Chapter 7
Promoting an Inclusive Approach to Benefit Sharing: Expanding the Scope of the CBD?

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Abstract The Convention on Biological Diversity (CBD) is a major international agreement to ensure the conservation of biological diversity, the sustainable use of various components of biological diversity, and fair and equitable access and benefit sharing of advances arising from the use of related genetic resources. The CBD excludes human genetic resources. In light of the rapid advances in biotechnology, genetic resources are increasingly being utilised by different types of users and in different industries. This usage is not confined to plants, animals or micro-organisms but includes human genetic resources and sometimes a mix of such resources. In the absence of any international agreement, various national governments are framing their own rules and guidelines. This patchwork of regulation may eventually impede global research efforts. This chapter argues that the CBD is qualified to be the central agency at the global level for the advance of broader benefit sharing frameworks. By implication, the scope of the CBD should be expanded to include human genetic resources.

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D. Schroeder and J. C. Lucas (eds.), *Benefit Sharing*,
DOI: 10.1007/978-94-007-6205-3_7,

Keywords Access and benefit sharing • Convention on Biological Diversity • Biomedical technology • Developing countries • Human genetic resources • World Health Organization

7.1 Introduction

Even by the most conservative estimates, the global debate on access and benefit sharing (ABS) for biodiversity has been going on for 20 years. Despite the high global stakes of this debate and the adoption of the Nagoya Protocol to the Convention on Biological Diversity (CBD) in 2010, there is no clear pathway for its resolution in sight. ABS is one of the major stumbling blocks in the stalled negotiations on trade-related aspects of intellectual property rights (TRIPs) at the World Trade Organization (WTO), and its current fluid state internationally is the source of different, and at times contradictory, approaches at national levels. In the medium to long term this may adversely affect research and technology transfer prospects. The absence of clear international guidelines further complicates global research initiatives as national governments evolve their own ABS frameworks.[1] This situation is frustrating for negotiators, disheartening for non-governmental organizations (NGOs) and other civil society organizations, and disappointing for many others involved in the process.

The CBD's Ad Hoc Open-Ended Working Group on Access and Benefit Sharing concluded its work with the adoption of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization at the tenth meeting of the Conference of the Parties to the CBD (COP 10) in Nagoya, Japan, in October 2010.[2] The deliberations of the CBD have thus far, however, overlooked technological trends in the realms of synthetic biology and pharmacogenomics, and these may undermine the relevance of the definitions currently being employed by negotiators for 'biological resources'. One of the factors that may be responsible for this approach is the continued compartmentalization of the CBD and the World Health Organization (WHO), which are independently discussing ABS issues with little input from each other. One can observe some movement towards more collaboration, but it is not enough.

[1] Glowka (2008) calculates that more than 60 countries have established their own ABS regimes.

[2] After nearly 20 years of negotiations, 193 governments adopted the 'historic' Nagoya Protocol as a supplementary agreement to the CBD. It provides a transparent legal framework for the effective implementation of one of the three objectives of the CBD: the fair and equitable sharing of benefits arising out of the utilization of genetic resources. The instrument outlines legally binding international rules for sharing benefits from resources (including traditional knowledge) used in food, pharmaceuticals, cosmetics and other products. The protocol was open for signature at the United Nations Headquarters in New York from 2 February 2011 until 1 February 2012 and will enter into force on the 90th day after the date of deposit of the 50th instrument of ratification, acceptance, approval or accession (CBD 2010, see also Chap. 3).

The Nagoya text does refer to human pathogens and provides a way for some human genetic resources eventually to be included in the CBD. The protocol has added the following text in Annex 1:

> Mindful of the International Health Regulations (2005) of the World Health Organization and the importance of ensuring access to human pathogens for public health preparedness and response purposes… (CBD 2010).

The key question appears to be how biological (genetic) resources are defined. Is it possible to continue the customary approach of separating ABS regimes for plants and traditional plant-based community knowledge from leads based on human genetics research? It is currently unclear how benefits would be distributed in cases where products are derived from a combination of human genetics research and community-based knowledge of plants, despite the increasing frequency of such combinations.

The decision by the second meeting of the Conference of the Parties to the CBD in 1995 (CBD 1995a) not to include human genetic resources under the purview of ABS appears to have been made with the understanding that, unlike plant-based resources, human genetic resources would always remain removed from the sphere of commercial gain (Nijar 2009). Subsequent trends in the patent regime, however, increasingly reveal a pattern of commercial gain becoming inextricably involved with human genetics research (Hopkins et al. 2007). This is a major departure from the premise on which the Human Genome Project was launched. Since the establishment of the Human Genome Project and the identification of genes in human DNA which play a role in human diseases and disorders, a long moral and political battle has been fought over the extension of intellectual property rights to information contained in human genetic material (Papaioannou 2008) (see also Caulfield 2006; WHO 2009a).

The estimated total of 26,000 to 30,000 genes in the human genome includes approximately 3,000 to 5,000 targets that are potentially amenable to pharmacological interventions. Within the *in vitro* diagnostic industry, molecular diagnostics is the fastest-growing segment. The market for molecular diagnostic products has surged from US$50 million to over US$1 billion in the United States in little more than a decade and, it is anticipated, will reach US$35 billion globally by 2015. The US demand for *in vitro* diagnostic products is growing by an estimated 6.1% annually (Visiongain 2009).

This raises the question: does the continued exclusion of human genetic resources from the CBD remain a viable proposition? Is it not possible to have an international ABS understanding regarding human genetic resources, as we now have for plant genetic resources? Are human genetic resources not part of genetic resources? These are some of the issues we attempt to address in this chapter. Section 7.2 examines the concept of genetic diversity and the evolution of the idea in the context of the CBD, and Sect. 7.3 gives a detailed account of the impact of new technologies on the use of human genetic resources. Section 7.4 looks into instances of ABS in human genetic resources, and the final section suggests possible ways forward.

7.2 ABS Debate

At the eighth Conference of the Parties to the CBD (COP 8), held at Curitiba, Brazil, from 13 to 17 March 2006, it was decided that the negotiations on an international ABS regime should be completed by COP 10, scheduled to meet in 2010. And indeed, the negotiations did result in the adoption of the Nagoya Protocol in October 2010. However, the ABS debate is still raging simultaneously in various major intergovernmental forums, such as the World Intellectual Property Organization (WIPO) and the WTO, where these issues are being tackled in different ways and from widely diverse perspectives, with the result that the agencies concerned are all going in different directions – and, at times, in circles.

