

Access to genetic resources and benefit-sharing from their use (ABS) – state of implementation and research gaps

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Abstract

Commissioned by the PBL Netherlands Environmental Assessment Agency the report provides an international review of the current situation in access and benefit sharing (ABS) related to genetic resources and the research needs in this field. The report concludes that even if an international ABS regime has been in place for more than 20 years, implementation at the national level has been slow both in terms of enacting access legislation and legislation to support compliance with access legislation. A fairly large amount of bioprospecting activities have been generated but - apparently - few with a commercial intent and thus with few examples and low amounts of monetary benefits. Research on ABS has mainly been theoretical and less research has been conducted on ABS in practice. Main research gaps are: 1) Actual and potential contribution of ABS to conservation and sustainable use of biodiversity; 2) ABS, equity and standard setting; 3) ABS beyond genetic resources; 4) Business approaches to ABS; 5) Mapping the value chain of genetic/biological material from its collection to an end product.

Key Words

Genetic resources, biological resources, biodiversity, ecosystem services, international environmental governance and law.

Contents

Executive Summary	vii
Acronyms	x
Preface	xi
1 Introduction	1
2 State of the art in access to genetic resources and benefit sharing from their utilization (ABS)	2
2.1 The Convention on Biological Diversity (CBD)	2
2.2 From the CBD to the Nagoya Protocol (NP)	5
2.3 The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization	7
2.4 Interaction and complexity: ABS and other international regimes	9
2.4.1 The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)	9
2.4.2 FAO Commission on Genetic Resources for Food and Agriculture (CGRFA)	11
2.4.3 World Health Organization (WHO)	12
2.4.4 International fora on intellectual property rights (TRIPS, WIPO and UPOV)	12
2.4.5 United Nations Convention on the Law of the Sea (UNCLOS)	14
2.5 Perceptions of ABS by the business sector and other non-state actors	14
3 ABS in practice	16
3.1 Background	16
3.2 Trends in use of genetic resources	16
3.3 ABS case studies	17
3.3.1 The Merck/InBio agreement	17
3.3.2 The Teff case	18
3.3.3 The Hoodia case	18
3.4 ABS domestic legislation	19
3.4.1 Examples of national legislation to regulate access to genetic resources	20
3.4.2 Concluding remarks on domestic access legislation	25
3.4.3 Examples of national legislation to regulate users of foreign genetic resources under the country's jurisdiction	28
3.4.4 Concluding remarks on user-country legislation	29

3.5	ABS between equity and ecosystem services	29
3.6	Benefit sharing beyond genetic resources	31
4	General concluding remarks	31
	References	33

Executive Summary

The Fridtjof Nansen Institute (FNI) has been commissioned to prepare a report for the PBL Netherlands Environmental Assessment Agency on the current situation in access and benefit sharing (ABS) related to genetic resources.

Genetic resources are essential for a significant proportion of the world's economic activity. They are used for a wide variety of purposes, ranging from basic research to the development of products in sectors such as pharmaceuticals, agriculture, horticulture, agriculture, cosmetics and biotechnology. The combined annual global markets for products derived from genetic resources have been estimated at between USD 500 and 800 billion.

Developing countries saw the Convention on Biological Diversity (CBD) as an opportunity to achieve fair and equitable sharing of the benefits derived by developed countries from the use of genetic resources stemming from developing countries. And indeed, they succeeded in getting this concept included as the third objective of the CBD, together with conservation and sustainable use. The CBD establishes that states have sovereign rights to genetic resources; further, that access to these from outside the country is subject to prior informed consent (PIC) from the provider country and mutually agreed terms (MAT) on benefit sharing with the user. One reason for the strong insistence on the part of the developing countries on this approach was the desire to counter-balance the rapid expansion of intellectual property rights ownership to living material mainly through patents and plant breeders' rights.

ABS remained controversial after the CBD entered into force in 1992. Developing countries, as the main providers of genetic resources, held that the main users – the developed countries – were not doing enough to support compliance with the access regulations of provider countries, and wanted a legally binding ABS regime to set user-country measures. The result was the 2010 Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, aimed at further developing the legal ABS of framework provided by the CBD on this and other measures. The Protocol now has 55 Parties.

The CBD/Nagoya Protocol ABS regime cuts across several other international regimes with sectoral approaches. This has led to turf battles, but also to the advancement of ABS approaches. The FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) is an ABS treaty for one specific type of genetic resources; the Nagoya Protocol provides that other specialized ABS instruments may be developed and may prevail over the Protocol, if they are consistent and do not run counter to the Protocol's objectives. Among other regimes with close relations to the CBD/NP regime are the WHO's Pandemic Influenza Preparedness (PIP) Framework for the Sharing of Viruses and Access to Vaccines and Other Benefits, the WTO Agreement

on Trade-Related Aspects of Intellectual Property Rights (TRIPS), the Union for the Protection of Plant Varieties (UPOV), the UN World Intellectual Property Rights Organization (WIPO) and the United Nations Convention on the Law of the Sea (UNCLOS).

The ABS concept arose from the great demand in the late 1980s for bioprospecting – the examination of organisms, molecules and genes with a view to determining their medicinal, industrial and other values – and thereby high expectations of ‘green gold’. However, the last 20 years have seen rapid developments in relation to the use of genetic resources, changing the initial conditions for the ABS regime. Patenting of biological products and processes has increased. Biotech and pharmaceutical companies have merged into a few big companies, and *ex situ* collections of genetic material have expanded. At the same time, science and technology have developed, implying greater speed, scale and efficiency in research – and in turn requiring lesser amounts of genetic material. Still, more than 50% of pharmaceutical products are derived from genetic resources; and the cosmetic industry, for example, has experienced an increase in the need for genetic resources due to growing consumer interest in natural products and traditional knowledge.

