co-chairs' non-paper for WGABS-9/1 in 2010 maintained these references. Developing countries underlined the need to ensure food security without undermining the ABS Protocol. WGABS-9/2 finally drafted Article 6(c):

"Consider the importance of genetic resources for food and agriculture and their special role for food security and climate change adaptation and mitigation"

This formulation remained intact through the next negotiation rounds. The wording of Article 8(c) of the Nagoya Protocol does not formulate any obligations or concrete tasks for the Parties when developing and implementing their national ABS systems. One possible aspect that certainly would benefit from national consultations would be access to wild or domesticated resources *in-situ* with the intent adding them to the

collection of national or international *ex-situ* collections that are part of the Multilateral System.

Article 9 – CONTRIBUTION TO CONSERVATION AND SUSTAINABLE USE

Article 9 aims to integrate the first two objectives of the CBD on conservation of biodiversity and sustainable use of the components of biodiversity with the implementation of its third objective, fair and equitable sharing of benefits arising from the utilization of genetic resources.

> Article 9 – CONTRIBUTION TO CONSERVATION AND SUSTAINABLE USE
>
> The Parties shall encourage users and providers to direct benefits arising from the utilization of genetic resources towards the conservation of biological diversity and the sustainable use of its components.

Development

Applying the benefits gained from utilization of genetic resources to finance protection and sustainable use of biological diversity is a central theme of the CBD, and was quickly reflected in the Nagoya Protocol negotiation. WGABS-4 in 2006 include a provision that:

> [Benefits should be directed in such a way as to promote conservation and sustainable use of biological diversity [in countries of origin of genetic resources.]]

The issue was parked in later negotiations as a "component for further consideration". The Co-chairs non-paper for WGABS-9/1 in 2010 took the concept and developed it into a stand alone article:

> "Parties shall encourage users and providers to direct benefits arising from the utilization of genetic resources towards the conservation and sustainable use of biological diversity in support of the objectives of the Convention."

This drafting was accepted at WGABS-9/2 in 2010.

While the content of Article 9 deals with the linkage of the three CBD objectives, it is unfortunate that it remains very vague. Parties shall only "encourage" users and providers to direct a share from the profits they gain through the utilization of genetic resources to finance activities for conservation and sustainable use of biodiversity. In coming years it will be interesting to monitor how Parties to the Nagoya Protocol implement this central feature of ABS policies.

Article 10 – GLOBAL MULTILATERAL BENEFIT-SHARING MECHANISM

Article 11 – TRANSBOUNDARY COOPERATION

Article 10 (inserted on October 29 from a closed door process without any negotiation) and Article 11 (draft Article 8) are discussed together. Their primary purpose is to overcome shortcomings of the bilateral approach under the CBD when setting up national ABS regimes and negotiating contracts.

In practice, differing implementations of the Nagoya Protocol in neighbouring countries sharing the same genetic resources, and traditional knowledge associated with them, will likely lead potential users to approach the country with less stringent ABS obligations. A frequently suggested way to avoid such a "race to the bottom" is the establishment of (sub)regional agreements to address transboundary ABS issues, a possibility offered in Article 11. In addition, the multilateral approach of Article 10, the genesis of which was proposed by the African Group, aims to develop solutions for several controversial issues of temporal, political and geographical scope that are not explicitly resolved by the final Protocol text.

ARTICLE 10 – GLOBAL MULTILATERAL BENEFIT-SHARING MECHANISM

Parties shall consider the need for and modalities of a global multilateral benefit-sharing mechanism to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent. The benefits shared by users of genetic resources and traditional knowledge associated with genetic resources through this mechanism shall be used to support the conservation of biological diversity and the sustainable use of its components globally.

Article 11 – TRANSBOUNDARY COOPERATION

1. In instances where the same genetic resources are found *in-situ* within the territory of more than one Party, those Parties shall endeavour to cooperate, as appropriate, with the involvement of indigenous and local communities concerned, where applicable, with a view to implementing this Protocol.
2. Where the same traditional knowledge associated with genetic resources is shared by one or more indigenous and local communities in several Parties, those Parties shall endeavour to cooperate, as appropriate, with the involvement of the indigenous and local communities concerned, with a view to implementing the objective of this Protocol.

Development

By the time of WGABS-2 in 2003 it was widely believed that the ABS Protocol needed elements to take into account the fact that the occurrence of genetic resources often does not align with political borders. Developing countries and representatives of ILCs explained the problems that might arise when a strictly bilateral approach is taken. At first the issues were dealt with under scope; WGABS-6 2009 discussed them as benefit sharing components for further consideration: Multilateral benefit sharing options when origin is not clear or in transboundary situations; and establishment of trust funds to address transboundary situations.

When the issues were elaborated further at WGABS-7 in 2009, traditional knowledge associated with genetic resources entered into the discussion of transboundary measures. The Co-chairs' non-paper for WGABS-9/1 in 2010 then offered the following draft on "Transboundary Cooperation":

> "In instances where the same genetic resources are found *in-situ* within the territory of neighbouring Parties, those Parties shall cooperate, as appropriate, with a view to implementing this Protocol."

The idea of establishing multilateral benefit sharing options was dropped and WGABS-9/1 agreed on the suggested text while replacing "shall" by "are encouraged".

Developing countries brought back the issue of a multilateral mechanism during WGABS-9/2 in 2010. After informal discussions during ING in 2010 in Nagoya, at COP 10, the African Group introduced the idea of a multilateral fund with an October 25 informal paper explaining the concept as "a new and innovative financial mechanism that would put in a place a multilateral approach in parallel to the dominant bilateral ABS modalities currently being negotiated." The African Group had in fact floated this idea since 2007 at WGABS-5.

During the closed-door process on October 29, Article 10 was created in response to the African proposal, however, rather than adopting it, the text is far from the African proposal. It is also about a mechanism in general and not a fund, and is a subject for future consideration. The language to do this was adapted from CBD Article 19(3) ("Parties shall consider the need for and modalities of ..."). Once the ABS protocol has entered into force Parties will likely face lengthy negotiations on the need for and modalities of such a mechanism. Article 10's language will give some Parties room to delay any real decision. It took the CBD Parties three years to decide on the need to negotiate a biosafety protocol but only due to the strong pressure of developing countries and the growing public concerns about the risks of genetically modified organisms in Europe. It remains to be seen if such political constellation builds up in the context of the further ABS-negotiations.

The "scope" of a future multilateral mechanism would cover two areas:

1. Genetic resources that "occur in transboundary situations": Since all genetic resources can be of a transboundary nature and are already covered by the ABS protocol, careful clarification will be needed of which genetic resources would be covered by a multilateral mechanism.

2. Genetic resources "for which it is not possible to grant or obtain prior informed consent".

The second area refers in an abstract manner to several issues debated during the negotiation of the scope of the ABS Protocol but ultimately was not covered by operational text, such as:

- Marine genetic resources outside of the areas of jurisdiction of Parties;
- Genetic resources in the Antarctica;
- Genetic resources in *ex-situ* collections with unclear provenance and without PIC and MAT; or
- Continuing utilization that does not follow the principles of the CBD and the Nagoya Protocol, namely being based on PIC and MAT,

Particularly with respect to *ex-situ* collections, the idea of covering these utilizations that fall outside of the scope of the Protocol has raised questions about whether they need to be stopped and newly negotiated, or if financial compensation would remedy the absence of PIC and MAT.

Article 12 – TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

While the 2004 mandate from COP-7 integrated the topic of traditional knowledge associated with genetic resources into the negotiations of the ABS protocol, the exact meaning of the term traditional knowledge associated with genetic resources remained unclear. A widely recognized definition of associated traditional knowledge in the context of ABS did not exist in 2004 and was still lacking at the time of COP-10 in 2010.

During negotiations it became clear that the ABS protocol should deal with associated traditional knowledge in a cross-sectional approach and in stand alone paragraphs. This was termed a "tandem approach". Article 12 (draft Article 9) is a stand alone provision that aims to clarify understanding of traditional knowledge associated with genetic resources at the international level and give guidance for national implementation of core issues such as recognition of customary laws and practices but without strong obligations for Parties.

Another controversial issue that is perhaps the biggest missing piece of the Nagoya Protocol relates to publicly available traditional knowledge. Proposals were put forward by developing countries to address two special situations: (a) the traditional knowledge was not obtained directly from ILCs and can be in an oral or documented or other form; and (b) where the original holders of the traditional knowledge is not identifiable, e.g. knowledge that is diffused in a society and handed down over generations such as Chinese traditional medicine or Indian Aryuvedic system. These were draft Article 9(5) and 9(5)bis respectively. Developed countries were strongly opposed to including this in the Protocol for benefit sharing and on the final day, the close door process deleted the last version of draft Article 9(5) in its entirety. National ABS legislation, however, can regulate this important area, and CBD Parties should do so already.

Article 12 – TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

1. In implementing their obligations under this Protocol, Parties shall in accordance with domestic law take into consideration indigenous and local communities' customary laws, community protocols and procedures, as applicable, with respect to traditional knowledge associated with genetic resources.
2. Parties, with the effective participation of the indigenous and local communities concerned, shall establish mechanisms to inform potential users of traditional knowledge associated with genetic resources about their obligations, including measures as made available through the Access and Benefit-sharing Clearing-House for access to and fair and equitable sharing of benefits arising from the utilization of such knowledge.
3. Parties shall endeavour to support, as appropriate, the development by indigenous and local communities, including women within these communities, of:
(a) Community protocols in relation to access to traditional knowledge associated with genetic resources and the fair and equitable sharing of benefits arising out of the utilization of such knowledge;
(b) Minimum requirements for mutually agreed terms to secure the fair and equitable sharing of benefits arising from the utilization of traditional knowledge associated with genetic resources; and
(c) Model contractual clauses for benefit-sharing arising from the utilization of traditional knowledge associated with genetic resources.
4. Parties, in their implementation of this Protocol, shall, as far as possible, not restrict the customary use and exchange of genetic resources and associated traditional knowledge within and amongst indigenous and local communities in accordance with the objectives of the Convention.

Development

WGABS-3 2005 took up the issue when it suggested that the certificate of origin/source/legal provenance for compliance purposes could include traditional knowledge associated with genetic resources, and rules of customary law among other additional elements that could be considered later in the negotiations. In discussing compliance, WGABS-6 in 2008 listed "Measures to ensure compliance with customary law and local systems of protection" as one possibility. In light of Article 31 of UNDRIP, in 2009 WGABS-7 developed draft paragraphs on the recognition of the rights of ILCs to their genetic resources and traditional knowledge associated with them. This also addressed ILCs participation in compliance, for example:

> "Contracting Parties [shall][should]: [...] With the full and effective participation of the indigenous and local communities concerned support and facilitate local, national and/or regional community protocols regulating access to traditional knowledge associated with genetic resources taking into consideration the relevant customary laws and ecological values of indigenous and local communities in

order to prevent the misappropriation of their associated traditional knowledge and to ensure the fair and equitable sharing of benefits arising from the utilization of such associated traditional knowledge;"

The meeting also focused on how compliance with customary law could be promoted including the new issue of community protocols.

In 2009, WGABS-8 introduced the issues at various other places in the draft text. The Co-chairs' non-paper for WGABS-9/1 in 2010 compiled these many suggestions, placing them in a stand-alone draft Article 9 (now Article 12 of the Nagoya Protocol). The essence of the first four paragraphs were agreed upon at WGABS-9/2 and ING meetings.

Draft Article 9(5) of the non-paper, however, provoked highly controversial discussions that continued until Nagoya:

"Parties shall encourage the users of publicly available traditional knowledge associated with genetic resources to take all reasonable measures, including due diligence, to enter into fair and equitable benefit-sharing arrangements with the holders of that knowledge."

It was this issue that was the last item on the agenda of the COP-10 negotiations before the unfinished draft protocol text was passed to the closed-door process on 29 October. Draft Article 9(5) was deleted with no discussion among all other Parties. The only legacy in the Protocol is a preambular paragraph that had been agreed to earlier by the negotiators: "*Further recognizing* the unique circumstances where traditional knowledge associated with genetic resources is held in countries, which may be oral, documented or in other forms, reflecting a rich cultural heritage relevant for conservation and sustainable use of biological diversity…"

On Publicly Available Associated Traditional Knowledge

Traditional knowledge associated with genetic resources is not only held by individuals as sacred knowledge or by distinct groups as specialized knowledge - with whom a PIC and MAT could be negotiated. It also can be widely spread and used as communal knowledge by many different users – even on a commercial basis - who are not the original creators and holders of this knowledge. Prominent examples of communal traditional knowledge that is highly aggregated and very successful are Chinese traditional medicine and the Indian Ayurvedic system. Delegations from these two countries especially felt that the ABS protocol needed provisions on how to deal with ABS and publicly available traditional knowledge.

The term "publicly available" further implies that traditional knowledge associated with genetic resources published in scientific articles would fall under ABS rules or that applicants for patents dealing with traditional knowledge associated with genetic resources need to comply with PIC and benefit sharing obligations.

These classes of traditional knowledge are relevant to the negotiations at WIPO on traditional knowledge and genetic resources. Existing intellectual property (IP) law and legal instruments, however, cannot protect publicly available knowledge. Since developed countries – together with the representatives of their industries – prefer to

protect traditional knowledge within the existing IP framework and do not support the creation of *sui generis* options for communal traditional knowledge, they strongly opposed the establishment of any rules for such knowledge in the context of the Nagoya Protocol.

Negotiations on draft Article 9(5) at COP-10 started with a debate on who might be the rightful holder in the context of PIC and benefit sharing when publicly available traditional knowledge associated with genetic resources is to be accessed, and what obligation should users have to locate these rights holders.

A group of developing countries proposed the following draft Article 9.5:

> "Parties shall take appropriate legislative, administrative or policy measures so that users of TK associated with genetic resources, whether oral or documented or in other forms, obtained from a source other than directly from ILCs, to enter into fair and equitable benefit-sharing arrangements with the rightful holders of such knowledge as may be determined by the provider Party."

They also proposed draft Article 9.5bis:

> "Where TK is held by a Party on behalf of ILCs and the original holders within these communities cannot be identified, such Parties may take legislative, administrative or policy measures, as appropriate, so that users of such TK enter into fair and equitable benefit-sharing arrangements with that Party for the benefit of the ILCs."

These two were strongly worded proposals addressed two sets of circumstances of publicly available knowledge that is widely utilized but without benefit sharing. These faced tremendous opposition from developed countries.