The centrifugal force needed to break out of these circles is likely to come once something that should have been done initially is achieved: namely, defining clearly the terms being used in this debate in order to resolve many of the current ambiguities (Pisupati 2008; Schroeder 2007). It is evident from the history of the CBD that as the end of the original negotiations approached, definitions were problematic and, in fact, became an impediment to the conclusion of the CBD itself. Rather than resolving this issue, the negotiators instead agreed to remove the problematic definitions, or let them remain vague. For example, no further effort was made to clarify the definition of 'conservation of biological diversity'. The adoption of the relatively weak definition '"technology" includes biotechnology' was a way to avoid controversy on the definition of this critical concept and many others.

In this section, we explore a number of cases that are relevant to our current concerns regarding ABS. We examine the debate on what is covered by the definition of 'biological diversity' and how this question is being addressed by different organizations. Another important aspect of this debate is the determination of how benefits may best be distributed and how the proper recipients of these benefits will be identified, but a discussion of these issues is beyond the scope of this chapter.

7.2.1 Concepts and Coverage

It is important to understand the definitions adopted by the CBD in order to appreciate the broader implications for our current concerns regarding ABS. It should be recognized that the focus of the CBD as originally proposed was significantly broader and more comprehensive than it became later, after an extremely wide process of consultation. When the Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity met in Nairobi in 1992, the document had already gone through three meetings of technical experts and seven negotiating sessions, held between November 1988 and May 1992. This process was led by the General Council of the United Nations Environment Programme (UNEP), initially through the Ad Hoc Working Group of Experts on Biological Diversity (between November 1988 and July 1990), followed by the Ad Hoc Working Group of Legal

and Technical Experts (between November 1990 and March 1991). This group was eventually renamed the Intergovernmental Negotiating Committee for the CBD.

At the Nairobi conference in 1992, three resolutions were passed, of which Resolution 2 was articulated in a very broad framework:

> Further recognizing that the preparation of biological diversity country studies is the first systematic attempt to assist countries in establishing baseline information on their biological diversity and is the basis for national action programmes on conservation of biological diversity and the sustainable use of its components … (CBD 2005: 404).

Resolution 2 also suggested that the CBD Secretariat would identify components of biological diversity that were of importance for conservation and sustainable use, including the collection of data needed for effective monitoring, upon request from the national governments, and while doing so would also evaluate potential economic implications. The text consistently referred to 'biological' and 'genetic' resources. Nowhere did it confine itself to plant-based components of biological or genetic diversity. In Resolution 3, however, while identifying the work agenda, the conference narrowed this definition to 'plant genetic resources for food and sustainable agriculture' (CBD 2005: 407) and further:

> Recognize[d] the need for the provision of support to the implementation of all activities agreed upon in the programme area on conservation and sustainable utilization of plant genetic resources for food and sustainable agriculture and in the programme area on conservation and utilization of animal genetic resources for sustainable agriculture in the Agenda 21 proposed to be adopted at the United Nations Conference on Environment and Development in Rio de Janeiro (CBD 2005: 408).

This narrowing of the focus of the CBD was contested by some member countries. The definition of biological resources was one area where a lack of initial consensus about the scope of the CBD was evident in individual country submissions to the process. For instance, in the early stages of drafting, Peru observed that:

1. Article 2 lacks a definition of the term 'conservation of biological diversity,' which should cover the preservation or integral protection, maintenance, sustainable use and recovery of its components.
2. In Article 19, paragraph 3, there is no express mention of the human being within the scope of this paragraph, that is, the protection of the human being from the adverse effects that may be produced by living organisms modified by biotechnology (CBD 2005: 392).

Biological Diversity

It is evident from the literature that approaches to defining the scope of this concept have remained ambiguous. The four major concepts that appeared in the 1970s and 1980s – biological diversity, biological resources, genetic diversity and genetic resources – were never fully defined or adopted. The expression 'genetic diversity' appears in the Stockholm Declaration (1972), the World Conservation Strategy (1980), the International Union for Conservation of Nature (IUCN) General Assembly Resolution (1984) and the Protocol Concerning Mediterranean

Specially Protected Areas (1982) (Van Heijnsbergen 1997: 261). The classic example is the report of the UN Conference on the Human Environment (1973) that refers throughout Recommendations 35 to 45 to the need to preserve the world's genetic resources, yet in Recommendation 40 uses the term 'genetic diversity', where the subject to be protected is referred to as 'genetic resources' (Van Heijnsbergen 1997). The International Undertaking on Plant Genetic Resources (FAO 1983) refers to genes as part of 'genetic diversity'. In this context, Bergman (1986), as quoted in Van Heijnsbergen (1997), observes that biological diversity includes much more than genetic diversity.

In this section we will emphasize those issues that were suspended at the time of the final adoption of the CBD, and have since failed to be successfully resolved. There are three important definitions with regard to biological diversity, biological resources and genetic material.

The concept of biological diversity initially arose in a resolution of the IUCN's General Assembly in 1984, the main purpose of which was to address the conservation of wild genetic resources (Van Heijnsbergen 1997). A commentary on this from the IUCN (Miller et al. 1984) argues that 'biological diversity covers all life forms, with their manifold variety, which occur on earth'. Almost the same concept of biological diversity was articulated at the 17th session of the General Assembly of IUCN and 17th technical meeting at San José, Costa Rica in 1988. The first draft of what would later become the Convention on Biological Diversity provided the definition:

> [B]iodiversity comprises the sum total of plant and animal species in the world today and exists at the level of individuals, populations, species, communities and ecosystems and applies to the genetic diversity they contain and to their relationships and interactions between them.

However, the final draft produced by the 17th meeting was more limited in its approach:

> Biological diversity means the genetic variation represented by the aggregate of species living in the world, or in respect of any State or area, by the aggregate of indigenous species living in the territory of that State (Van Heijnsbergen 1997: 198).

The June 1989 draft of the biological diversity treaty returned to species diversity and presented a very broad concept of biological diversity. This approach was consistently present until the Nairobi conference for the adoption of the agreed text of the Convention on Biological Diversity in February 1992 (UNEP 1992). At this conference the distinction between variety and variability was dropped and only variability remained (Van Heijnsbergen 1997).

Article 2 of the CBD, Use of Terms, states that:

> For the purposes of this Convention:
> '*Biological diversity*' means the variability among living organisms from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems.

> '*Biological resources*' includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity. …
> '*Genetic material*' means any material of plant, animal, microbial or other origin containing functional units of heredity (CBD 1992: article 2).

Annex I of the CBD proposes a number of explanations relevant to identification and monitoring. It is important here to note that Annex 1 also identifies 'genomes and genes of social, scientific and economic importance' to be monitored (CBD 1992: annex I).

Access

When deciding to open negotiations on the CBD, the UNEP Governing Council specifically mandated that the convention should be 'broad in scope' (Miller et al. 1984). The implications of this were most evident in the early stages of negotiating; for instance, in early drafts the concept of 'access' was included, but only in the context of the promotion, funding and access of researchers. Researchers were to get 'priority access' to the wildlife of other countries, but first they had to get permission. Virtually from the moment this statement was drafted, most of the pre-discussion team was opposed to it, as they believed that requiring permission would give developing countries a monopoly on wildlife. There were others in the early negotiations, however, who argued that developing countries would not agree to the convention without some recognition of their rights. This marked the beginning of ABS.

The expression 'access' remained in the UNEP document, but now with a focus on access to 'biodiversity' or 'genetic materials' (a term originally defined to mean essentially 'biological specimens'). The first UNEP meeting in 1989 was attended by invited experts and called an 'expert group'. It discussed and then abandoned the idea of the 'rationalization' of existing conventions, but continued to focus on the protection of wild genetic material, protected areas, the concerns of an advisory committee on the conservation of biological diversity in situ, and 'ecosystems' relevant to wild genetic material. Regarding ABS, only the phrase 'any material of plant, animal or microbial origin' was used. This draft did not distinguish between biological resources, genetic resources and biological diversity; all were included in ABS.

At the same time, the concept of benefit sharing entered the negotiating arena. The initial focus was on the transfer of technology, and many discussions were held to identify which technologies should be transferred and how. This was intended not to be solely conservation technology, but also to include technologies that could enable developing countries to get a higher level of value from the sustainable use of their biological resources. At the time, there were some detailed discussions on 'biotechnology', and many attempts were made to define this term in detail, but a definition was never actually adopted, and as a result the term was not included in the final draft of the CBD.

Towards the end of the formal negotiations (a few months before the UN Conference on Environment and Development, also known as the 'Rio Earth

Summit', from 3 to 14 June 1992), the term 'genetic resources' was substituted for the original expression 'biological resources' or 'genetic material'. The negotiators were under significant pressure to finalize the draft in time for the summit, so all definitions and concepts that were still controversial were either deleted or cut down to the lowest common denominator (i.e., language that was acceptable to everyone but generally legally ambiguous). For this reason, there was little discussion of the definition of 'genetic resources'. The process of proposing and adopting a definition was simply aimed at cutting down the language to the point that no party found it objectionable. Because the negotiations were at a very late stage, it appears that no scientists or experts in biotechnology were consulted and no detailed analysis of the potential administrative and political interpretations of the term was undertaken.

Exclusion

The decision of the second meeting of the Conference of Parties of the CBD (1995a) not to include human genetic resources in the definition of biological resources was based on very limited discussion. One of the official COP2 meeting documents (CBD 1995b), which would have given rise to the explicit (negative) reference in the COP2 decision, contains the following discussion, which may help contextualize the evolution of this idea. (This quotation includes the related footnote.)

> **4. Human genetic resources**
>
> 64. Medical researchers are increasingly interested in the diversity of the human gene pool as a source of valuable scientific and medical information. The genetic material found in human beings is 'genetic material' as defined under the Convention, in that it is material of animal origin containing functional units of heredity. The collection and analysis of samples of human genetic material from many different ethnic groups around the world could provide insight into the evolution of the human species as well as the nature of human susceptibility and resistance to diseases.[43] This value for humanity indicates that these samples constitute genetic resources – genetic material 'of actual or potential value' – again fitting a definition under the Convention. Yet from the history of its negotiation, it is clear that the Convention was not formulated with human genetic resources in mind.
>
> The collection and use of human genetic resources raises difficult ethical and political issues. For example, the direct, physical interest of affected individuals in their own genetic resources argues strongly for extensive consultations with affected citizens. Given all the serious concerns surrounding this issue, the Conference of the Parties may wish to study the question of human genetic resources and the Convention on Biological Diversity to determine how it may be approached by the Conference of the Parties.

[43] See Anna Maria Gillis, 'Getting a Picture of Human Diversity: Population geneticists and anthropologists plan to use variation in human genes to get a sense of Homo sapiens History,' *BioScience* 44:8 (994); Mary Claire-King, *Celebrating Identity and Diversity: The Human Genome Diversity Project* (testimony to the U.S. Senate Committee on Governmental Affairs, April 26, 1993) (CBD 1995b).

As is evident from the above, during its evolution the CBD went through a complex and arduous negotiation process that oscillated between the need to be all-inclusive of relevant concepts and, at the same time, specific about their

meanings and functions within the convention. Nowhere is this tension more apparent than in the definitions of 'biodiversity' and 'access', and the inclusion/exclusion criteria, which provide a good insight into the issue of human genetic resources within the scope of the CBD.

7.2.2 ABS Issues in International Negotiating Forums

ABS has emerged as an important policy option for addressing concerns regarding biopiracy and related issues. As is clear from Table 7.1, it was and is being discussed by a large variety of organizations.

While some individual nations have come to a decision regarding formulating a policy on the issue of ABS, no international agencies have done so. This includes WIPO, UNEP, the United Nations Food and Agriculture Organization (FAO), the World Medical Association and the United Nations Educational, Scientific and Cultural Organization (UNESCO). This does not imply a lack of interest in the subject, as the many ongoing debates in various international forums attest, but rather an inability to achieve consensus on basic facts related to ABS issues and how these relate to international treaties. The differences in opinion between developed and developing countries are again evident, and are the main reason behind the continuing deadlock.