After an extensive debate among the Parties the following text was proposed:

> "Parties shall encourage the users of traditional knowledge associated with genetic resources which has been obtained by that user from a source other than an indigenous and local community, to take reasonable measures to enter into fair and equitable benefit-sharing arrangements with the rightful holders of such knowledge within the indigenous and local communities."

At this stage, the EU, New Zealand and Australia rejected the entire paragraph. China and the Philippines insisted on including the concept of publicly available traditional knowledge associated with genetic resources. This was supported by Canada but with the proviso that the language has no IPR relevance.

The next text proposed by some developing countries, tried to accommodate the concerns:

> "Parties shall take legislative, administrative and policy measures, as appropriate, for users of traditional knowledge associated with genetic resources obtained from a source other than an indigenous and local community, inter alia traditional knowledge associated with genetic resources, whether oral or documented or in

other forms, to enter into fair and equitable benefit-sharing arrangements with the rightful holders of such knowledge."

The EU would not agree to the obligatory character of the paragraph. Canada pointed out that the mentioned forms of traditional knowledge associated with genetic resources would be better covered through copyright, and China opposed the reference to rightful holders because of its inconsistency with many forms of publicly available traditional knowledge associated with genetic resources.

After more lengthy discussions, China suggested a compromise text on 28 October to resolve its own and Canada's problems:

"Parties shall take legislative, administrative or policy measures so that users of traditional knowledge associated with genetic resources obtained from a source other than directly from an indigenous and local community in different forms, enter into fair and equitable benefitsharing arrangements with the rightful holders as may be defined in domestic law considering the uniqueness of these circumstances."

While the GRULAC delegations agreed to this solution, the EU proposed to replace "shall" by "are encouraged to". South Korea insisted that the basic concept of the draft article on benefit sharing that refers to the rightful holder of traditional knowledge associated with genetic resources as agreed in draft Article 4(4) (now Article 5 of the Nagoya Protocol) must also apply to draft Article 9(5).

The debate on draft Article 9(5) turned out to be the final round of transparent debates between governments. When it became apparent that the compromise offered by China was not accepted by all others as a basis for further negotiation, the Co-chairs of the Informal Consultative Group stopped the negotiations in the early morning of 29 October. In the closed door process that followed, draft Article 9(5) was deleted. The ABS protocol thus does not deal with traditional knowledge associated with genetic resources that is dispersed in a society or even worldwide through publications, in many cases without the PIC of the original creators and holders or the Party to the CBD or Nagoya Protocol in cases where the holder is the country.

Article 13 – NATIONAL FOCAL POINTS AND COMPETENT NATIONAL AUTHORITIES

National Focal Points as set up by Article 13 (draft Nagoya Article 10) serve as contact points to foster the relations of a national government with the Secretariat of an international treaty to which it is a Party. They might also have functions in the process of the national implementation of that treaty for example give technical information on ABS procedures for potential users. The Competent Authority serves as governmental institution that fulfils certain functions, which a Party of this treaty needs to perform. In the case of the Nagoya Protocol such functions could be setting rules and standards for PIC and MAT negotiations or deciding on the completeness of applications and correct procedures when negotiating for PIC and MAT.

Article 13 – NATIONAL FOCAL POINTS AND COMPETENT NATIONAL AUTHORITIES

1. Each Party shall designate a national focal point on access and benefit-sharing. The national focal point shall make information available as follows:
(a) For applicants seeking access to genetic resources, information on procedures for obtaining prior informed consent and establishing mutually agreed terms, including benefit-sharing;
(b) For applicants seeking access to traditional knowledge associated with genetic resources, where possible, information on procedures for obtaining prior informed consent or approval and involvement, as appropriate, of indigenous and local communities and establishing mutually agreed terms including benefit-sharing; and
(c) Information on competent national authorities, relevant indigenous and local communities and relevant stakeholders.
The national focal point shall be responsible for liaison with the Secretariat.
2. Each Party shall designate one or more competent national authorities on access and benefit-sharing. Competent national authorities shall, in accordance with applicable national legislative, administrative or policy measures, be responsible for granting access or, as applicable, issuing written evidence that access requirements have been met and be responsible for advising on applicable procedures and requirements for obtaining prior informed consent and entering into mutually agreed terms.
3. A Party may designate a single entity to fulfil the functions of both focal point and competent national authority.
4. Each Party shall, no later than the date of entry into force of this Protocol for it, notify the Secretariat of the contact information of its national focal point and its competent national authority or authorities. Where a Party designates more than one competent national authority, it shall convey to the Secretariat, with its notification thereof, relevant information on the respective responsibilities of those authorities. Where applicable, such information shall, at a minimum, specify which competent authority is responsible for the genetic resources sought. Each Party shall forthwith notify the Secretariat of any changes in the designation of its national focal point or in the contact information or responsibilities of its competent national authority or authorities.
5. The Secretariat shall make information received pursuant to paragraph 4 available through the Access and Benefit-sharing Clearing-House.

Development

During WGABS-7 in 2009 in Paris, the first elements on National ABS Focal Points were introduced in the text section on access; WGABS-8 in 2009 in Montreal expanded these elements. The co-chairs non-paper of WGABS-9/1 in Cali created a self-standing article on these Focal Points that was adopted with some amendments at WGABS-9/2 in 2010 in Montreal. The debate on the functions of a Competent Authority as a governmental essential element in the PIC and MAT procedures started at WGABS-

4 in 2006 in Granada in the context of the international certificate. WGABS-6 in 2008 in Geneva saw competent authorities as essential in the context of the compliance debate; WGABS-8 in 2009 in Montreal foresaw several different functions for such a competent authority. Although the topic featured prominently in the reports so far, the co-chairs' non-paper and the following meeting reports did not mention the term in the context of compliance and the certificate any longer.

Since no tasks related to compliance or benefit sharing were assigned to the National Focal Point and the Competent Authority, the negotiations on the final Article 13 went rather smoothly. Instead of concentrating the administrative tasks at these two established bodies, the negotiators of the Nagoya Protocol set up so called check points under Article 17 to deal with matters related to compliance without describing their relationship to the bodies under Article 13.

Interestingly, ABSWG-9/1 introduced – and ABSWG-9/3 2010 in Nagoya accepted - the term "competent authorities of indigenous and local communities" as one item that could be included in the information presented in the ABS clearing house according to Article 14. This wording seemed to be taken from the meeting of the "Group of Technical and Legal Experts on Traditional Knowledge Associated with Genetic Resources" in 2009 in Hyderabad while the intention of the expert group was quite different. This expert group elaborated extensively on the role of a Competent National Authority in the context of effective and fair rules and procedures. The meeting identified a "competent authority at the level of indigenous and local communities with a statutory authorization/mandate as competent authorities of indigenous and local communities" as a desirable element of the ILC PIC procedure.

Article 14 – THE ACCESS AND BENEFIT-SHARING CLEARING-HOUSE AND INFORMATIONSHARING

The CBD has an established clearing house mechanism that is an internet-based information tool on various aspects of the Convention. While there is no treaty obligation for Parties to post information, the CBD clearing house was given a new role in the Cartagena Protocol on Biosafety. Cartagena Parties are obliged to post certain legal and administrative information at the Biosafety Clearing-House to assist national decision making on the transboundary movement of genetically modified organisms.

Article 14 establishes an ABS clearing house with functions similar to the CBD clearing house. A pilot phase is underway at the time of writing and the debate has already started on what types of information would be helpful for Parties and to support the Protocol's information. Developing countries would like, among other things, to see the clearing house provide information that can help to monitor the utilization of genetic resources, and information that can assist in decision-making, as in the Biosafety Clearing-House. Most developed countries prefer a general information role, with more focus on access-related information for users.

A contentious issue that has emerged in 2011 at the Intergovernmental Committee for the Nagoya Protocol (ICNP) centres on some proposals made by the Expert Meeting on the Modalities of Operation of the Access and Benefit-Sharing Clearing-House (document UNEP/CBD/ABS/EM-CH/1/4 – paragraph 7 of the Annex) which did not

get included in the pilot phase due to lack of agreement among the Parties at the first ICNP meeting. The issues include: notification of permits or its equivalent; the updating of the internationally recognized certificate of compliance, including information on third party transfers; tracking the utilization of genetic resources across sectors; identification of subject matter on genetic resources covered by the certificate in the light of possible changes in its nomenclature; and examining how the ability of the clearinghouse may be developed to keep confidential information and keep it confidential until confidentiality may no longer be required. A group of developing country Parties are continuing to insist on this. See Annex III on the ongoing work of the Intergovernmental Committee for the Nagoya Protocol on this debate.

Article 14 – THE ACCESS AND BENEFIT-SHARING CLEARING-HOUSE AND INFORMATION SHARING

1. An Access and Benefit-sharing Clearing-House is hereby established as part of the clearinghouse mechanism under Article 18, paragraph 3, of the Convention. It shall serve as a means for sharing of information related to access and benefit-sharing. In particular, it shall provide access to information made available by each Party relevant to the implementation of this Protocol.
2. Without prejudice to the protection of confidential information, each Party shall make available to the Access and Benefit-sharing Clearing-House any information required by this Protocol, as well as information required pursuant to the decisions taken by the Conference of the Parties serving as the meeting of the Parties to this Protocol. The information shall include:
   (a) Legislative, administrative and policy measures on access and benefit-sharing;
   (b) Information on the national focal point and competent national authority(ies); and
   (c) Permits or their equivalent issued at the time of access as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms.
3. Additional information, if available and as appropriate, may include:
   (a) Relevant competent authorities of indigenous and local communities, and information as so decided;
   (b) Model contractual clauses;
   (c) Methods and tools developed to monitor genetic resources; and
   (d) Codes of conduct and best practices.
4. The modalities of the operation of the Access and Benefit-sharing Clearing-House, including reports on its activities, shall be considered and decided upon by the Conference of the Parties serving as the meeting of the Parties to this Protocol at its first meeting, and kept under review thereafter.

Development

The concept of an ABS-specific clearing house was aired at WGABS-7 in 2009. The 2010 Co-chairs' non-paper proposed an article to create an ABS clearing house. Delegations debated the type of information and to what extent information generated in the PIC procedure should be made available. Issues of included provision of information on and from ILCs, and how to reflect private ABS contracts in the public ABS clearing house. At ABSWG-9/3 in October 2010, outstanding matters were resolved apart from the information related to the PIC procedure, which remained as follows:

> "2. The information shall include: ...
> (c) [When access is granted, decisions related to prior informed consent][Decisions to grant prior informed consent] [for access to genetic resources, as appropriate and where applicable]."

This contested obligation was the only provision in draft Article 11 that dealt with revealing substantial information on concrete ABS cases. Other provisions cover technical information or are of non-binding nature. It was developed countries that were reluctant to accept an obligation to use the ABS clearing house to post substantive information. This position reflected the strategy of developed countries to weaken the compliance provisions of the draft text as much as possible.

In Nagoya, at the final day of the negotiations open to observers, a compromise language for draft Article 11 2 (c) was found:

"2. The information shall include: ...

(c) Permits or their equivalent issued at the time of access as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms."

The Protocol is not really clear if the "permits or their equivalents at the time of access" and the international certificate as introduced by Article 17 are actually the same or different documents. While Article 17 describes a list of minimum information of the international certificate, the content of permits as elements of the national decision making procedure are left to national legislation. The debates at ICNP-1 in June 2011 in Montreal could not advance this issue.

OVERVIEW OF COMPLIANCE ISSUES (ARTICLES 30, 15-18)

Development until WGABS-8

Compliance was at the centre of the negotiations because ABS rules, enforceability and potential sanctions are the elements that constitute the difference between voluntary guidelines and binding treaties. The negotiations on compliance covered three levels:

a. Compliance with the rules of the Nagoya Protocol
b. Compliance in user countries with national ABS legislation and regulatory requirements of provider countries
c. Compliance with the mutually agreed terms of ABS contracts.

The negotiations were complex and developed slowly. Discussions gelled in five final Articles that cover the three levels (Article 30; Articles 15, 16, 17; and Article 18). This section starts with a common analysis of the compliance debate as such and breaks down the different issues later on, each of which became increasingly complex in its own right at the negotiations drew to an end.

When the Bonn Guidelines were adopted at COP-6 in 2002, developing country Parties to the CBD already called for a process to address the obvious gaps, among which the main one was compliance with PIC and MAT. Developing countries argued that even if their national ABS laws were strong and implemented, the transboundary nature of users and the utilization outside their territory rendered those laws ineffective. As a result, COP Decision VI/24 includes compliance in the mandate for the 2nd meeting of the Ad Hoc Open-ended Working Group on ABS (WGABS):

> "8.c. Measures, including consideration of their feasibility, practicality and costs, to support compliance with prior informed consent of the Contracting Party providing such resources and mutually agreed terms on which access was granted in Contracting Parties with users of genetic resources under their jurisdiction;"

WGABS-2 subsequently recommended various measures to support compliance with PIC, including the controversial issues related to IP, through disclosure of origin in patent applications, and the relationship to the idea of an internationally recognized certificate of origin/source/legal provenance as evidence of compliance. With continued resistance to discussing IPRs in the CBD from developed countries, however, COP-7 in 2004 agreed to invite WIPO and UNCTAD to examine and address the relationships between IPR and ABS.

COP-7's Decision VII/19 that mandated Parties to negotiate an "International Regime on ABS" (which became the Nagoya Protocol) also required a report to COP-8 in 2006, on eight out of the 23 specific measures Parties shall consider are directly related to the issues of compliance and the IPR-ABS relationship, as follows:

> "(viii) Measures to facilitate the functioning of the regime at the local, national, subregional, regional and international levels, bearing in mind the transboundary

nature of the distribution of some *in-situ* genetic resources and associated traditional knowledge;

(ix) Measures to ensure compliance with national legislations on access and benefit-sharing, prior informed consent and mutually agreed terms, consistent with the Convention on Biological Diversity;

(x) Measures to ensure compliance with prior informed consent of indigenous and local communities holding traditional knowledge associated with genetic resources, in accordance with Article 8(j);

(xi) Measures to ensure compliance with the mutually agreed terms on which genetic resources were granted and to prevent the unauthorized access and use of genetic resources consistent with the Convention on Biological Diversity;

(xiii) Internationally recognized certificate of origin/source/legal provenance of genetic resources and associated traditional knowledge;

(xiv) Disclosure of origin/source/legal provenance of genetic resources and associated traditional knowledge in applications for intellectual property rights;

(xx) Monitoring, compliance and enforcement;

(xxi) Dispute settlement, and/or arbitration, if and when necessary;"

Future negotiations on compliance were shaped by WGABS-5 in 2005, when delegates settled on three issues for further consideration:

(a) Measures to support compliance with prior informed consent and mutually agreed terms;
(b) Internationally recognized certificate of origin/source/legal provenance;
(c) Monitoring, enforcement and dispute settlement.