The situation is nowhere more apparent than at the negotiations of the TRIPS Agreement of the WTO. The TRIPS negotiations have become the main international stage for contentious debates on ABS, not least because WTO treaties include strong enforcement rules that make them akin to international law. In the

Table 7.1 ABS Discussions in Global Processes

Food and Agriculture Organization	Commission on Genetic Resources (ongoing)
Food and Agriculture Organization	International Treaty on Plant Genetic Resources for Food and Agriculture (Rome, 2001)
World Trade Organization	TRIPs (ongoing)
Convention on Biological Diversity	Nagoya Protocol (2010)
Antarctic Treaty System	Bioprospecting in Antarctica (1999)
World Intellectual Property Organization	Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (2001)
General Assembly of United Nations	United Nations Informal Consultative Process on Ocean Affairs and the Law of the Sea (UNICPOLOS) (2001) and Ad Hoc Working Group on Biodiversity Beyond the Limits of Any National Jurisdiction (2004)
World Summit on Sustainable Development	International Regime on ABS (2002)
United Nations	Declaration on the Rights of Indigenous Peoples (2007)

Source: Glowka (2008)

effort to make the TRIPS Agreement an instrument of international legislation on property rights that does not disregard the issue of biopiracy and works in accordance with the CBD provisions, ABS is seen as the missing link that would both enhance the functioning of TRIPS and promote the values of the CBD.

A strong alliance among developing countries, including the Africa group and the group of 17 Like-Minded Megadiverse Countries (which includes India, China, Brazil, Bolivia, Colombia, Cuba, the Dominican Republic, Ecuador, Peru and Thailand), has requested the introduction into the TRIPS Agreement of a mandatory requirement to disclose the origin of biological resources and/or associated traditional knowledge used in inventions for which intellectual property rights are applied. In a case where the country of origin of biological resources is identified in the patent application, applicants would have to provide information that includes evidence of compliance with the applicable legal requirements in the providing country for prior informed consent and for access and fair and equitable benefit-sharing (WTO 2006b). This amendment would incorporate into TRIPS the ABS objectives as developed in the CBD, thereby making the two treaties compatible. In the absence of proper consent or authorization for the use of resources, the country of origin could claim law infringement and apply for the patent to be revoked.

The main opponent of incorporating ABS provisions into TRIPS is the United States, followed by Japan and, to some extent, the European Union and Australia. The US has argued against changing the status quo of patent approval in TRIPS, asserting that the prerequisites for granting a patent (novelty, non-obviousness and utility) represent the only lawful arrangement and any other addition would complicate matters unnecessarily (RIS 2007).[3]

These opponents are not, however, against ABS rules per se. They argue that the value of ABS is best governed by means other than intellectual property laws, such as contracts, conservation laws and export controls, that responsibility for keeping track of the use of genetic resources lies with the countries that provide them and not the patent offices of other countries, and that requiring additional disclosure would increase the costs of research because of the record keeping required, thereby reducing research and increasing the cost of products. They maintain that the purpose of TRIPS is to establish minimum levels of intellectual property rights protection and not to specify contractual obligations regarding access to genetic materials in other countries' territories.

The arguments against the incorporation of ABS in TRIPS are technically valid, but proponents of such a move argue that perhaps this misses the point. In new submissions, developing countries (e.g. WTO 2006a, 2006c, 2008) are adamant that ABS is a key issue in protecting intellectual property rights and that without the amendment there is an apparent contradiction between TRIPS and the CBD. To

[3] Patent revocation can only occur on the following grounds: that the invention for which patent protection is sought is not new, lacks true innovation or is not capable of industrial application, or that the application does not disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art.

clarify this point, Peru has submitted a dossier of cases of patent applications that are based on the country's biological resources without proper acknowledgement (WTO 2007a).

A robust debate continues, with new submissions in the WTO TRIPS Council for and against the amendment proposal. On the main arguments, both sides remain unmoved. Norway has sided with developing countries on the issue (WTO 2006d: WT/GC/W/566), while Japan has proposed as a compromise the creation of a global database on traditional knowledge that can be easily accessed by patent officials (WTO 2007b). It remains to be seen which argument will prevail, but the alliance of developing countries on this issue is impressive in its depth and strength.

It is also extremely important to stress that the understanding of the term 'biological resources' by the countries that have initiated the amendment proposal includes human genetic resources. Although this issue has not yet been at the centre of negotiations (presumably because the CBD is seen to cover the definitions of relevant terms adequately), developing countries have made it clear that 'human genetic resources' are not to be excluded from the amendment. In their own words:

> Taking the above definitions into account, we can see that biological resources may refer to something that exists in the natural or crude form and to the whole organism including human beings … (WTO 2006a).

No other international forum has taken up the issue of ABS with such force and intensity as the WTO. ABS tends otherwise to be a side issue on the main agenda or a formal discussion point for peripheral initiatives that deal with capacity-building and technology transfer.

At WIPO, for instance, a stage for a similar debate on intellectual property rights commenced officially with the establishment of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) in 2000. The IGC mandate is to develop, first, 'guidelines, and model intellectual property clauses for contractual agreements on access to genetic resources and benefit-sharing, taking into account the specific nature and needs of different stakeholders, different genetic resources, and different transfers in different sectors of genetic resource policy', and, second, 'appropriate provisions or guidelines for national patent laws which facilitate consistency with measures of States concerning access to genetic resources and which are consistent with existing international intellectual property standards' (WIPO 2001). It has agreed upon principles for the development of guidelines for intellectual property aspects of ABS with regard to genetic resources, but has fallen short of developing a legally binding international instrument, owing to limitations in the WIPO remit to develop such instruments. The work of the IGC continues along these lines.

The debate on ABS in UNEP, on the other hand, focuses on more practical aspects of the issue. UNEP follows the CBD closely and is the designated global agency for ABS under the CBD processes. The organization is working with national, regional and global stakeholders to aid the formalization of ABS management systems. These include support for the ongoing finalization

of negotiations for the international regime on ABS, and support to national and regional capacity-building efforts to help stakeholders appreciate the relevance of ABS issues and the need to address them within ecosystem management options. Along these lines, UNEP has undertaken a series of capacity-building programmes, mainly in Africa, based on the recommendations of the voluntary Bonn Guidelines, which were adopted by the Conference of the Parties to the CBD in April 2002, with the aim of helping countries achieve CBD objectives, and have since been superseded by the Nagoya Protocol. These programmes mainly deal with legal aspects of ABS, analysing national capacities, initiating training programmes and promoting regional cooperation.

The issue of ABS has also been debated at the FAO. Although it is not in the mandate of the FAO to establish guidelines on ABS matters, these issues were deemed important enough to be incorporated into the organization's International Code of Conduct for Plant Germplasm Collection and Transfer (1993). The code sets out the responsibilities of collectors, donors, sponsors, users and curators of plant genetic resources. Among these responsibilities, curators are to:

> take practical steps, inter alia by the use of material transfer agreements, to promote the objectives of this code including the sharing of benefits derived from collected germplasm by the users with the local communities, farmers and host countries… (FAO 1993: article 13.3).

The international debate on ABS issues has therefore proven to be one of the most complex aspects of negotiations in international forums outside the CBD, particularly in so far as it relates to the inclusion or exclusion of human genetic resources.

7.2.3 ABS and WHO

The WHO is a late entrant into the debate on ABS. It was only at the 60th session of the World Health Assembly (WHA), WHO's supreme decision-making body, from 14 to 23 May 2007, that the issue of ABS came up in a major way. Within the framework of the International Health Regulations (WHO 2005), the WHA adopted Resolution 60.28 (WHO 2007a, 2007b). The work relating to the resolution was undertaken at the intergovernmental meeting and the open-ended working group.

The importance of WHA Resolution 60.28 in the context of the CBD is that it acknowledged the sovereign right of states over their biological resources. This was a marked departure from earlier practices; for more than 50 years, the WHO's Global Influenza Surveillance Network of laboratories, including its collaborating national influenza centres, H5 reference laboratories and other expert laboratory reference centres, had been sharing samples without clear obligations. The issue came to the fore in 2007, when Indonesia refused to share its samples with the WHO and observed that it was not fair to pass on ownership of samples to the WHO collaborating centres without getting any benefit from the resulting papers

or patents (*Nature News* 2007). Indonesia pressed for a material transfer agreement (MTA) that would allow research use, but give Indonesia sovereign ownership of its samples, apart from access to vaccines emanating from its samples (Siti 2007) (see also Chap. 5).

The concern basically comes from a growing trend in biomedical research involving the patenting of viruses (Table 7.2) that has triggered a major debate in various groups (Regalado 2003). Experts such as Richard Gold have argued for reforms of the patent system, particularly in the context of the patenting of the SARS virus (Gold 2003). Similar views have come from Peter Yu (2003). In this context, the debate on the TRIPS Agreement's article 27.3(b) on the lack of harmonization over the criteria of novelty and 'inventive steps' has remained inconclusive.

Some progress has been made with the WHA's adoption in 2011 of the Pandemic Influenza Preparedness Framework. As described in more detail in Chap. 5, WHA resolution 62.10 urged the facilitation of 'a transparent process to finalize the remaining elements [of the virus and benefit sharing framework], including the Standard Material Transfer Agreement' (WHO 2009b). One year later, WHA resolution 63.1 urged continued 'work with Member States and relevant regional economic integration organizations, on the Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits', and the undertaking of 'technical consultations and studies as necessary' to support this work (WHO 2010). Finally, in April 2011, the WHO Open-Ended Working Group on Pandemic Influenza Preparedness for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits reached agreement on terms and conditions that will govern the sharing of influenza viruses and other benefits, and these were approved in May 2011 by the WHA.

Table 7.2 Examples of Virus-related Patents

Patent	Applicant	Concept	Application
US Patent 6,528,066 4 March 2003	University of Iowa	First known mutant chicken-pox virus	May be useful for potential new diagnostic test for chicken-pox
US Patent 414319 28 April 2006	Rabinowitz, Joseph E. (Carrboro, NC, US), Samulski, Richard Jude (Chapel Hill, NC, US), Xiao, Weidong (Jenkintown, PA, US)	Viral vectors and methods of making and administering the same	The parvoviruses of the invention provide a repertoire of vectors with altered antigenic properties, packaging capabilities, and/or cellular tropisms as compared with current AAV vectors
US Patent 4,983,387 31 July 2001	Zimmerman, Daniel H. (Bethesda, MD) Sarin, Prem S. (Gaithersburg, MD)	Modified HGP-30 peptides	Forms part of the core of the AIDS virus for a potential vaccine against AIDS

Sources: WHO (2009a), Regalado (2003)

Thus we see that ABS has also been a major issue in WHA negotiations in respect of human virus research, a fact that was reflected in the addition of the text referring to human pathogens in the CBD ABS decision adopted at COP 10 in Nagoya in October 2010.

7.3 New Technologies that Blur Traditional Boundaries

After this historical overview, this chapter now approaches its main argument for expanding the scope of the CBD to include human genetic resources, namely the practical impossibility of separating the origins of genetic resources in the innovation process. The lines between human genetic resources and those covered by the CBD are becoming increasingly blurred. Drug development is already inextricably integrating the use of these resources into the same discovery programmes, and even into the same molecules.

The publication of the human genome in 2000 led to a plethora of ideas as to the use of the emerging information on genetics in diagnosis and treatment of human diseases and the creation of new diagnostic and therapeutic tools.[4] The earliest and most obvious applications of genome research are tests for genetic disorders, but less obvious diagnostic uses may prove at least as important (e.g. in forensics to establish identity). Genome research also holds the promise of identifying genes expeditiously, making a genetic approach attractive as the first step in the study not only of complex diseases, but also of normal biological functions and of human diversity. Identifying relevant genes gives investigators a molecular handle on problems that have previously proven intractable.

One distinctive aspect of the genome project was its explicit attention to technology development in addition to basic science. The development of new biological methods, instruments, automata and robots, as well as other new technologies, became an explicit objective. An unprecedented commitment to supporting research on the ethical, legal and social implications of human genome research has been a key feature of the project since its earliest phases. Existing genome research focuses on ties to industry, with plans to locate genes through mapping techniques and an eye to drug discovery through collaborative research. Identification of relevant

[4] In the scientific community this initial optimism has waned, since it has proved more difficult than first anticipated to connect one gene to one trait. There is an emerging view that the way genes interact may be more important, and might even be essential in predicting the effect of a certain allele (form of a gene). This means that the entire genetic background of a gene determines its effect and/or function. A gene found in a person from South Asia may very well not have the same effect when introduced into a person from South America, or even someone from another ethnic group in South Asia. This will affect the speed of discovery and perhaps the effectiveness of therapeutic use. So, although it may take longer than first thought, the approach of using genetic information to find novel therapies is still promising.

genes has many possible uses, including the determination of potential drug targets, the use of a gene itself as a therapeutic agent (gene therapy), controlling the expression of a gene, and using a gene product as a protein therapeutic.