Negotiations then focused on (b) and (c) above, while (a), a matter of compliance with the rules of the treaty itself, was put aside until later. WGABS-6 in 2008 entered into more detailed discussion in order to provide a comprehensive report to COP-8, but division between developing and developed countries became apparent. This division caused tensions over the meaning of the "international access standards" proposed by the EU as tool for compliance.

WGABS-6 moved to a two tiered approach, marking agreed issues as "bricks" and those, which needed further consideration as "bullets". Three compliance "bricks" were identified as components to be further elaborated with the aim of incorporating them in the international regime on ABS. The uncontroversial measures underlying these "bricks" were:

1) Development of tools to encourage compliance: Awareness-raising activities;
2) Development of tools to monitor compliance: Mechanisms for information exchange, and Internationally recognized certificate issued by a domestic competent authority;
3) Development of tools to enforce compliance.

WGABS-6 also suggested a set of 17 further measures to bring life to the three "bricks". These essentially shaped the entire ABS negotiation on compliance until COP-10 in 2010 when negotiations ended. WGABS-7 and WGABS-8 worked on upgrading other issues identified as "bullets" into "bricks" and finally delivered a template for the negotiations until Nagoya that lists four compliance issues with 19 measures (see Table 3 below).

At WGABS-8, Mexico reintroduced the idea of a Compliance Committee to oversee the implementation of the ABS protocol. Delegates agreed to this idea but postponed substantial discussions to a next meeting. The final result is Article 30 of the Nagoya Protocol (Procedures and Mechanisms to Promote Compliance with this Protocol) that does not itself establish a Compliance Committee, but leaves it to the first Meeting of Parties when the Protocol enters into force to decide on "institutional mechanisms to promote compliance". Since the package of compliance issues was ultimately a major part of the standstill in negotiations at COP-10, and brokered in a closed-door process by the EU and Brazil, the road ahead to clarify and implement the Protocol promises to be rocky. (See resurged divergence and debate at the Intergovernmental Committee for the Nagoya Protocol, reported in Annex III.)

Structuring the Negotiations at WGABS-9/1

Five of the 19 measures identified at WGABS-8 related to an effective tracking system, including for the utilization of genetic resources and compliance with PIC and MAT. Sanctions were not taken up in the crucial 2010 Co-chairs non-paper, while the highly controversial issue of a disclosure requirement related to IPR applications was deleted from the draft text on the way to COP-10 Nagoya. The linkage between publicly funded research and compliance with ABS requirements was skipped in the final closed-door process.

As Table 3 shows, all four compliance issues (development of tools to encourage compliance, to monitor compliance, to enforce compliance, as well as to ensure compliance with customary law and local systems of protection) including 12 of the measures suggested by WGABS-8 were eventually reflected in the final articles of the Nagoya Protocol. How the individual measures were directed to different parts of the Nagoya Protocol follows a certain logic. Measures under the issue "tool to encourage compliance" found their way into articles 6(3), 14, 19, 20, and 21. Measures under the issue "tools to monitor compliance" are taken up in Articles 14 and 17, while measures related to "tools to enforce compliance" formed the basis of Article 18. Suggested measures for compliance related to customary law are dealt with indirectly in Articles 12 and 16.

The Co-chairs' non-paper in addition drafted three new Articles dealing with compliance on more general grounds:

- Article 30 on compliance with the Protocol itself;
- Article 15 on compliance with domestic ABS legislation concerning genetic resources;
- Article 16 on compliance with domestic ABS legislation concerning traditional knowledge associated with genetic resources.

The following discussion deals with Articles 30, 15 and 16 while the specific measures in Articles 17 and 18 will be discussed after these.

Article 30 – PROCEDURES AND MECHANISMS TO PROMOTE COMPLIANCE WITH THIS PROTOCOL

The establishment of a strong compliance committee according to Article 30 is an urgent task due to the obvious gaps in the Nagoya Protocol that must be addressed for it to effectively stop and prevent biopiracy. For example, in several cases documented in 2011 and 2012 as part of a research project to contribute to the implementation of the Protocol and national ABS legislation, it was shown that there was disregard for proper ABS agreements among bioprospectors and disrespect for traditional knowledge and developing country science. In one case, Rutgers University (USA) claiming patents on African plants with no material transfer agreements and blatantly appropriates traditional knowledge. Nestle, the Swiss food giant, was found to lay claim to uses of a Middle Eastern medical plant that are widely documented in traditional medicine and studies by scientists from the region. In yet another case, microbes found in Malaysia by an academic bioprospector were conveyed to a biotechnology company in California without knowledge of the authorities. These and other cases also show the indistinguishable line between "non-commercial" and "commercial" research. They also underscore the importance and urgency for mandatory disclosure requirements in patent applications that involve genetic resources and/or associated traditional knowledge.[17]

A compliance committee under the Protocol can address different interpretations that exist on some provisions and anticipate challenges posed by the complex nature of access and benefit sharing, in particular the transboundary dimension.

> Article 30 – PROCEDURES AND MECHANISMS TO PROMOTE COMPLIANCE WITH THIS PROTOCOL
>
> The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, consider and approve cooperative procedures and institutional mechanisms to promote compliance with the provisions of this Protocol and to address cases of non-compliance. These procedures and mechanisms shall include provisions to offer advice or assistance, where appropriate. They shall be separate from, and without prejudice to, the dispute settlement procedures and mechanisms under Article 27 of the Convention.

[17] Edward Hammond, Biopiracy Continues: A Compilation of Some Recent Cases (2013), Third World Network, Malaysia. This is the first of a series. Available at: http://www.twn.my/title2/biotk/misc/TO%20PRINT%20Biopiracy%20Compilation_10%20Dec2012.pdf

Table 3: Suggested issues and measures for compliance and their reflection in the Nagoya Protocol

Issues and Measures	Reflection in Nagoya Protocol
1) Development of tools to encourage compliance	
(a) Awareness-raising activities	Art. 21
(b) International understanding of misappropriation/misuse	Not taken up in Co-chairs non-paper
(c) Sectoral menus of model clauses for material transfer agreements	Art. 19
(d) Codes of conduct for important groups of users	Art. 20
(e) Identification of best-practice codes of conduct	Art. 20
(f) Research funding agencies to oblige users receiving research funds to comply with specific access and benefit-sharing requirements	Co-chairs non-paper draft Art. 13 1.(a) *(Deleted in final closed-door process on October 29, 2010 at COP-10 in Nagoya)*
(g) Unilateral declaration by users	Not taken up in Co-chairs non-paper
(h) International access standards (that do not require harmonization of domestic access legislation) to support compliance across jurisdictions	Art. 6 3.
2) Development of tools to monitor compliance	
(a) Mechanisms for information exchange	Art. 14
(b) Internationally recognized certificate issued by a domestic competent authority	Art. 17 2. - 4.
(c) Tracking and reporting systems	Art. 17 1. (b) & (c)
(d) Information technology for tracking	Not taken up in Co-chairs non-paper
(e) Disclosure requirements	Taken up in Co-chairs non-paper Abandoned during WGABS-9/3
(f) Identification of check points	Art. 17 1. (a)
3) Development of tools to enforce compliance	
(a) Measures to ensure access to justice with the aim of enforcing ABS arrangements	Art 18 3. a
(b) Dispute settlement mechanisms	Art. 18 1. & 2. as well as Art. 30
(c) Enforcement of judgments and arbitral awards across jurisdictions	Art 18 3. b
(d) Information exchange procedures between national focal points for access and benefit-sharing to help providers obtain relevant information in specific cases of alleged infringements of prior-informed-consent requirements	Not taken up in Co-chairs non-paper
(e) Remedies and sanctions	Not taken up in Co-chairs non-paper
4) Measures to ensure compliance with customary law and local systems of protection	Art. 12 in combination with Art. 16

Development

The 2010 Co-Chairs' non-paper took up Mexico's suggestion at WGABS-8, and included a draft Article 25 on compliance. It opted not to create an international Dispute Resolution Mechanism as was suggested during WGABS-7. Rather, the non-paper opted for a provision leaving the issue to be decided at the first Meeting of Parties (MOP) of the Nagoya Protocol. Parties accepted the draft text during the ING meeting in September 2010.

Several fundamental issues on the interpretation of Article 30 have emerged at the Intergovernmental Committee for the Nagoya Protocol that met in 2011 and 2012 to prepare for the entry into force of the Protocol. See Annex IV for more information.

Article 15 – COMPLIANCE WITH DOMESTIC LEGISLATION OR REGULATORY REQUIREMENTS ON ACCESS AND BENEFIT-SHARING

The development of effective user measures to prevent biopiracy – or misuse and misappropriation – was a core demand of developing countries from the time that the Bonn Guidelines were developed. User measures mean national rules applied to users of genetic resources within the countries where users are located. In the context of the negotiations, this often meant laws in developed countries that apply to companies located there, requiring those companies to follow the ABS rules adopted by the developing countries where they access genetic resources.

It was due to the initiative of developing countries at COP-6 in 2002 that the draft text of the Bonn Guidelines was amended to include recommendations on user measures. Article 15 of the Nagoya Protocol is its core article with regard to user measures. It obliges Parties to ensure the compliance with the ABS system of other Parties, by users acting in its territory and provides for a system to address non-compliance. Further details are left to national implementation.

> Article 15 – COMPLIANCE WITH DOMESTIC LEGISLATION OR REGULATORY REQUIREMENTS ON ACCESS AND BENEFIT-SHARING
>
> 1. Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures to provide that genetic resources utilized within its jurisdiction have been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the other Party.
> 2. Parties shall take appropriate, effective and proportionate measures to address situations of non-compliance with measures adopted in accordance with paragraph 1.
> 3. Parties shall, as far as possible and as appropriate, cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements referred to in paragraph 1.

Development

The ABS Protocol as an instrument to support compliance in the user country with national or domestic ABS legislation of the provider country was a topic from the beginning of negotiations. Delegations at WGABS-3 in 2005, for example, listed this issue as a potential element of the objectives. In 2009, WGABS-7 developed the idea of the protocol requiring provider countries to issue certificates of compliance with national regulation. These would be published in the ABS clearing house as a means to enable monitoring and prevent misappropriation. Another issue discussed at WGABS-7 and 8 dealt with the cross-border aspects of compliance in this context, for example recognition and enforcement of foreign judgements.

The 2010 Co-chairs' non-paper developed a draft Article 12 (now Article 15 of the Protocol on compliance with domestic ABS legislation) on user measures that was delinked from the debate over tools for ensuring compliance, with suggestions of international instruments and mechanisms such as the internationally recognized certificate of compliance or the ABS clearing house. This reads as follows:

> "1. Parties shall take appropriate, effective and proportionate measures to ensure that genetic resources utilized within their jurisdiction have been obtained in accordance with the national legislation on access and benefit-sharing of the country providing such resources.
> 2. Parties shall take appropriate, effective and proportionate administrative, civil and/or criminal measures to sanction or remedy situations of non-compliance with measures adopted in accordance with paragraph 1.
> 3. Parties shall cooperate in cases of alleged violation of the national legislation of the country providing genetic resources."

This suggestion did not take up the detailed provisions developed with regard to the enforcement of foreign jurisdiction or other tools to ensure compliance by the Group of Technical and Legal Experts. Instead it provided very general language in its paragraphs 2 and 3 (see above). During WGABS-9/1 developing countries (but also Switzerland and Norway) sought for the ABS protocol to provide for internationally recognized tools to monitor compliance with national legislation. These calls and further efforts, which aimed to use the draft Article 12 as place to define the term misappropriation, remained unsuccessful. Instead, the breadth of draft Article 12(1) significantly contracted when compliance with all provisions of national legislation was replaced by the narrower obligation of ensuring compliance with PIC and MAT. The ING Meeting in September 2010 concluded substantive discussions on this Article with wording only slightly altered from that suggested in the non-paper.

During COP-10 the narrow scope of draft Article 12(1) gave rise to debate but the text was not changed. A larger debate ensued on the relationship between draft Articles 12 and 13. Developing countries argued that draft Article 13 (now Article 17 of the Protocol on monitoring utilization of genetic resources) be used to set up binding standards and tools for implementing draft Article 12, without which the latter article would remain an "empty promise". Developed countries including the EU and New

Zealand stressed that they had agreed to a strong obligation to create user measures but insisted on considerable flexibility in how to implement them. Therefore international standards and tools would not be helpful, they claimed. Some brackets remained until the negotiations were stalled. These reflected unresolved issues under other Articles.

Article 15 obliges Parties to ensure the lawful utilization of genetic resources for research and development within its jurisdiction. To implement Article 15 meaningfully, the installation of effective checkpoints at the level of research and development seems to be inevitable. The compliance obligations of a Party relating to the phase of "subsequent applications and commercialization" are covered later, in Article 18.

Article 15 can be regarded as the central "anti-biopiracy" article of the Protocol, although it does not use the term "misappropriation". Efforts of Parties to include this term in draft Article 12 stalled at WGABS-9/2 in July 2010. Nevertheless, Article 15(2) obliges Parties to take appropriate, effective and proportionate measures and these could include sanctions or remedies in situations of non-compliance. As soon as a country becomes a Party to the Nagoya Protocol it is obligated to take actions on the utilization of genetic resource biopirated from other Parties. The language of this Article covers utilization of those genetic resources brought into the country before it became a Party to the Protocol. The implementation of Article 15 will thereby be a litmus test for the political will of a Party to fight biopiracy and to ensure fair and equitable benefit sharing on a broad basis, targeting users in their countries, and not just vis-à-vis other Parties.

The suggestion to create a certificate of origin with respect to compliance with ABS law, was a central element of the debate in international IP fora to include mandatory disclosure requirements in IP laws.

In their first substantive decision on ABS, at COP-4 in 1998, CBD Parties asked the first meeting of the ABS expert group they established to address "reference to the country of origin, where available, in relevant publications and patent applications" as one possibility for creating CBD-compliant ABS systems.

As result of the early discussions, in 2002 COP-6 invited WIPO to conduct a technical study "on methods consistent with obligations in treaties administered by WIPO for requiring the disclosure within patent applications." with disclosure meaning the origin of genetic resources and associated traditional knowledge. In 2004, COP-7 again invited WIPO provide information on disclosure, this time with a more concrete request for a report on "issues regarding the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications". This request presented examples of model provisions that could be integrated into international or national IP laws. COP-7's request was also extended to UNCATD and other organizations.