Private investments necessitated a means to stake claims in this territory, which have taken the form of patents or trade secrets. These claims necessarily changed the complexity of research, altering the rules by which materials and data were exchanged. The seriously conflictual nature of this issue came to the surface in the international controversy provoked by US patent applications on thousands of human DNA sequences filed by the National Institutes of Health in 1991, where opponents to these applications made ethical claims about direct links between human genes and human dignity (United States Congress 1994).

It is evident, however, that DNA is a universal genetic code, and it will be difficult, if not impossible, to distinguish human genes from those derived from other organisms. While it is obvious that the human genome in aggregate contains the instructions for creating a human – instead of a monkey or nematode or yeast – it is equally clear that very few, if any, genes are exclusively human in origin. A classic 1975 paper by King and Wilson showed that the average protein sequence differed by only 1% between humans and pygmy chimps and the difference at the DNA level was only slightly greater than 0.3938% (King and Wilson 1975). The obvious implication is that humans differ more in the parameters of gene expression than in the genes themselves. Furthermore, with the advent of human-animal, human-microbe and human-plant chimeric proteins, which involve creating synthetic genes combining genetic material from humans with that of other species, these distinctions become extremely difficult to delineate on a purely practical basis.

These increasingly molecular-based approaches have made target-based drug discovery easier than was the case with the traditional *in vivo* approach. This is not surprising, considering the superiority of molecular approaches in screening capacity and the ability to define rational drug discovery programmes. In part, these ideas have helped to re-evaluate the enormous costs involved in the drug discovery process and have streamlined the strategies being employed by pharmaceutical and biotechnology companies. Constantly improving genomics technologies, such as ribonucleic acid interference, have satisfactorily validated targets that would have taken much longer (and cost more) with traditional transgenic technologies. Drug targets identified by these techniques involving human genetic resources could end up being the basis for drug discovery programmes using molecules isolated from plant sources (Table 7.3).

Molecular diagnostics is the fastest growing segment of the *in vitro* diagnostics industry. In little more than a decade, the clinical market for molecular diagnostic products has surged from US$50 million to over US$1 billion in the United States, and it is likely to reach US$35 billion globally by 2015. These astonishing exponential figures are an indication of the profitability of the molecular diagnostics market. A major proportion of this may be attributed to advances in genetics, genomics and proteomics. Driven by perceived commercial benefits, pharmaceutical companies are increasingly interested in developing tests that can eventually be used to individualize the prescription of their drugs (Mancinelli et al. 2002).

Table 7.3 Examples of the increasingly inextricable utilization of plants, human genetic resources and microbes in drug development

Use of human genetic resources	Example	Covered by CBD?[5]
Drug target	A genetic study conducted by Swedish scientists using samples from different ethnic groups in Africa implicated C-reactive protein as a potential target for an adjunct treatment for malaria. An unrelated study by Japanese scientists has suggested that the compound AHCC isolated from shiitake mushrooms native to East Asia lowers levels of C-reactive protein	Partially (para. 13.7)
Vaccine target	A large number of studies use samples from individuals living in Africa and other malaria endemic regions to identify potential candidate antigens for malaria. A novel way of administering malaria vaccine antigens through the consumption of transgenic tomatoes was suggested	Partially (para. 43.3)
Antibodies	During the avian influenza pandemic, samples taken from Vietnamese survivors by scientists in the US were used to identify antibodies that could be used to design antibody-based therapies for the treatment of H5N1 infections. Technologies for creating recombinant antibodies are becoming increasingly sophisticated, and using these kinds of samples to guide the development of antibody-based therapeutics is likely to have increasing importance. Such antibodies would often be produced through the use of microbial cells. These antibodies can also be used to guide the selection of avian influenza virus antigens for use in vaccines	Partially (para. 13.2)
Chimeric proteins	A strategy seen with increasing frequency in anti-cancer drug development is the creation of chimeric proteins that combine a human protein with a plant toxin into a single molecule that selectively kills cancer cells; the expression of these protein constructs thus involves both human genetic material and plant genetic material	Partially (para. 43.3)
Gene therapy	A major strategy for gene therapy is to insert a human gene into a virus, which will then deliver the gene to human cells; these virus constructs thus contain both human genetic material and viral genetic material	Unclear (para. 13.2)
Diagnostics	Genetic diagnostics are becoming an increasingly important area, as can be seen in the example of Herceptin and HER2/neu. Creation of genetic diagnostics relies on the identification of important polymorphisms, and there are a large number of studies in many different ethnic populations all over the world to identify these polymorphisms for use in potential diagnostics. A study by a group in France compared alleles that predispose to rheumatoid arthritis across ten different ethnic populations from 17 countries	Unlikely (para. 13.2)

Sources Israelsson et al. (2009), Yanagimoto et al. (2008), Perlaza et al. (2001), Chowdhury and Bagasra (2007), Khurana et al. (2009), Ben-Yehudah and Lorberboum-Galski (2004), Barnetche et al. (2008), http://www.fusionantibodies.com//index.cfm

[5] References in this column are to the annex to the CBD (2009), which begins on page 6 of that document.

Take the case of Herceptin, which is indicated for metastatic breast cancer, and also gained approval in the UK for early-stage breast cancer in 2006. Herceptin treatment is seriously considered only when a patient scores within a particular range on a diagnostic test that selectively identifies a subgroup of breast cancer patients who may maximally benefit from Herceptin and, equally importantly, those for whom Herceptin will not be useful. Herceptin is the epitome of personalized medicine in its fundamental approach, providing the appropriate drug to the appropriate patient and at the appropriate dosage – thus improving considerably the safety and well-being of the patient (Madsen 2004).

This is an area where sequence data from the Human Genome Project, and the subsequent Human Proteome Project, is making an enormous impact. As long as there is a demand in discovery research for the identification of key genes involved in common disease aetiology, this area of the market is likely to grow. Information on key genes involved in drug metabolism or transport has also been exploited for pharmacogenomic studies. This is an area where pharmaceutical companies, in their quest for safer, more efficacious and more cost-effective medicines, require indicative answers as to how subjects are metabolizing or excreting drugs to discover if there may be genetic reasons for medicinal effects on humans. Again, the indications are that tools for pharmacogenetics will potentially provide rich pickings for the diagnostic market.

Hence human genetics and genomic studies have resulted in widespread global collaborative studies (see also Majengo sex worker case in Chap. 5), with the transportation of human biological materials across continents and between academic institutions and commercial organizations underlining the ongoing ethical debates over the ownership of material, informed consent, material transfer agreements, and ABS. A number of instances have surfaced in which the collection of such material has been undertaken without informed consent, and these are barely the tip of the ABS iceberg, as we show below.

7.3.1 Developing Country Experiences

India

Being a country rich in biodiversity, India attracts global interest in the genetic diversity of its anthropologically well-defined populations, including a number of tribal groups. This has not only global evolutionary implications, but also potential applications in pharmacogenetics for personalized medicine. India's strength in the area of drug development complicates the situation, especially with the existence of Indian biobanks as national repositories of biological samples, which gives rise to issues of privacy protection and confidentiality. When international collaborative studies are conducted, the main concerns are exploitation, stigmatization, ownership, MTAs and benefit sharing, especially when a gene-based product is likely to be commercialized eventually. Biopiracy is even more worrying in a

developing country that has appropriate ethical guidelines and regulations in place, but lacks proper implementation mechanisms to monitor misuse.

The potential for obtaining valuable information which may result in academic laurels or commercial benefits is leading to increasing instances of biopiracy. Of late, more and more instances are coming to light of guidelines being flouted by researchers associated with foreign investigators who are funded by agencies that in their own countries are required to adhere strictly to high ethical standards concerning human research.

For instance, samples from two Indian tribes were subjected to genetic analysis without permission being obtained from the local authorities concerned. This situation arose in relation to a study funded by the US National Institutes of Health, the European Commission and the Estonian Medical Research Council and published in the *American Journal of Human Genetics* (Kivisild et al. 2003). It listed 18 authors from seven institutions in six countries. It was not clear who had given permission to collect the samples, nor was any Indian institution or author acknowledged for any kind of collaboration. The article mentions that informed consent was obtained. On enquiry however, the European Commission could only provide the information that the samples had been collected 25 years previously and kept in the archives of one of the collaborators. Considering that even today the concept of informed consent is still not understood by many Indian patients or volunteers, particularly those from the tribal populations, the possibility of having obtained valid informed consent 25 years ago is highly questionable.

Later, a number of further articles on the genetic make-up of Indian tribes were published by the same team in the *European Journal of Human Genetics* and *Current Biology* (See Cardaux et al. 2003, 2004) but this time with the name of an Indian investigator and institution that had contributed the samples. However, it appears that approval from the authorities concerned was not obtained for sending the samples abroad for the study. The issues of prior informed consent, ownership of the biological material, appropriate MTA and ABS remained unattended to. The onus of vigilance about this in collaborative studies falls on the editorial boards of journals and the ethics committees of the developed world's partner institutions (The Hindu, 2006). However, as the next chapter explains (Chap. 8 on ethics review), these parties may, for a variety of reasons, fail to ensure that such issues are addressed.

China

The controversial case of Harvard researcher Dr Xu Xiping, who took and exported millions of DNA samples from poor areas in Anhui province, central China, sparked heated international, national, and local debates on bioethics issues such as informed consent and benefit sharing. This episode came to light in 1999, when Dr Gwendolyn Zahner, a former faculty member at the Harvard School of Public Health, exposed the unethical conduct in Dr Xiping's research programme. These debates led to in-depth discussions on the protection of vulnerable participants in biomedical research, and on the pursuit of best practices in informed

consent procedures and mutually beneficial models of international scientific cooperation (Sleeboom-Faulkner 2005).

One of the outcomes is China's 1998 Interim Measures for the Administration of Human Genetic Resources. This crucial set of regulations underscores the importance of the ethical and scientific review of international cooperative projects that involve exporting human genetic resources from China or importing them into the country. Yihong Hu, the divisional director of Bioresource and Biosafety at the China National Centre for Biotechnological Development, explicated the function of the Chinese Human Genetic Resources Management Office at the fourth Bionet workshop, entitled 'Biobanking and personal genomics: Challenges and futures for EU–China collaborations', held in April 2009, in Shenzhen, China:[6]

- Drafting the implementation details and documents, coordination and supervision of the implementation of this approach
- Management and registration of important family genealogy and special genetic and specific areas of genetic resources
- Administrative approval of international cooperation projects on human genetic resources
- Acceptance of applications for the export of human genetic resources
- Other tasks related to human genetic resources management (Hu 2009).

Since the launch of the interim measures, every international cooperative project that involves the transportation of genetic resources across Chinese borders must apply for permission from the Human Genetic Resources Management Office. An expert panel was established to review the applications according to both scientific and ethical considerations. From January 1999 to April 2009, the office received 303 applications and rejected 59 of them. Taking into account the advancement of biomedical research and emerging issues in benefit sharing and intellectual property, the office has been consulting with international and national experts since 2005 in order to revise the *Interim Measures*.

The current regime, however, does not necessarily cover all international cooperative projects. Exceptions can occur in the case of research that involves investments by a foreign institution or company, but is conducted in China. For example, a large-scale epidemiology project, led by a researcher at a prestigious UK university, was successfully launched in China in 2004 without reporting to the Human Genetic Resources Management Office (see www.ckbiobank.org). Although the study collects and stores blood samples and extensive health-related data, it does not actually export any 'human genetic resources' out of China. While there is every reason to believe that the research being approved by the university ethics committee and Chinese partner institutions is appropriately obtaining informed consent from participants, this kind of research alerts the office to potential loopholes in the current regulations. How to protect research participants effectively

[6] http://www.bionet-china.org

and efficiently, while promoting genuine international cooperative biomedical and pharmaceutical research, therefore remains a major issue.