The call triggered responses by several organizations at WGABS-3 in 2005, including the International Chamber of Commerce (ICC) and the International Seed Federation. These industry groups warned against CBD decisions exerting any influence on the IP system. The ICC for example stated, "this exaggerated focus on the patent process as an ABS tool may actually inhibit progress on ABS. The reason is that it invites the ABS process to become a forum for a broader range of potentially divisive

issues. This is already evident in efforts by some countries to migrate concerns relating to genetic resource IPR from primary intergovernmental institutions responsible for IPR, WIPO and the WTO TRIPS Council, into the CBD. This not only threatens to undermine global forums charged with IPR responsibility, but threatens to mire access and benefit-sharing in intractable debate."

Studies by WIPO, UNCTAD and others were presented at WGABS-4 in 2006. These prompted the drafting of a series of provisions dealing with disclosure issues.

The next round of substantive deliberations on disclosure took place at WGABS-7, which also elaborated on sanctions in the case of missing or inaccurate statements on disclosure in IP applications. Developing countries continued at WGABS-8 to expand provisions on disclosure, while developed countries announced they were unwilling to talk about disclosure and other IP-related issues as part of ABS negotiations. Instead, they proposed that IPR issues only be mentioned in the preamble of an ABS agreement and offered the following text to do so:

"Recognizing that patents and other intellectual property rights may have an influence on the implementation of the Convention in accordance with Article 16(5), Parties may encourage providers and users to include contract clauses relating to intellectual property, as appropriate, in mutually agreed terms."

The 2010 Co-chairs' non-paper tried to balance the contrasting views in a draft Article stating that Parties shall take appropriate measures such as disclosure requirements at patent offices. These would not require substantial changes in IP laws in order to implement the ABS protocol. Parties to the Protocol only need to request IP applicants to submit national ABS permits when applying for IP protection on inventions related to genetic resources as a means to monitor their utilization. Further detail was left to national IP legislation. Developed countries and their industries would not accept the Co-chair's proposed Article on this matter, regarding it as an unjustified interference with the IP system.

On Confidential Information

The issue of confidentiality of data was brought into the negotiation text during WGABS-7 in relation to discussion on the internationally recognized certificate of compliance. There were concerns about a possible requirement for government institutions to publish details contained in private contracts and that ILCs might not want to make certain provisions public. The issue of confidentiality was exploited by opponents of compliance provisions to make the provisions as weak as possible. During WGABS-8, confidentiality was raised for practically all provisions dealing with information sharing. In its draft article on the ABS clearing house, the Co-chairs' non-paper provided for protection of confidential information, but without further specification of what this might be and who determines the need for secrecy:

"Without prejudice to the protection of confidential information, each Party shall make available to the Access and Benefit-sharing Clearing-House any information required by this Protocol, as well as information required pursuant to the decisions taken by the Conference of the Parties serving as the meeting of the Parties to this Protocol."

The non-paper did not refer to "confidential business information" which at least is a relatively established concept, but rather to "confidential information" which is a comparatively broad and unspecific term.

The final provision is in Article 17(4) of the Nagoya Protocol that lists 9 items of minimum information that must be in the certificate "when it is not confidential" – as seen from the text of this paragraph above, such information includes the issuing authority, date of issuance, the provider, the person or entity to whom PIC was granted etc. If such information can be successfully claimed to be confidential it would make a mockery of the certificate and the Protocol. It is thus crucial for the MOP to clarify this provision in favour of transparency and for national ABS legislation to set out clearly what is NOT confidential.

Finalization of Article 17

When negotiations on the Co-chairs' non-paper started at WGABS-9/1, the EU rejected the draft Article in its entirety and, indeed, opposed any international standards on monitoring. Norway took a different position and added text on sanctions in cases of non-compliance with national ABS legislation and IP disclosure obligations. Switzerland supported legally binding elements in the international compliance provisions. Developing countries accepted the draft Article as a basis for further negotiations but stressed that improvements are necessary. At the end of the meeting, the draft Article was maintained, and developing countries succeeded in bringing back detailed provisions on the certificate of compliance.

At WGABS-9/2 in July 2010, the scope of the eventual Article 17 was extended to cover associated traditional knowledge. Its provisions were amended in several variations, including a provision making confidential all elements of the list of minimum requirements for the certificate of compliance. Norway brought suggestions on sanctions in cases of non-compliance with disclosure requirements, which were bracketed in a draft Article 13bis.

Subsequent meetings could not resolve the contentious issues contained in the heavily bracketed text. During the ING meeting in October 2010 in Nagoya, Parties confirmed their contrasting positions with regard to the legal nature of the provisions, international standards, inclusion of associated traditional knowledge, and disclosure in IP applications. The EU, for example, said its acceptance of strong user obligations than required by the CBD meant there was no need to include international compliance standards in the Protocol. Developing countries replied that international standards were the only way in which transboundary cases of misappropriation could be tackled effectively. They also questioned how far EU had actually come, maintaining that the CBD already required effective user measures and that the draft protocol merely clarified the obligation.

Developed countries rejected the indicative list of checkpoints, especially Canada. At several instances Canada complained that it would need to change its laws if such provisions were adopted in the Nagoya Protocol. Some developing countries and observers questioned how earnest Canada's concern was, because they viewed Canada

as unlikely to ratify the ABS protocol, just as it had declined to ratify the Cartagena Protocol on Biosafety.

Another strand of discussions concerned the tasks that checkpoints were to perform. Should they wait to receive information or actively collect it? Should they check submitted information for completeness or verify the content of PIC and MAT agreements? Developed countries dug deep into these issues while developing countries reminded them that checkpoints typically gather responses to questions rather than verify information. An example used was the question "Have you visited a farm in the last 14 days?", something asked of travellers arriving on international flights in the country hosting the CBD Secretariat.

On IP-related issues, Brazil, Norway and Switzerland stated that their intellectual property laws had been amended with disclosure requirements, and this had not caused serious problems or triggered complaints by the WTO or WIPO. Discussing market approval offices, the EU and New Zealand admitted that they have no experience at all with such checkpoints in relation to ABS matters and hardly any experts. They said they could not judge the implications of this provision in the draft Article and therefore rejected it.

WGABS-9/3 did not result in substantial progress in matters of developing tools to monitor compliance.

The first week of COP-10 continued to debate the certificate of compliance. Colombia proposed to include basic elements and initial ideas but to leave the rest for the first meeting of Protocol Parties (MOP-1). This idea gained approval from many delegations.

Confidentiality again proved to be a controversial point. Many developing countries noted that most of the listed elements of the certificate are not confidential to begin with, while the EU said it needed a discussion with stakeholders to decide which elements of the list are likely to be confidential and which not. The first week's discussion seemed to establish a compromise by which the Protocol would contain an obligation to create checkpoints and a list of their functions rather than a list of institutions.

At the beginning of the second week of COP-10 hopes faded when the co-chairs of the group negotiating compliance stated that the discussions were in a "deep crisis". Additional talks on the IP-related issues in a very small circle could not bring the opposing delegations together, while the EU continued to demand strict separation of IPRs and ABS, as requested by its industrial interests. On October 27 the co-chairs presented a compromise text that beforehand was only discussed in small private meetings. In parallel and in anticipation of the failure of the negotiations, a closed-door ministerial meeting started to prepare the Protocol text in a "green room" manner that would later be imposed on all Parties ("green room" is the reference to the precedent started by the WTO of having selected small groups of negotiators decide on a deal and then to get other members to agree without having a say). This group excluded delegations from the Asia-Pacific Group, some of which were the EU's strongest opponents on the issue.

After these meetings, Article 17 did not move beyond the draft previously presented by the co-chairs.

Left in an immature and partly confusing state, Article 17 neither applies to traditional knowledge nor tackles IP-related issues, two major desires of developing countries. The language in many parts is chosen in a way to avoid concrete activities and obligations, and does not even specify which of the three levels of compliance that guided the negotiations should be supported.[18]

While the Article offers a list of functions that the checkpoints need to fulfil, it leaves to the discretion of the Parties whether to appoint one or more checkpoint but this checkpoint(s) must be "effective". It is interesting to note that while the first paragraph of the article at (a)(iv) states that checkpoints should have functions at all stages of the value chain, including commercialization, that this obviously contradicts the scope of Article 17, which is restricted to the phase of research and development. Such is the contradiction again of provisions caused by the process of the final days.

The Norwegian proposal for measures addressing situations of non-compliance were incorporated in the first paragraph at (a)(ii), but in vague language lacking guidance or standards on the nature of such measures.

Paragraphs two through four, elaborating the certificate of compliance, appears delinked from the rest of the Nagoya Protocol. The certificate takes effect through publication of national ABS permits in the ABS clearing house, yet the Article does not specify the exact relationship between the national permit and the international certificate. While the Protocol leaves detail on the content of a permit to national ABS legislation, minimum requirements for the international certificate appear in Article 17(4). Since the EU could not consult its stakeholders on the question of confidential information, Article 17(4) states that all nine items of minimum information could be declared as confidential, including the provider, the date of issuance or the number of the certificate. If the potential confidentiality claims permitted under this provision were fully applied, this would have the effect of turning the international certificate into an empty piece of paper.

Article 19 – MODEL CONTRACTUAL CLAUSES

Article 20 – CODES OF CONDUCT, GUIDELINES AND BEST PRACTICES AND/OR STANDARDS

Both Articles 19 and 20 stem from a long debate over whether the ABS protocol should develop a common regulatory approach for all groups of genetic resource users, or take a sectoral approach (for example, treating one industry differently than another). The proponents for the latter approach were the various industrial users and non-commercial research entities. They argued that the mode of utilization of genetic resources and associated traditional knowledge varied greatly between the groups hence

[18] Compliance with the rules of the Nagoya Protocol, Compliance in user countries with national ABS legislation and regulatory requirements of provider countries, and Compliance with the mutually agreed terms of ABS contracts.

they required different ABS rules that they considered more appropriate for themselves. Agricultural interests called for plant genetic resources for food and agriculture to be excluded from the ABS protocol because the ITPGRFA establishes a separate model. Agricultural sectors also called for the exclusion of microbial and animal genetic resources from the ABS protocol, arguing that the FAO would develop comparable ABS treaties for those resources when used for food and agriculture.

Article 19 – MODEL CONTRACTUAL CLAUSES

1. Each Party shall encourage, as appropriate, the development, update and use of sectoral and cross-sectoral model contractual clauses for mutually agreed terms.
2. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall periodically take stock of the use of sectoral and cross-sectoral model contractual clauses.

Article 20 – CODES OF CONDUCT, GUIDELINES AND BEST PRACTICES AND/OR STANDARDS

1. Each Party shall encourage, as appropriate, the development, update and use of voluntary codes of conduct, guidelines and best practices and/or standards in relation to access and benefit-sharing.
2. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall periodically take stock of the use of voluntary codes of conduct, guidelines and best practices and/or standards and consider the adoption of specific codes of conduct, guidelines and best practices and/or standards.

Development

Sectoral approaches were discussed by the group of technical and legal experts (GTLE-1) in 2008. Representatives from various sectors agreed that they use different operating models, but the forms of benefit sharing they highlighted did not extend beyond those compiled in the 2002 Bonn Guidelines or those suggested as Annex I in the Co-chairs non-paper of 2010. Sector representatives also stressed different modes of accessing genetic resources: while non-commercial research mainly accesses genetic resources in *in-situ* conditions, the agricultural and industrial sectors mainly access *ex-situ* collections, the resources of the non-commercial research sector or simply purchases the needed genetic resources as commodities on the open market. Apart from the ITPGRFA no specific access models within the framework of the Nagoya Protocol were cited.

Industry and non-commercial interests suggested that the ABS protocol provide only a default framework that could be amended or replaced by more specific approaches developed by those users themselves. Both interest groups favoured voluntary agreements over binding rules. Negotiators rejected this conception during WGABS-9/1 when they agreed to negotiate a legally binding protocol that would set specific ABS rules applicable to all sectors. In accepting draft Article 15 of the Co-chairs' non-

paper (the eventual Article 19 of the Nagoya Protocol), the negotiators agreed that the preferences of different "sectors" should be reflected in the MAT. Despite the legally binding character of the Protocol, the negotiators also accepted draft Article 16 (Article 20 of the Nagoya Protocol), obliging Parties to "encourage, as appropriate, the development, update and use of voluntary codes of conduct, guidelines and best practices and/or standards".

One explanation why this contradictory approach is retained in the final Protocol could be to keep the door open for the establishment of a general ABS framework system. Parties might opt for a national ABS system that allows various user sectors to apply their own ABS models to avoid ABS requirements in a national system that do not fit their purposes.

Article 24 – NON-PARTIES

As an international treaty, the Nagoya Protocol cannot impose obligations on non-Parties. The main purpose of an article on non-Parties ideally is to oblige Parties to treat non-Parties using principles and rules comparable to those applied to Parties. The Cartagena Protocol on Biosafety, for example, prescribes that the transboundary movement of GMOs between Parties and non-Parties shall be consistent with the Protocol's objectives. The intended effect is to avoid free riding and offer an incentive for non-Parties to become a Party. The ABS Protocol, however, did not take this approach. It does not specifically encourage similar treatment of non-Parties, rather, it only provides for non-Parties to be encouraged to adhere to the Protocol.

Article 24 – NON-PARTIES The Parties shall encourage non-Parties to adhere to this Protocol and to contribute appropriate information to the Access and Benefit-sharing Clearing-House.

Development

The issue of non-Parties to the Nagoya Protocol was first addressed late in the negotiations. The 2010 and previous meeting documents did not include a reference to an Article on non-Parties. It was during WGABS-9/1 that the LMMC, Like-minded Asia-Pacific Group, GRULAC, African Group, and Saudi Arabia asked for inclusion of such a text. The short paragraph as agreed upon in WGABS-9/1 remained intact through the adoption of the Protocol in Nagoya.

Article 27 – SUBSIDIARY BODIES

Article 27 provides for the possibility of creating subsidiary bodies under the Protocol. Subsidiary bodies should be established for those tasks and issues with greatest potential for disputes during the implementation and thus require specific attention and expertise.

Article 27 – SUBSIDIARY BODIES

1. Any subsidiary body established by or under the Convention may serve this Protocol, including upon a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any such decision shall specify the tasks to be undertaken.
2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of any such subsidiary bodies. When a subsidiary body of the Convention serves as a subsidiary body to this Protocol, decisions under this Protocol shall be taken only by Parties to this Protocol.
3. When a subsidiary body of the Convention exercises its functions with regard to matters concerning this Protocol, any member of the bureau of that subsidiary body representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.