7.4 ABS in Human Genetic Resources

Notwithstanding the complexity of identifying the origin of the 'biological resources' that constitute the raw material and the focal point of ABS guidelines, there is growing acceptance that some kind of benefit sharing should take place when human genetic material is involved (Schroeder and Lasen-Diaz 2006). We can find examples of this in international debates and guidelines, as outlined in Chap. 3. For instance, the Statement on Benefit Sharing by the Hugo Ethics Committee (2000), the WHO report *Genetic databases: Assessing the benefits and the impact on human and patient rights* (WHO 2003) and the UNESCO Declaration on Human Genetic Data (UNESCO 2003) have forcefully called for benefit sharing with participating populations in genetic studies. What constitutes benefit sharing in such cases is widely debated, as it may vary depending on the needs, values and cultural parameters in a given case. What is clear, however, is that benefit sharing is considered a key aspect of research involving human beings and human genetic material. Yet, because there are currently no legally binding obligations requiring ABS agreements to be concluded in such cases, there is little evidence that this is actually done in any formal or meaningful manner anywhere in the world. While research groups prefer to offer participating individuals in research studies (which are usually of a clinical nature) free health care as a 'benefit' (see Chap. 5), formal arrangements between the parties appear to be rare.

One exception is the formal benefit-sharing agreement that involved a genetics research company, a drug manufacturer and the government of Iceland. In this case the research company planned to develop a database of the Icelandic population to identify particular genetic polymorphisms that could eventually lead to drug development. Interestingly, the plans for the database were ruled unconstitutional, partly on the basis of issues of informed consent and privacy, and the result of the remaining scientific collaboration so far has been disappointing, with no commercial developments. The case, which is described in detail in Chap. 5, has nevertheless opened up new perspectives on ABS agreements in terms of basic research in population genetics studies.

7.5 Exploring the Way Forward

The CBD is an important global agreement that provides national sovereignty over the biological resources found within national geographical borders, and spells out that any commercial benefit derived from these resources should, among other things, acknowledge the supplier country and/or indigenous and local

communities for their conservation efforts, and also recognize any prior knowledge about a resource's potential utility. This is a commitment incorporating the principles of fairness and equity. It needs to be appreciated that the CBD is fundamentally an effort to protect the world's biodiversity and to ensure the conservation of all the varied components of the earth's biological resources, which must include all species. Sustainable use of the various components of biological diversity, with fair and equitable ABS arising from the use of such genetic resources, is an institutional objective towards that goal. This focus of the CBD qualifies it to be the central agency at the global level to evolve broader frameworks for ABS.

The ABS mechanism is also being discussed at the WHO, largely in the context of the sharing of viruses for vaccine development, which resulted in the adoption of the Pandemic Influenza Preparedness Framework in 2011. It would be extremely useful if the WHO and CBD would work together more closely and generate common ABS guidelines. It is evident from the technological trends in various streams of biomedical research that clearly delineating the precise sources of a drug will become increasingly difficult as greater convergence is achieved between plant and human genetic resources in drug targeting, selection and development. This will require a far more refined and focused ABS regime. The efforts to address unresolved elements of ABS continue at CBD meetings (Balmford et al. 2005), but certain issues remain outside the scope of the CBD due to its non-inclusive approach to biodiversity. The fact that many of the important human genetic resources for drug development come from indigenous communities makes this a matter of even greater concern (Hammond and Mayet 2009).

The proliferation of patents involving human genetic resources is a case in point. From 1980 to 2005 nearly 15,603 patent families[7] claiming human DNA sequences were filed (Hopkins et al. 2007). Of these, nearly 5,669 were filed at the world's three leading patent offices, namely the US Patent and Trademark Office, the European Patent Office and the Japan Patent Office (Hopkins et al. 2007). The growing realization of this valued resource for technology (and product) development has received varying responses from national governments. For example, the Indian Ministry of Health and Family Welfare has already issued guidelines restricting the transfer of biological material for collaborative research subject to the approval of institutional review and ethics committees (GOI 1997). These guidelines also discuss the exchange of biological material for commercial purposes and stipulates that approval is on a case-by-case basis with a three-month lead time (GOI 1997). China's National Office of Administration on Genetic Materials has been revising the 1998 regulation on the administration of genetic material, which specifically regulates the export and import of genetic material (including human genetic resources) in that country. The office has also been concerned with the way ABS is defined and how best to ensure justified benefit sharing in international collaborative studies.

[7] A patent family comprises all the patent applications and granted patents resulting from a specific invention.

This could eventuate in a huge cobweb of national statutes that may seriously hamper international drug development efforts. It is necessary to consider whether international technology efforts using biodiversity can work effectively if there are diverse kinds of national legislation determining the nature and focus of ABS, as opposed to a single clear and transparent system facilitating global drug development efforts. It seems, therefore, that an international comprehensive ABS regime is urgently needed.

Further research in this field should address issues such as who the beneficiaries of such arrangements would be, how they should be identified, and how the benefit sharing would be effected. The extent of benefit sharing also needs to be defined, and a strategy for doing so elucidated: whether it is to be achieved by a share in the profits from the drug, fixed royalties, or else free or low-cost access to drugs, for example. How would ABS be accomplished for human genetic resources when the source is mixed or unknown? Since implementing benefits from human genetic resources, unlike plant genetic resources, would require not only highly advanced technology but also huge capital inputs, global arrangements for ensuring cost-effective access to medicines will have to be viewed as a priority. This may also require re-evaluating the way in which we cover human genetic research databases or population databases in this context.

At the practical level, administrative challenges will certainly arise from the inclusion of human genetic resources in ABS regimes. This will raise a multitude of issues that require us to draw upon the experience of expert institutions in the field and to consult with diverse stakeholders.[8] Chapter 8 begins this process by bringing to bear the experience of those involved with international research ethics.

Whichever route the inclusion of human genetic resources in ABS regimes might take, it must be evident from this chapter that it is becoming increasingly important to consider the inclusion of human genetic resources in international treaties that deal with biodiversity issues. To exclude such resources from these agreements for the sake of simplicity merely weakens those instruments by excluding a crucial area, potentially with major repercussions in science, the economy and society. It is our common position that this should not happen, and we heartily support the wording of the Nagoya Protocol on ABS, which takes the first step towards inclusion.

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[8] See Hodges and Casas (2008) for the need to involve industry in this process.

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