On Ombudsperson

One pertinent issue debated during the ABS-negotiations is the imbalance of legal, financial, and political power of ILC during negotiation and execution of ABS contracts. In order to support ILC in ABS matters, the establishment of an ombudsperson office was suggested as appropriate means to address this imbalance. Such an office could be established as a subsidiary body. The idea of an ABS ombudsperson was first launched at the group of technical and legal experts on Traditional Knowledge associated with Genetic Resources GTLE-3 held in Hyderabad in 2009:

"51. It was suggested that the International Regime could establish a legal aid body, such as an ombudsperson, that includes representatives of indigenous and local communities that could assist in addressing imbalances in legal capacity between providers and users of genetic resources and associated traditional knowledge in order to create a level playing field. This authority could be empowered to take action on behalf of indigenous and local communities and provide evidence of customary law and practices, as and where appropriate."

The recommendation of GTLE-3 was taken up in the compilation of options by WGABS-8 in 2009 in Montreal. The concept of an ombudsperson was dropped in the Co-Chairs Non-Paper of March 2010. During WGABS-9/2 in July 2010 in Montreal, GRULAC and the African Group could successfully reintroduce language on an ombudsperson in the draft Article 14bis "International access and benefit-sharing ombudsperson":

"[An office of an access and benefit-sharing ombudsperson shall be established to support developing countries and indigenous and local communities to identify breaches of rights and to provide technical and legal support in ensuring effective redress of such breaches. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall implement this provision no later than two years after entry into force of this Protocol.]"

During COP-10, a small negotiating group on compliance suggested that the ombudsperson be retained somewhere in the text, a call supported at the last-minute by GRULAC, shortly before the negotiations were stalled on October 28. The Article (14bis) was deleted in the closed-door process, making this another issue that did not get the benefit of a thorough round of negotiation to consider its merits.

The concept of an ombudsperson could be considered in the implementation of Article 21(c), which includes "Establishment and maintenance of a help desk for indigenous and local communities and relevant stakeholders" among potential national measure to raise awareness. This would be at the national level. At the same time, Parties also have the authority, if there is political willingness, to adopt a MOP decision to establish an ombudsperson at the international level.

Article 31 – ASSESSMENT AND REVIEW

The Nagoya Protocol has an in-built evaluation of its effectiveness that is to taken place four years after the entry into force of the Protocol. With the gaps and lack of certainty shadowing many of the provisions, this is an important opportunity to take steps that are necessary to bring the objectives of the Protocol and CBD to fruition. Periodic review is also to take place as decided by the MOP.

There is nothing, however, to prevent Parties from already rectifying the imbalance and gaps that resulted from the closed-door process which gave birth to the Protocol. The work of the Intergovernmental Committee for the Nagoya Protocol that has met twice and will meet again in 2014 can be a crucial first step towards that end.

ARTICLE 31 – ASSESSMENT AND REVIEW

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall undertake, four years after the entry into force of this Protocol and thereafter at intervals determined by the Conference of Parties serving as the meeting of the Parties to this Protocol, an evaluation of the effectiveness of this Protocol.

CHAPTER 4

DEVELOPMENT OF EFFECTIVE ABS SYSTEMS

4.1 OVERVIEW

THE core articles of the Nagoya Protocol on access, benefit-sharing, traditional knowledge and compliance contain a mix of provisions ranging from obligatory to non-binding. Many fall somewhere between, in the sense that they may be subject to national legislation or applicable only in specific circumstances.

Table 4 is the authors' classification of the core provisions of the Protocol according to their level of obligation: strong, medium or weak.

Table 4: Core provisions of the Nagoya Protocol and their level of legal obligation

(Colour code indicates the level of obligation: strong, medium, weak)

	Issue	Level of obligation
Art. 5	**Fair and Equitable Benefit-sharing (BS)**	
5(1)	BS of utilization of genetic resources based on mutually agreed terms (MAT)	Obligatory
5(3)	Different types of measures (legislative, administrative or policy) for BS of GR utilization	Obligatory, but type of measures as appropriate
5(2)	Different type of BS measures for utilization of GR of indigenous and local communities (ILC)	Obligatory, but type of measures as appropriate With the aim of ensuring BS with ILC and based on MAT, according to domestic legislation,
5(5)	Different types of BS measures for traditional knowledge associated with GR (ATK)	Obligatory, but type of measures as appropriate
Art. 6	**Access to Genetic Resources**	
6(1)	Access to GR based on prior informed consent (PIC)	Obligatory, unless otherwise determined by Party providing GR

6(2)	Measures for PIC or approval and involvement of ILC for access of GR of ILC	Obligatory, but as appropriate according to domestic law
6(3)	Measures for access standards	Obligatory, but type of measures as appropriate
6(3)(f)	Criteria and processes for PIC or approval and involvement of ILC for access of GR of ILC	Subject to domestic legislation
6(3)(g)	Terms of MAT	Non-binding open list
Art. 7	**Access to Traditional Knowledge Associated with Genetic Resources**	
	Measures for PIC and MAT for ATK of ILC	Obligatory, but as appropriate, and in accordance with domestic law
Art. 8	**Special Considerations**	
(a)	Access for non-commercial research purposes	Obligation at domestic level to create conditions to promote and encourage research, particularly in developing countries
(b)	Cases of present or imminent emergencies that threaten or damage human, animal or plant health as determined nationally or internationally	Obligation at domestic level to pay due regard to such cases May take into consideration need for expeditious ABS
(c)	GR for food and agriculture	Obligation at domestic level to consider importance of GR for food and agriculture
Art. 10	**Global Multilateral Benefit-sharing Mechanism**	
	BS of utilization of GR and ATK occurring in transboundary situations or for which PIC is not possible	Obligatory but to consider the need for such a Mechanism
Art. 12	**Traditional Knowledge Associated with Genetic Resources**	
12(1)	Take into considerations ILC's customary laws, community protocols and procedures	Obligatory but as appropriate, in accordance with domestic law
12(2)	Information mechanisms for potential users	Obligatory with effective participation of ILC concerned At domestic level and through ABS Clearing-House of the Protocol
12(3)	Support ILC development of community protocols of ABS, MAT minimum requirements for BS and model contractual clauses for BS	Obligation to endeavor, as appropriate

Art. 15	**Compliance with Domestic Legislation of Regulatory Requirements on ABS**	
15(1)	Different types of measures by Party in whose jurisdiction GR is used, so that such utilization is in accordance with PIC and MAT is established, as required by providing Party	Obligatory, but type of measures as appropriate Measures to be "appropriate, effective and proportionate"
15(2)	Measures to address non-compliance	Obligatory, and measures to be appropriate, effective and proportionate
15(3)	Parties' cooperation in cases of regulatory requirements of Party providing GR	Obligatory, but as far as possible and as alleged violation of legislation or appropriate
Art. 16	**Compliance with Domestic Legislation or Regulatory Requirements on ABS for TK associated with GR**	
16(1)	Measures by Party in whose jurisdiction ATK is used, so that such utilization is in accordance with PIC or approval and involvement of ILC and MAT is established, as required by Party where ILC is located	Obligatory, but type of measures as appropriate
16(2)	Measures to address non-compliance	Obligatory, and measures to be appropriate, effective and proportionate
16(3)	Cooperation in cases of alleged violation of legislation or regulatory requirements of Party where ILC is located	Obligatory, but as far as possible and as appropriate
Art. 17	**Monitoring the Utilization of Genetic Resources**	
17(1)	Measures to support compliance	Obligatory, but as appropriate Obligatory indicative list in 17(a) to (c)
(a)	Designated checkpoint(s)	One or more
(i)	Collect or receive relevant information related to access and/or utilization of GR	As appropriate
(ii)	Require user to provide information in 17(1)(a)(i)	As appropriate and depends on characteristics of checkpoint
(ii)	Measures to address non-compliance	Obligatory
(iii)	Provide user information to relevant national authorities, Party providing PIC, ABS Clearing House	Recipients, as appropriate Dependent on (a)(i) and (a)(ii)

(iv)	Checkpoints must be effective Relevant to utilization of GR or collection of information at any stage of research, development, innovation, pre-commercialization or commercialization	Obligatory
(iv)	Functions to be relevant to (a)(i) – (a)(iii)	Qualifications in (a)(i) to (a)(iii)
(b)	Information sharing requirements in MAT	Not obligatory (“encourage”)
(c)	Using cost-effective communication tools	Not obligatory (“encourage”)
17(2)	National permit (as evidence of PIC and MAT) published in ABS Clearing House, constitutes internationally recognized certificate of compliance	Obligatory
17(3)	Function of internationally recognized certificate	Obligatory
17(4)	List of minimum information in internationally recognized certificate of compliance	Obligatory, when not confidential and yet the required information should not be confidential at all1
Art. 18	**Compliance with Mutually Agreed Terms**	
18(1)	Dispute settlement clauses in MAT	Parties shall encourage providers and users to include clauses in MAT
18(2)	Opportunity to seek recourse in domestic legal systems	Obligatory
18(3)	Effective measures on access to justice and enforcement of foreign judgments	As appropriate
18(4)	Review of Art. 18	Obligatory
Art. 23	**Technology Transfer, Collaboration and Cooperation**	
	Collaborate and cooperate in research and development	Obligatory
	Access to technology by, and technology transfer to, developing country Parties and Parties with economies in transition	Promote and encourage
	Collaborative activities to take place in and with provider Party/Parties	Where possible and appropriate

This classification may vary based on the interpretation of different readers of the Nagoya Protocol. In essence, however, it shows that many provisions of the Protocol are weak or impose no international obligation on the Parties, especially with respect to compliance and the rights of ILCs. Since these and other underlying issues of importance need to be clarified in order to create effective ABS systems, responsive provisions in national ABS legislation and decisions by the Parties to the Protocol and to the CBD will be needed to meet the Protocol objective.

As detailed in Chapter 3, basic issues concerning the definition of traditional knowledge and its utilization, how to treat publicly available traditional knowledge not attributable to ILCs, and disclosure in patent applications are not resolved within the Protocol. These require further discussion and decisions that are consistent with the Protocol at other international fora, too, including the WIPO and WTO TRIPS Council.

When drafting national ABS legislation, Parties also need to understand that a strict dichotomy of "provider" and "user" countries does not reflect the growing reality in many countries. The South-North equity principle remains relevant as reflected in the Protocol's provisions on technology transfer and finance, and the bulk of the genetic resources and associated traditional knowledge covered by the Protocol come from developing countries. The Protocol, however, was constructed with the knowledge that many countries are providers and users at the same time, and that they may also benefit from a fair ABS system to govern domestic situations. In the course of negotiations, countries, especially the more advanced developing countries, became aware that only seeing the provider's perspective would not match future interests. Their willingness to accept obligations related to users and a strong compliance system was a challenge to those industrialized country Parties that were reluctant to undertake such obligations. Further, it is obvious that any ABS system needs to capture two categories of economic value of genetic resources and associated traditional knowledge:

- Utilization based on ABS agreements agreed at the time of (first) access; and
- Continuing and new utilization based on unregulated (earlier) access for which benefit-sharing agreements have to be negotiated.

When drafting national ABS legislation, the full range of potential users in and outside the country needs to be considered. Several sectors are typical users of genetic resources and associated traditional knowledge in research and development as well as in commercialization. One group of products is based on the utilization and commercialization of biochemical compounds contained in the genetic resource. These include:

- Phytopharmaceuticals, based on complex plant extracts;
- Pharmaceuticals, based on single active ingredients;
- Cosmetics, based on natural extracts or using specific natural compounds; and
- Neutraceuticals, based on natural extracts or using specific natural compounds.

A second group of products is based on the utilization of the genes contained in genetic resources or their proteins, developed through biotechnology, and often also through the application of genetic engineering, for example:

- Enzymes for industrial, processing or household utilization, produced by optimized or genetically engineered micro-organisms, using specific genes from natural sources; and
- Organisms under the scope of the CBD and their genes used for breeding purposes.

A further important activity within the process of creating national ABS legislation is to take stock of existing utilization and commercialization of genetic resources and associated knowledge inside the country and abroad. It would be useful to screen domestic and foreign p patents to ascertain if they are based on genetic resources and associated knowledge coming from the country, and to assess the catalogues of *ex-situ* collections to identify accessions from a country.

The following sections present general recommendations for the development of national ABS systems and how to advance international ABS discussions. These are based on the analysis in Chapter 3 and state practice since the entry into force of the CBD, including since the adoption of the Nagoya Protocol.

4.2 Scope and Definitions

The scope of the Nagoya Protocol exhibits gaps. Provisions that are unclear include those relating to benefit sharing for genetic resources and traditional knowledge accessed before the entry into force of the CBD. Nevertheless it is clear that the benefit sharing obligations of Article 5 apply to genetic resources accessed before the entry into force of the Nagoya Protocol." While the Nagoya Protocol does not mandate retrospective regulation of individual access acts, national ABS systems should not reward bio-pirates by exempting from ABS regulation the continuing and new utilization and commercialization of genetic resources and traditional knowledge accessed earlier. Parties should aim to bring all utilization and commercialization of genetic resources and traditional knowledge under a broad benefit-sharing system irrespective of the date of access.

National ABS systems also must decide on regulating access to derivatives that do not contain functional units of heredity and are thus not "genetic resources" according to the CBD. The definition contained in the Protocol clarifies this point in Article 2 on Use of Terms that states in paragraph (e): "Derivatives" means a naturally occurring biochemical compound resulting from the genetic expression of metabolism of biological or genetic resources, even if it does not contain functional units of heredity.

When read together with the definitions of "Utilization of genetic resources" in Article 2(c)[19] and "Biotechnology" in Article 2(d)[20], the Protocol also clarifies that access to derivatives can be addressed in national ABS legislation, though it does not expressly require it in Article 6 as an international obligation. Benefit-sharing under Article 5 clearly covers derivatives through the definition of "Utilization of genetic resources".

Several pre-Nagoya Protocol national and regional ABS systems have already included derivatives in their scope and provisions. This would be the logical step for all ABS systems to take.

The recommendations that follow are based on the analysis in Chapter 3.

Recommendations for the National Level

- All genetic resources of a country should fall under the ABS system.
- Derivatives as defined by the Nagoya Protocol should be included in the scope and provisions of national ABS systems.
- A definition for traditional knowledge associated to genetic resources and its utilization needs to be developed, consistent with the objectives of the CBD and Nagoya Protocol.
- Benefit-sharing for the continuing utilization and commercialization of genetic resources and associated traditional knowledge accessed without PIC and MAT should be ensured.
- A system that regulates the continuing utilization and commercialization of genetic resources and associated traditional knowledge accessed before the entry into force of the CBD should be developed.
- The utilization and commercialization of genetic resources accessed in territories beyond national jurisdiction should come under the benefit-sharing provisions.
- Effective monitoring and tracking systems should be built to ensure that utilization and commercialization of genetic resources and associated traditional knowledge accessed outside the scope of the Nagoya Protocol is captured by ABS rules when a change in utilization occurs.
- *Ex-situ* collections need to be brought under the national ABS system, where generally the same rules should apply.

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[19] Utilization of genetic resources" means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention."

[20] Biotechnology" as defined in Article 2 of the Convention means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use."

Recommendations for the International Level

- Specialized ABS systems that are supportive of and do not run counter to the objectives the CBD and Nagoya Protocol for territories beyond national legislation should be discussed internationally, e.g. UNCLOS and the Antarctic Treaty System.
- The representation of CBD negotiators, regulators and stakeholders need to be ensured when other international fora discuss ABS matters.
- The WIPO IGC negotiations related to genetic resources and associated traditional knowledge need to be supportive of the objectives of the CBD and Nagoya Protocol.
- The Nagoya Protocol MOP should discuss specialized ABS agreements with regard to their supportiveness of the objective and provisions of the Nagoya Protocol and establish mechanisms for ensuring such supportiveness.
- The MOP should negotiate and agree on a Global Multilateral Benefit-sharing Mechanism in a timely manner to address those cases that cannot be resolved otherwise.
- The MOP should decide on effective cooperation with regard to monitoring and tracking.
- The MOP should decide on cooperation with international *ex-situ* collections on ABS matters.

4.3 Access to Genetic Resources of States and ILCs and to Associated Traditional Knowledge of ILCs

The access provisions of Articles 6 and 7 of the Nagoya Protocol cover three cases:

- Access to genetic resources;
- Access to genetic resources of Indigenous and Local Communities; and
- Associated traditional knowledge held by Indigenous and Local Communities.

Although the Nagoya Protocol builds upon the UN Declaration on the Rights of Indigenous Peoples (UNDRIP), which recognizes the universal rights of indigenous peoples over their genetic resources and associated traditional knowledge, national recognition of these rights in ABS legislation is necessary in order for them to have effect. UNDRIP Article 31(1) states that indigenous peoples the right to "control and protect" their traditional knowledge and genetic resources. Without the national implementation of this Article, ABS legislation in countries with indigenous peoples would be incomplete. The provision reads as follows:

"Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and

flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts. They also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions."

Article 7 of the Nagoya Protocol should be used in implementing this right at the national level in in accordance with UNDRIP Article 31(2) that reads as follows:

"In conjunction with indigenous peoples, States shall take effective measures to recognize and protect the exercise of these rights."

National ABS systems should develop procedures to assess whether the planned utilization of genetic resources and associated traditional knowledge is environmentally sound as required in CBD Article 15(2). This could be done by using established procedures of environmental impact assessment (EIA).

Furthermore, implementation and monitoring of international access standards should receive further guidance from MOP decisions and potentially the Protocol's Compliance Committee.

Recommendations for the National Level

- National legislation needs to enable ILCs to exercise their rights over genetic resources and associated traditional knowledge in giving PIC and negotiating MAT.
- National legislation should be able to prohibit utilization of genetic resources accessed in countries that are not countries of origin, and require remedial action from the user.
- National legislation should enable PIC to be linked to the existence of effective user measures in the country where the genetic resource or associated traditional knowledge will be utilized.
- EIA procedures should be explored as a possible element in the PIC procedure in order to confirm environmentally sound use of the genetic resource in accordance with Article 15(2) of the CBD.
- Access rules for traditional knowledge that is not held by any distinct groups of ILCs but spread in society should be discussed and, where possible, established.
- A national ombudsperson to give support to ILCs on access procedures and effective agreements should also be discussed.

Recommendations for the International Level

- The MOP should take a decision clarifying that accessing genetic resources outside the country of origin contravenes the Nagoya Protocol.
- The MOP should discuss a decision on what information and documentation is necessary for users utilizing genetic resources from Parties that have waived PIC.

4.4 Benefit-Sharing

Article 5 of the Nagoya Protocol differentiates among three cases of utilization in which benefit sharing is obligatory:

- Utilization of genetic resources as well as subsequent applications and commercialization;
- Utilization of genetic resources held by ILCs; and
- Utilization of associated traditional knowledge held by ILCs.

In view of the history of negotiations and the definitions in Article 2, it is obvious that the term "subsequent applications and commercialization" was introduced to capture a wide range of activities that is consistent with the Protocol objective. Article 5, therefore, covers the benefits arising from the application of biotechnology and/or digital techniques to DNA and protein sequence data, as well as other molecular information.

There are two asymmetries. In the case of genetic resources and traditional knowledge associated with genetic resources of ILC, the Nagoya Protocol requires benefit-sharing but does not prescribe any international standards. This is an asymmetric treatment of the central obligation of CBD Article 15 when compared to the establishment of international access standards in the Protocol, benefit-sharing obligations are to be implemented by the Parties as well. The Protocol also does not state explicitly how Parties should handle their benefit-sharing obligations in cases where the providing Party has waived PIC.

The Nagoya Protocol requires that ILCs have established rights over their genetic resources in accordance with domestic legislation before a Party must consider them as benefit-sharing recipients. The Protocol does not, however, oblige its Parties to grant such rights when joining the treaty. Therefore, as is the case with Article 7 (discussed above), national implementation of UNDRIP Article 31 is indispensable to making Article 5 effective for ILCs.

A second asymmetry is that the benefit-sharing obligation in Article 15(1) of the Protocol includes the attractive monetary benefit phase of "subsequent applications and commercialization" of genetic resources belonging to the State but this is not explicitly stated in the benefit sharing obligation concerning genetic resources belonging to ILCs in Article 15(2).

In general, any new and/or continuing utilization and commercialization of genetic resources and/or associated traditional knowledge that was acquired between the entry into force of the CBD and that of the Protocol needs to come under benefit sharing rules and this should be included in national ABS systems.

When implementing Article 9, Parties will need to develop stronger obligations on users and providers to ensure that benefits are applied for the conservation and sustainable use of biodiversity. An effective approach to this issue will be necessary to prevent diversion of benefits from the purposes consistent with the objectives of the CBD, for example, to prevent ABS agreements between foreign users and national

research institutes that solely aim at enriching institutions. Such agreements have become common practice and are even promoted as best practices for ABS agreements.

Article 10 presents two problems and one, albeit vague, opportunity. Those Parties who intend to minimize or avoid benefit sharing obligations in their national implementation can use this Article as a basket to deposit elements of the Protocol that they reject. That is, Parties with an only vague interest in fighting biopiracy can use Article as a back door to enable them to escape their benefit-sharing obligations by pointing at unresolved problems that need to be addressed by the Global Multilateral Benefit-sharing Mechanism. The wording of this text that was not negotiated, but imposed as a "deal-breaker" to get the Protocol adopted, requires that Parties first consider the need for the mechanism and if they agree to this, to then consider the modalities. Therefore, countries of origin and provider countries should cooperate to generate political momentum for the mechanism to be established. At the same time, they should fill the gaps of the Nagoya Protocol to the maximum by national legislation, specifically with regard to the continuing and new use of genetic resources from *ex-situ* collections.

Article 11 appears to be a promising tool. Transboundary cooperation could be useful not only for complying with the Protocol but also for practical reasons. In cases where a genetic resource and/or the holders of the associated traditional knowledge are located in more than one Party's territory, providers can work together in concerted manner in their responses to potential users, thereby avoiding a race to the bottom.

Recommendations for the National Level

- National legislation needs to enable indigenous people and local communities to partake in benefit-sharing.
- National legislation should prevent utilization of genetic resources accessed in countries that are not countries of origin.
- The continuing utilization and commercialization of genetic resources and associated traditional knowledge acquired before the entry into force of the CBD until the entry into force of the Protocol should come under similar benefit-sharing rules.
- Benefit-sharing rules should be established for traditional knowledge that is no longer held by distinct groups of ILCs but spread in society or documented as recognized in the Nagoya Protocol[21].
- Benefit-sharing for utilization and commercialization of genetic resources acquired beyond the borders of national jurisdiction should be addressed.

[21] Nagoya Protocol preambular paragraph 25 states: "Further recognizing the unique circumstances where traditional knowledge associated with genetic resources is held in countries, which may be oral, documented or in other forms, reflecting a rich cultural heritage relevant for conservation and sustainable use of biological diversity." The operational Article 9(5) in the text of the draft Protocol as of October 27, 2010 noon was deleted in the "secret" negotiations of a select few making this the biggest missing piece of the Protocol.

- National legislation should ensure that benefit sharing is directed to support the conservation of biological diversity and the sustainable use of its components (CBD objectives).
- Appropriate means, e.g. taxes, should be established to ensure that a share of commercial profits arising from the utilization and commercialization of genetic resources and associated traditional knowledge are redirected to support the CBD objectives.

Recommendations for the International Level

- The MOP should decide on guidance on benefit-sharing standards.
- The MOP should decide on guidance for situations where benefits accrue from the utilization and commercialization of genetic resources provided by Parties that have waived PIC.
- Regional cooperation should be undertaken to prevent and resolve potential conflict, including a race to the bottom, in transboundary ABS cases.
- The MOP should negotiate and agree on a Global Multilateral Benefit-sharing Mechanism in a timely manner to address those cases that cannot be resolved otherwise.

4.5 Associated Traditional Knowledge

Omission of reference to the rights of ILCs in the Protocol's objectives is a major shortcoming, and inconsistent with both the COP-7 mandate and the content and spirit of the Protocol's operational articles. National ABS systems need to recognize the customary rights of ILCs over their genetic resources and associated traditional knowledge. Without such recognition, the rights of ILCs related to ABS will not be realized at the national level.

Nevertheless, it is a step forward that the Nagoya Protocol holds ILCs' customary laws, community protocols, and procedures as an appropriate legal basis for the development of ABS arrangements. Parties to the Protocol should, through their legislation and implementation of Article 12(2) and 12(3), secure recognition and enforcement of customary laws and instruments relevant to ABS.

The customary rights of ILCs do not cease to exist when genetic resources and associated traditional knowledge are made available publicly. Thus, in their national ABS legislation, it is highly recommended that Parties address ABS for publicly available traditional knowledge associated with genetic resources that can be attributed to specific ILCs. Processes for the full and effective participation of ILCs to develop the rules and mechanisms should be established.

Recommendations for the National Level

- National legislation needs to enable ILCs to exercise their rights over genetic resources and associated traditional knowledge in the context of ABS and that recognizes customary rights and practices
- Establishment of ABS rules for traditional knowledge that is no longer held by distinct groups of ILC but spread in society should be addressed by Parties with the effective participation of ILCs.
- Comprehensive information system to document and monitor potential users of associated traditional knowledge needs to be developed.

Recommendations for the International Level

- In the WIPO IGC, the alignment of its work to ensure that it is supportive of and contributes to the implementation of the Nagoya Protocol.
- The MOP should decide on a clarification on the scope of CBD Article 8(j).
- The MOP should decide on ABS rules for traditional knowledge that has been made public, with such a decision predicated on the respect of customary laws, community protocols and procedures.

4.6 Compliance

The compliance provisions of the Protocol make reference to three distinct levels:

- Compliance of Parties with the Nagoya Protocol (Article 30);
- Compliance of users and providers with national ABS legislation (Articles 15, 16, 17); and
- Compliance of users and providers with MAT in private ABS contracts (Article 18).

On Article 30, the ABS compliance committee that will be established should learn from the experience of the Biosafety Compliance Committee under the Cartagena Protocol on Biosafety, also a treaty under the CBD. It is suggested that an ABS Compliance Committee should be specifically mandated to:

- Consider submissions by Parties, ILCs and stakeholders residing within the jurisdiction of Parties; and
- Address issues under Articles 24 (Non-Parties) and 29 (Monitoring and Reporting) on a regular basis.

Although Articles 15 and 16 contain a strong obligation to set up user measures, they do not give guidance on which tools should be developed and used nationally. Likewise, they oblige Parties to cooperate in alleged violations of ABS legislation but leave open how this is to be done.

To overcome the lack of clear and obligatory international provisions, national ABS legislation should establish a comprehensive monitoring system with checkpoints at all levels of the value chain.

Special regard should be paid to the implementation of Article 18(3) on access to justice and mutual recognition and enforcement of foreign judgments and arbitral awards related to compliance with MAT. National ABS legislation or other measures should establish the procedures for access to justice and enforcement of foreign judgments, especially for foreign plaintiffs in cases of biopiracy.

Recommendations for the National Level

- National legislation needs to contain provisions that enable ILCs to exercise their rights over genetic resources and associated traditional knowledge in the context of ABS.
- ABS regulation and procedures that affect ILCs should be discussed and approved by them.
- ABS rules and procedures should be able to stop the utilization and commercialization of genetic resources and associated traditional knowledge accessed without PIC or MAT, as well as continuing utilization and commercialization in the absence of a benefit sharing agreement.
- The checkpoint system needs to go beyond one checkpoint (the minimum required under Article 17) in order to cover the entire value chain and be able to detect changes in utilization that would bring the utilized genetic resources or associated traditional knowledge under the rules of an ABS system.
- Existing and possible checkpoints such as intellectual property offices, drug and other product registration offices, customs controls, sanitary and phytosanitary offices, the CITES system (Convention on International Trade in Endangered Species of Wild Flora and Fauna), public research approval systems and others should be used in ABS monitoring and tracking.
- A checkpoint system to monitor privately funded research and development should be considered.
- Tracking systems should be developed that follow the value chain of genetic resources and associated traditional knowledge used both domestically and abroad.
- Disclosure requirements (origin of GR and ATK, PIC and MAT) for intellectual property applications to be mandated in national legislation in support of the ABS legislation.

Recommendations for the International Level

- A MOP decision on confidential information under Article 17(4) that favours disclosure and transparency in relation to internationally recognized certificates, by clearly stating the information that cannot be claimed as confidential[22].
- The obligations of Parties to the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters need to be checked against the far-reaching confidentiality clause of the Nagoya Protocol Article 17(4).
- Parties should work internationally (WIPO, WTO) to create requirements for the disclosure of origin of genetic resources and associated traditional knowledge in intellectual property applications, and ensure mutual supportiveness of these treaties with the Nagoya Protocol.
- A MOP decision should give guidance on addressing cases of alleged misappropriation by non-Parties or users under their jurisdiction.
- The Compliance Committee of the Nagoya Protocol should accept suggestions and complaints from non-governmental institutions.
- The Compliance Protocol of the Nagoya Protocol should be able to address cases where genetic resources and associated traditional knowledge from a Party is utilized and commercialized in non-Parties.
- A MOP decision should identify the most favorable ways for developing countries and ILCs for dispute settlement procedures, and alternatives to expensive private arbitration.
- The Compliance Committee needs to address issues related to non-Parties (Article 24) and monitoring and reporting (Article 29) on a regular basis.

4.7 Sectoral Approaches and Guidelines under the National Law

From numerous cases that are being documented[22] there is a cautionary tale as countries move to implement the Nagoya Protocol in which Article 8 (a) calls on Parties to adopt "simplified measures" for access to genetic resources when the access is for "non-commercial research purposes".

A considerable part of "academic" or "educational" work on its face suggests a "non-commercial" purpose. However, in reality, as documented cases reveal, academic bioprospectors are usually linked to commercial aims – either through established relationships with companies or, increasingly, a personal and institutional intent to patent and profit.

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[22] The minimum information list that could be claimed as confidential under Article 17(4) is as follows: Issuing authority; date of issuance; the provider; unique identifier of the certificate; the person or entity to whom prior informed consent was granted; subject-matter or genetic resources covered by the certificate; confirmation that mutually agreed terms were established; confirmation that prior informed consent was obtained; and commercial and/or non-commercial use.

It would thus be quite short sighted for countries implementing the Nagoya Protocol to make any presumption in law or policy that academic-affiliated bioprospectors have a "non-commercial" purpose. Indeed, the opposite should be the case. Academic bioprospectors should be presumed to have a commercial intent, unless they expressly disavow intellectual property claims and can convincingly demonstrate that the knowledge and materials they collect will not be patented by themselves, their institution, or any onward recipient. Failing such guarantees, academic bioprospectors must be treated as commercial entities.

Recommendations on Non-Commercial Research

If a Party decides to establish simplified access conditions for non-commercial research under Article 8(a), two critical issues need to be clarified:

- Criteria for non-commercial research purpose;
- The monitoring and tracking system to survey utilization and detect changes of the intended use.

In the ABS negotiations, criteria for non-commercial research were developed in 2008 by the international workshop on Access and Benefit-sharing in Non-Commercial Biodiversity Research convened by the CBD Secretariat. The participants decided that non-commercial research is characterized by six elements:

1. Results of research must be made public so that other members of the research community can:
   – test and confirm the results
   – use the results as a basis for future research
2. Willingness of the user to accept the terms of standardized documents that
   – require the open dissemination of research results
   – prohibit patenting or other retention of intellectual property rights over the research results that are not acceptable to the provider country
3. Requirements for the involvement of a recognized research institution in the user country (or countries), as well as cognizant researchers, in the ABS agreement;
4. Requirements for the involvement of research institutions and/or researchers in the provider country, with the understanding that these institutions and researches will represent the provider country's interests in identifying and protecting the potential commercial opportunities that may result from the research project;
5. Assurances that any manuscripts that result from the research and submitted for publication will also be provided to the provider country in advance of publication. Pre-publication access to these manuscripts will allow the provider country with the opportunity to file patent applications to protect any intellectual property prior to its release in the public domain; and

6. Restrictions on the supply of samples of the genetic resources to third parties. Standard clauses in ABS documents will need to accommodate international codes of taxonomic nomenclature which do not allow for restriction of access by third parties.

Furthermore, effective checkpoints with relevance to the funding of research and the publishing of its results should be established. The information gained through these checkpoints needs to be checked against the information of checkpoints working at higher levels of the value chain.

Recommendations on Emergency Situations and Pathogens

The WHO Pandemic Influenza Preparedness (PIP) Framework adopted in May 2011, after the conclusion of the Nagoya Protocol negotiations, has the objective of "a fair, transparent, equitable, efficient, effective system for, on an equal footing:

(i) The sharing of H5N1 and other influenza viruses with human pandemic potential; and
(ii) Access to vaccines and sharing of other benefits."

The Framework does not apply to seasonal influenza viruses or other non-influenza pathogens or biological substances that may be contained in clinical specimens shared under the Framework.[23] At the same time, the weaknesses and gaps of the Framework are already evident in its implementation so far. These include: (i) lack of transparency of the negotiations between the WHO and the users; (ii) inadequate benefit-sharing considering the scale of need in situations of an influenza pandemic, raising the question of whether the sharing is "fair and equitable"; (iii) largely voluntary benefit sharing by the vaccine/diagnostic/pharmaceutical manufacturers; (iv) benefits accruing to research entities and from licensing of intellectual property are not captured for sharing; and (v) lack of a monitoring and tracking mechanism of intellectual property claims over accessed genetic materials without benefit sharing.

Parties to the CBD and Nagoya Protocol also need to pay attention to the lack of consensus during the WHO PIP Framework negotiations to include a reference in the document on the relationship between the Framework and the CBD.

It is clear therefore that the CBD and Nagoya Protocol remain the international ABS legal instruments for pathogens.

[23] http://whqlibdoc.who.int/publications/2011/9789241503082_eng.pdf

We recommend the following:

At the national level

- National ABS legislative, administrative or policy measures must include microorganisms, including pathogens.
- Article 8(b) states that Parties to the Protocol "may take into consideration the need for expeditious access" in cases of health emergency situations when developing or implementing ABS legislation or regulatory requirements and if it is decided to do so, Parties should always still require PIC and MAT. If expeditious access is provided, there must be provision for expeditious fair and equitable sharing of benefits arising out of the use of genetic resources, including access to affordable treatments in cases of emergencies, in accordance with Article 8(b).
- Parties to the Protocol in developing their national legislative or administrative or policy measures do not have an obligation to take into account any ongoing work or practice in the WHO or other fora relating to pathogens. They need only to "pay due regard", i.e. consider taking into account any such work or practices, and even then, only if these are supportive of and do not run counter to the objectives of the CBD and Protocol according to Article 4(3).

At the international level

- The CBD COP and Protocol MOP should ensure that the ABS provisions of the CBD and Nagoya Protocol continue to apply to pathogens.
- The CBD COP, pending the entry into force of the Nagoya Protocol, should request for regular submission of information from the WHO Secretariat on the implementation of the PIP Framework, for example, the annual report from the Advisory Group to the WHO Director-General on its evaluation of the implementation of the Framework.
- The MOP should consider on a regular basis the implementation of the Framework to ensure that it is supportive of, and do not run counter to, the objectives of the CBD and Nagoya Protocol.
- Parties to the CBD and Protocol should cooperate to develop common positions that safeguard the objective of the Protocol in other international fora, such as the WHO. They can ensure that any material transfer agreement or obligation must include fair and equitable benefit-sharing from the utilization of the microorganisms, access to and the transfer of relevant technologies to develop vaccines and other medical products. Developing countries, in particular, can cooperate to ensure access to affordable treatments.
- Parties to the CBD and Protocol should cooperate to participate effectively in the review of the PIP Framework that is scheduled to take place by 2016 and that will propose revisions to the Framework reflecting developments in this area.

Recommendations on Genetic Resources for Food and Agriculture

The negotiators of the Nagoya Protocol agreed that there is one specialized ABS agreement outside of the Protocol, the International Treaty for Plant Genetic Resources for Food and Agriculture (ITPGRFA). The list of species in ITPGRFA Annex 1 defines which plant genetic resources are under that treaty's scope, when those resources are accessed for food and agriculture purposes.

ABS competency for all other genetic resources lies with the CBD and its Nagoya Protocol, including for species in ITPGRFA Annex 1 when they are accessed and utilized for purposes other than food and agriculture.

Access to genetic resources that are governed by the ITPGRFA is regulated by an SMTA building up a benefit-sharing mechanism that so far has not yielded the expected benefits. It seems to be evident that any new specialized systems should examine the experience of the ITPGRFA. Similar activities have been initiated by the FAO for animal genetic resources, among others and caution is needed. National approaches can learn from, and inform, international systems that are being implemented or are to be negotiated to ensure effective benefit sharing.

Recommendations on Model Contractual Clauses or Guidelines

Parties should set up comprehensive legally binding ABS system covering all ABS-related activities. While model contractual clauses or guidelines might be useful in specific cases it needs to be ensured that this additional measure is used to implement the national ABS system in a coherent and supportive manner.

4.8 ABS-related Institutions

Recommendations on National Focal Point and Competent Authority

Article 13 of the Nagoya Protocol creates National Focal Points and Competent Authorities. While under Article 13 the Competent Authority only plays a role in access, it is recommended that this institution also cover issues of benefit sharing. The creation of a competent authority with meaningful functions in the execution and review of PIC and MAT negotiations is highly recommended to avoid a situation where unequal parties negotiate the terms of access and MAT. It is also essential that the Competent Authority and the checkpoints established under the Nagoya Protocol be linked in a clear relationship in national ABS legislation, thus giving the Competent Authority a coordinating role in the compliance system.

In addition, the concept of the "competent authorities of indigenous and local communities" discussed by the 2009 Hyderabad Expert Group, should be taken up in instruments and procedures to guarantee the rights and interests of ILCs in PIC and MAT negotiations on their genetic resources and associated traditional knowledge. Parties should discuss also the possibility to introduce a national ombudsperson for ILC. All regulative provisions and administrative processes concerning ILC issues need to be developed with and approved by them.

Recommendations on the ABS Clearing House

The role of the ABS clearing house would have been of crucial importance for compliance if an obligatory international ABS certificate for a specific genetic resource and/or associated traditional knowledge had been required under the Nagoya Protocol. Under Article 14, however, the ABS clearing house does not inform decision making in a manner as effective as that of the Biosafety clearing house of the CBD's Cartagena Protocol on Biosafety, for example, in the case of importations of genetically modified organisms for food and feed purposes.

As is the case with the CBD clearing house, the functions of the ABS clearing house are very limited. Information on the permits provided to the ABS clearing house could be almost zero if the provisions of Article 17 on "confidential information" are overbroadly interpreted and applied. The Nagoya Protocol does not set international minimum standards for what details in access permits must be public. The potential lack of detail in certificates may drastically reduce the value of the ABS clearing house as an instrument for compliance or monitoring, preventing it from playing the role of a checkpoint.

Therefore, we recommend that when the pilot phase of the ABS clearing house is reviewed, this shortcoming should be overcome. Meanwhile, national legislation can explicitly state which information cannot be claimed as confidential and require that certain information including those in the list in Article 17(4) be publicly available.

When Parties implement the ABS Protocol it will be critical to create national and regional mechanisms to ensure publication of essential information on ABS cases in order to enable monitoring of genetic resources and compliance with ABS agreements. When creating such mechanisms, the posting of a summary of PIC and MAT in analogy to a similar specific minimal standard of the Biosafety clearing house should be made obligatory. If such information is provided and made public, it would significantly enhance the transparency and effectiveness of the monitoring of compliance. In contrast, secrecy would benefit the bio-pirates.

At the ICNP and the MOP, appropriate decisions on the role of the ABS clearing house and the elements of the national permit and the internationally recognized certificate of compliance are needed.

4.9 Capacity Building and Technology Transfer

The CBD built upon a decade of scientific and political discussion about how to link nature conservation and development issues. During the 1980s when biodiversity came into focus, many experts propagated the idea that a country's biodiversity and associated traditional knowledge of ILCs is an abundant and cheap resource that could be used to foster the creation of domestic industries. This would, the argument went, make developing countries more independent by, for example, reducing the need for imports of expensive drugs from the North.

Others argued that market-based mechanisms would facilitate the exchange of genetic resources from developing countries for technologies from developed countries.

This model was predominantly used during the negotiations of the CBD because it seemed to offer a relatively quick and easy path to development and industrialization, especially in the context of the popularity of market-based policy approaches in the late 1980s and early 1990s.

It is noteworthy to mention that Article 22 on capacity building takes up this early debate linking biodiversity to development. Article 23 on technology transfer also suggests that research and development based on genetic resources should preferably be undertaken in the country of origin or providing Party. Therefore, at the national level and MOP, the forms of capacity building and technology transfer that can best foster endogenous development should be discussed and, in particular, how MAT could be used effectively to enable such measures. In this respect the model for rewarding innovation should be clear – this could be based on intellectual property claims in which case the ABS agreement should provide for automatic free access or title to the outcomes for the provider; or on a non-proprietary basis where the parties involved have a fair and equitable share of the results of the research and development.

CHAPTER 5

CONCLUSION

WHEN the Nagoya Protocol was adopted, a lengthy negotiation process came to an end. But this end was, in its most crucial aspects, shaped by the unusual (and unfortunate) process of the closed-door negotiation of the final text. CBD parties had the choice between taking or leaving a draft text final choices of far-reaching consequences made mainly by EU officials. Parties accepted this text, with many reasoning it was the best that could be achieved, and leaving behind many items for which they fought hard during the negotiations. Others felt cheated as the process until then had been welcomed as an admirable example of multilateralism and participation of governments and civil society participants. The formalized participation of representatives of indigenous peoples and local communities in treaty-making that directly affected them was also unprecedented.

It is unsurprising that the "compromise" tailored by the EU reflects its own perspective more than that of developing countries that more often are providers of genetic resources. A central problem for provider countries is that the CBD provides insufficient means to track utilization of genetic resources and to initiate proceedings in user countries to stop and prevent misappropriation. This gap could not be closed by national legislation, and the CBD was too weak to overcome the resistance of user countries to vigorously and in good faith implement its ABS provisions. This created the need for an instrument to prevent biopiracy, leading to the negotiation of the Protocol. From a provider country perspective, the core of the new instrument should have been strong and effective user measures that would deter biopirates and, in cases of non-compliance, create concrete sanctions and provide redress. The Protocol should also have unambiguous provisions to create mechanisms that ensure fair and equitable benefit sharing that in turn would energise the other two CBD objectives of conservation and sustainable use.

But the Nagoya Protocol is altogether too vague or weak on key points, especially user measures. The initial idea was, in a nutshell, to have a an internationally recognized certificate confirming compliance with PIC and MAT that would be obligatory for patent applicants or market approvals, as a minimum. The outcome is much weaker. The main gaps are inadequate requirements for certificates of compliance and the lack of an obligation to include patent offices as checkpoints. As a result, the certificate is no longer an instrument to control use, although it can serve users as a tool for proving compliance with the national ABS law of the provider country. That gap remains to be filled.

Moreover, the Nagoya Protocol creates no explicit obligation for its Parties to sanction or penalize biopirates. Even in cases where an intellectual property claimant has failed to obtain PIC and MAT, the Nagoya Protocol has no provision obliging Parties to reject the application or revoke the claim. And, further protecting a user's interests, even where the Nagoya Protocol requires provision of information, authorities are not obliged to make this information public and there is no clarity on how confidentiality claims will be assessed. A user's claim for confidentiality could be sufficient to convince the authorities to avoid transparency – a crucial element for fighting biopiracy. From the providers' perspective, the Nagoya Protocol is unsatisfactory when compared against the initial idea to create strong and effective user measures.

The same is true is with the lack of justice that providers have suffered since the coming into force of the CBD. On one hand, according to Article 4(4), the Nagoya Protocol is the instrument for the implementation of the access and benefit sharing provisions of the CBD. But on the other, there is still insufficient obligation requiring concrete action, when it is user countries' failure to implement CBD provisions that led to the Nagoya Protocol in the first place. Yet the new agreement fails to create a clear path out of this dilemma. For example, on continuing and new uses of genetic resources and associated traditional knowledge accessed without ABS agreements, providers are essentially still left with the CBD. The user, in many cases a biopirate, may be allowed to continue to enjoy his unlawful but privileged situation.

The Nagoya Protocol clearly privileges users and user countries – and at the same time disadvantages provider and provider countries, which now have additional obligations related to the granting of access having surrendered part of their sovereign autonomy that is in the CBD. This is also true with respect to ILCs and their traditional knowledge. While there has been progress in a more explicit treatment of the rights and interests of indigenous peoples and local communities, this has not translated to concrete implementation when it comes to the Protocol's treatment of compliance with those rights. In this regard, some developed and developing countries had shared concerns that rights for ILCs independent of national law could be harmful to national sovereignty and integrity, and this is reflected in the inadequate protection of those rights when biopiracy moves in.

Thus, exercising the rights of ILCs in access and benefit sharing is still dependent on national legislation. ILCs only practically enjoy their rights as providers of genetic resources and associated traditional knowledge to the extent that those rights are acknowledged by the national legislation of the country where they reside. This leaves an unsettled and potentially unsettling situation on if and how traditional knowledge should be subject to PIC and MAT.

In that regard, solutions are available in the UN Declaration on the Rights of Indigenous Peoples that almost all UN Member States have endorsed. The Nagoya Protocol process provided a valuable opportunity for Parties, ILCs and civil society organizations to grapple with how to implement the Declaration in the context of ABS. We hope that from this experience, Parties can explore ways to implement UNDRIP in national legislation, thereby protecting the rights of indigenous peoples in matters related to the Nagoya Protocol. This would improve the basis for developing benefit-

sharing solutions, for example, in cases of continuous and new utilization of associated traditional knowledge. As the rights of indigenous peoples are human rights, they are not bound by temporal limitations and there are important principles to draw from this for implementing the Protocol and other ABS systems.

The impact of the Nagoya Protocol on the fight against biopiracy to a large extent depends on thorough implementation of well-designed user measures in user countries. In this context, many of the Protocol's obligations prescribe minimum standards to achieve the ultimate objective: fair and equitable sharing of the benefits arising from the utilization of genetic resources and associated traditional knowledge. Achievement of the objective remains subject to the political will and good faith of user countries.

National implementation in provider countries also plays a crucial role, especially with respect to the provisions related to compliance (Articles 15 and 16). The standard of compliance will be shaped in large part by the national legislation of the provider country. Consequently, in the absence of national legislation non-compliance (biopiracy) cannot be effectively addressed. Therefore, strong national legislation for a start (as described in Chapter 4) is crucial for provider countries if they aim to stop biopiracy and secure fair and equitable benefits.

Because the Nagoya Protocol only provides minimum standards, national legislation in provider countries is free to take stronger and additional steps. Nothing in the Nagoya Protocol prevents a Party from addressing issues such as publicly available traditional knowledge that is not held by ILCs, continuing use of genetic resources, transboundary cooperation, clearly defining derivatives, ensuring transparency and rejecting secrecy in the name of confidentiality, and so on. In national legislation, provider countries are encouraged to implement strong national standards while they engage in developing a Global Multilateral Benefit-sharing Mechanism. This mechanism may not become a reality and, if it does, may not be friendly to provider countries. To turn the Mechanism described in Article 10 of the Nagoya Protocol from an empty promise to a fair and just benefit-sharing tool will take time and resolve.

Thus the Nagoya Protocol represents more of a milestone than a finish line in the fight against biopiracy. Much work remains, in both national implementation and the further development of international law. The litmus test of the processes ahead will be the same as it was in the negotiations of the Nagoya Protocol: The question will always be what contributes to stopping biopiracy and promotes equity and justice, versus what does not.

Annex I: Status of the last negotiated version of the draft Nagoya Protocol at the Ad Hoc Open Ended Working Group on Access and Benefit-Sharing (Noon of October 27, 2010)	
Without brackets	**With brackets**
Preamble	
Paragraph 1.-16. **Paragrah 22.** **Paragraph 24.-30.**	**Paragraph 17.** (Access to pathogens) **Paragraph 18.** (Effect on IPR) **Paragraph 19.** (Work on other related forums) **Paragraph 20.** (ITPGRFA) **Paragraph 22.** (Other rights/obligations of Parties) **Paragraph 23.** (Relation to other treaties)
Article 1 Objective	
Article 2 Use of Terms	
(a) **(b)**	**(c)** "utilization of genetic resources", "derivatives", and "biotechnology"
	Article 3 Scope
	Paragraph 1. with bracketed words referring to temporal scope and definitions **Paragraph 2.** in brackets relating to geographic, political scope **Paragraph 3.** in brackets relating to temporal, political scope **Paragraph 4.** in brackets relating to Paragraph 3. **Paragraph 5.** in brackets relating temporal scope
Article3 bis Relationship	
Article 4 Fair and equitable benefit-sharing	
Paragraph 1. bis **Paragraph 2.** **Paragraph 3.**	**Paragraph 1.** with brackets relating to temporal scope **Paragraph 4.** with brackets relating to use of terms

Article 5 Access to Genetic Resources	
Paragraph 2. except (a) bis and (g) **Paragraph 3.**	**Paragraph 1.** with brackets relating to the characteristics of the providing country **Paragraph 1.bis** in brackets on PIC of ILC **Paragraph 1.ter** in brackets on environmentally sound use **Paragraph 2. (a) bis** in brackets on non-arbitrary/equal treatment **Paragraph 2. (g)** in brackets on access to justice
Article 5bis Access to traditional knowledge associated with genetic resources	
Article 6. [Considerations relevant to [non-commercial] research and emergency situation] [Special considerations]	
Paragraph (a)	**Paragraph (b) - (d)** in and with bracket on content as such
Article 7 Contribution to conservation and sustainable use	
Article 8 Transboundary cooperation	
Article 9 Traditional knowledge associated with genetic resources	
Paragraph 1.	**Paragraph 2.** with brackets relating to use of terms **Paragraph 3.** with brackets relating to use of terms **Paragraph 4.** with brackets relating to use of terms **Paragraph 5.** with bracket relating to benefit-sharing when using publicly available associated traditional knowledge and content as such
Article 10 National focal points and competent national authorities	
Article 11 The access and benefit-sharing clearing-house and information-sharing	
Paragraph 1. **Paragraph 2. (a) and (b)** **Paragraph 3.** **Paragraph 4.**	**Paragraph 2. (c)** in brackets on decisions related to PIC
Article 12 Compliance with domestic legislation or regulatory requirements on access and benefit-sharing	
Paragraph 2. **Paragraph 3.**	**Paragraph 1.** with brackets on use of terms and the specifications of the providing party

Article 12 bis Compliance with domestic legislation or regulatory requirements on access and benefit-sharing for traditional knowledge associated with genetic resources [and derivatives]	
Paragraph 2. **Paragraph 3.**	**Paragraph 1.** with brackets relating to use of terms
Article 13 Monitoring, [tracking] and reporting the [utilization] of genetic resources [and associated traditional knowledge]	
	Paragraph 1. with brackets relating to use of terms, legal nature and content as such **Paragraph 2.** with brackets relating to Article 5 and 11 **Paragraph 3.** with brackets relating to use of terms, specification of providing country and legal nature **Paragraph 4.** in brackets on content as such **Paragraph 5.** in brackets on content as such
Article 13 bis Non-compliance with mandatory disclosure requirement	
	In brackets on content as such
Article 14 Compliance with mutually agreed terms	
Paragraph 1. **Paragraph 2.** **Paragraph 3.(b)** **Paragraph 4.**	**Paragraph 3. (a)** with brackets relating to access to justice
Article 14 bis International access and benefit-sharing ombudsperson	
	In brackets on content as such
Article 15 Model contractual clauses	
Article 16 Codes of conduct, guidelines and best practices and/or standards	
Article 17 Awareness-raising	
(a) - (i)	**Chapeau** with brackets relating to use of terms
Article 18 Capacity	
Article 18 bis Technology transfer and cooperation	
	With brackets relating to specification of providing country and legal nature

Article 18 ter Non-parties	
Article 19 Financial mechanism and resources	
Paragraph 1. **Paragraph 2.** **Paragraph 5.** **Paragraph 6.**	**Paragraph 3.** with brackets relating to new and additional financial resources **Paragraph 4.** with brackets relating to new and additional financial resources
Article 20 Conference of the parties	
Article 21 Subsidiary bodies	
Article 22 Secretariat	
Article 23 Monitoring and reporting	
Article 24 Procedures and mechanisms to promote compliance with the protocol	
Article 25 Assessment and review	
Article 26 Signature	
Article 27 Entry into force	
Article 28 Reservations	
Article 29 Withdrawal	
Article 30 Authentic texts	

Annex II: Synopsis of Article numbers in the adopted text (October 29, 2010) and the final official edition		
Article	**Numbering as adopted by COP-10 (Referred to in Chapter 3 as "draft")**	**numbering in final edition**
Preamble		
Objective	Article 1	Article 1
Use of Terms	Article 2	Article 2
Scope	Article 3	Article 3
Relationship with international agreements and instruments	Article3bis	Article 4
Fair and equitable benefit-sharing	Article 4	Article 5
Access to Genetic Resources	Article 5	Article 6
Access to traditional knowledge associated with genetic resources	Article 5bis	Article 7
Special considerations	Article 6	Article 8
Contribution to conservation and sustainable use	Article 7	Article 9
Global multilateral benefit-sharing mechanism	Article 7bis	Article 10
Transboundary cooperation	Article 8	Article 11
Traditional knowledge associated with genetic resources	Article 9	Article 12
National focal points and competent genetic resources	Article 10	Article 13
The access and benefit-sharing clearing-house and information-sharing	Article 11	Article 14
Compliance with domestic legislation or regulatory requirements on access and benefit-sharing	Article 12	Article 15
Compliance with domestic legislation or regulatory requirements on access and benefit-sharing for traditional knowledge associated with genetic resources	Article 12bis	Article 16

Monitoring the utilization of genetic resources	Article 13	Article 17
Compliance with mutually agreed terms	Article 14	Article 18
Model contractual clauses	Article 15	Article 19
Codes of conduct, guidelines and best practices and/or standards	Article 16	Article 20
Awareness-raising	Article 17	Article 21
Capacity	Article 18	Article 22
Technology transfer, collaboration and cooperation	Article 18bis	Article 23
Non-parties	Article 18ter	Article 24
Financial mechanism and resources	Article 19	Article 25
Conference of the Parties shall serve as the meeting of the Parties to this Protocol	Article 20	Article 26
Subsidiary bodies	Article 21	Article 27
Secretariat	Article 22	Article 28
Monitoring and reporting	Article 23	Article 29
Procedures and mechanisms to promote compliance with this Protocol	Article 24	Article 30
Assessment and review	Article 25	Article 31
Signature	Article 26	Article 32
Entry into force	Article 27	Article 33
Reservations	Article 28	Article 34
Withdrawal	Article 29	Article 35
Authentic texts	Article 30	Article 36

ANNEX 1II

THE WORK OF THE AD HOC OPEN-ENDED INTERGOVERNMENTAL COMMITTEE FOR THE NAGOYA PROTOCOL ON ACCESS AND BENEFIT-SHARING (ICNP)

THIS Committee was established at the COP 10 in Nagoya, Japan and is tasked with undertaking the preparations necessary for the first meeting of the Conference of the Parties to the Convention on Biological Diversity serving as the Meeting of the Parties to the Protocol (COP-MOP). At the time of writing, the ICNP has met twice (6-10 June and 2-6 July in New Delhi) and will meet again on 3-7 February 2014. The Co-chairs are Mr. Fernando Casas (Colombia) and Ms. Janet Lowe (Canada).

The June ICNP-1 meeting considered the following issues:

(i) Access and Benefit-sharing Clearing-House;

(ii) Capacity building, capacity development and strengthening of human resources and institutional capacities in developing countries and countries with economies in transition;

(iii) Awareness raising of the importance of genetic resources and associated traditional knowledge and related access and benefit-sharing issues; and

(iv) Cooperative procedures and institutional mechanisms to promote compliance with the Protocol and to address cases of non-compliance.

The Delhi ICNP-2 meeting considered the following issues:

(i) The development of a programme budget for the biennium following the entry into force of the Protocol;

(ii) The elaboration of guidance for the financial mechanism and resources mobilization for the implementation of the Protocol;

(iii) Consideration of the rules of procedures for the COP-MOP;

(iv) Elaboration of the draft provisional agenda for the first meeting of the Parties (of the Protocol);

(v) The need for and modalities for a global multilateral benefit sharing mechanism; and

(vi) Continued consideration of items taken up at the first meeting of the ICNP in June 2011.

The fight against biopiracy and its injustices was the main impetus for the push to have an international treaty to be developed under the Convention on Biological Diversity (CBD). The Convention's third objective of fair and equitable sharing of the benefits from the utilization of genetic resources is itself the result of tough negotiations in the early 1990s when the misappropriation, even theft, of the resources of developing countries and of indigenous peoples and local communities gained international attention. After almost 20 years, when the Convention's broad provisions proved to be inadequate, the Nagoya Protocol on Access and Benefit-sharing was forged in October 2010. This new legally binding international treaty, however, was born in an atmosphere of controversy when its core content was ultimately decided by a few during the final days of the 10th meeting of the CBD's Conference of Parties in Nagoya, Japan. This book, co-authored by six civil society participants who were actively engaged with the government negotiators and negotiation process, provides a rich account of the background and development of the Protocol. It analyses the main provisions of the Protocol and recommends several actions that can be taken at the national and international levels to ensure that the Protocol objective of fair and equitable benefit-sharing can be delivered with justice restored.

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