Awareness of and commitment to the ABS regime have generally grown with the Nagoya Protocol, and the basic elements of ABS are widely accepted as standard practice in many industries.

However, even though the ABS regime has been in place for more than 20 years, only 57 countries have enacted ABS legislation of some kind. Besides the complexity of the ABS issue and lack of capacity in developing countries, this may also be due to the ongoing negotiation process towards a final ABS regime.

Very few states have implemented user-country measures to support compliance with provider-country legislation – which was the primary reason for the developing countries’ call for a supplementary ABS agreement to the CBD. Following the Nagoya Protocol, the EU has enacted a Regulation on compliance measures for users from the Nagoya Protocol; more generally, in many countries the Protocol has created new momentum for taking national ABS measures.

Studies of countries with legal and administrative ABS frameworks in place show that these have generated a fairly large number of bioprospecting activities, many of them with benefit-sharing arrangements, but – apparently – few with a commercial intent and thus with few examples and low amounts of *monetary* benefits shared.

Research on the ABS regime has been mainly theoretical, with considerable focus on the international legal implications, the negotiating process and the interaction with other international regimes. Less research has been conducted on ABS in practice. Below are proposals for research areas to fill this gap:

- Actual and potential contribution of ABS to conservation and sustainable use of biodiversity – could ABS serve as payment for

ecosystem services and thereby as an innovative financial mechanism for conservation and sustainable use?

- ABS, equity and standard setting – ABS as a parameter for corporate social responsibility?
- ABS beyond genetic resources – could benefit sharing in a wider context than genetic resources serve as an instrument to address the equity deficit within the green economy?
- Business approaches to ABS – what is the awareness and motivation of businesses to apply ABS and how could awareness and motivation be enhanced?
- Mapping the value chain of genetic/biological material from its collection to an end product.

Acronyms

ABS	Access and Benefit Sharing
BSA	Benefit Sharing Agreement
CBD	Convention on Biological Diversity
CGEN	Genetic Heritage Management Council (Brazil)
CGRFA	Commission on Genetic Resources for Food and Agriculture
DEA	Department of Environmental Affairs (South Africa)
FNI	The Fridtjof Nansen Institute
GR	Genetic resources
GRFA	Genetic resources for food and agriculture
ILCs	Indigenous peoples and local communities
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
IPR	Intellectual property rights
LMMC	Like-minded megadiverse countries
MAT	Mutually agreed terms
MLS	Multilateral system
MTA	Material transfer agreement
NBA	National Biodiversity Authority (India)
NP	The Nagoya Protocol
PIC	Prior informed consent
PGRFA	Plant genetic resources for food and agriculture
R&D	Research and development
TEEB	The Economics of Ecosystems Services and Biodiversity
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UETBT	Union for Ethical Bio Trade
WSSSD	World Summit on Sustainable Development

Preface

The Fridtjof Nansen Institute (FNI) has been commissioned to prepare a report for the PBL Netherlands Environmental Assessment Agency (PBL) that aims at the following topics:

The report looks into the state of the art in access and benefit sharing (ABS) along the following dimensions:

- ABS in environmental governance of genetic resources
- the interaction with other international institutions/agreements in a situation of international institutional complexity
- the role of key actors (users and providers of genetic resources), with special focus on the role of business
- ABS relating to biological resources and conservation of biodiversity.

Central questions here are:

- What opportunities does ABS offer for achieving the CBD objectives of conservation and sustainable use of biodiversity? How is ABS contributing to more equitable biodiversity governance?
- What are best practices in ABS governance among resource users and providers?
- Might ABS have a broader approach and lessons beyond genetic resources?

1 Introduction

‘Genetic resources’ – biological materials of actual or potential value containing functional units of heredity¹– are essential for a significant proportion of the world’s economic activity. They are the basis for improvement of agricultural crops and for development of traditional medicines on which the majority of the world’s population still depend. They are used for a wide variety of purposes ranging from basic research to the development of products in various sectors such as pharmaceuticals, agriculture, horticulture, agriculture, cosmetics and biotechnology. The combined annual global markets for the products derived from genetic resources have been estimated at between USD 500 and 800 billion (ten Kate and Laird, 1999). (See also Table 1.)

Table 1: Market Sectors and the Importance of Genetic Resources²

Sector	Size of total market in 2006	Importance of genetic resources
Pharmaceutical	USD 640 billion	20–25% derived from genetic resources
Biotechnology	USD 70 billion from public companies alone	Many products derived from genetic resources (enzymes, micro-organisms)
Agricultural seeds	USD 30 billion	All derived from genetic resources
Personal care, botanical, and food and beverage industries	USD 22 billion for herbal supplements USD 12 billion for personal care USD 31 billion for food products	Some products derived from genetic resources: represents ‘natural’ component of the market

Source: Greiber et al. 2012. pp. 4–5, based on P. ten Brink, ed., 2011: *The Economics of Ecosystems and Biodiversity in National and International Policy Making*. Abingdon, Routledge.

¹ Definition of genetic resources in CBD Article 2.

² Note: The following figures provide estimates for various categories of products derived from genetic resources. It should be noted that the markets are not entirely based on genetic resources

These markets have created a demand for *bioprospecting* – the examination of organisms, molecules and genes with a view to determine their medical, industrial or other values. Often such bioprospecting has benefited from the traditional knowledge of indigenous peoples and local communities.

Recent examples of bioprospecting activities include studies on:

- hibernating animals and the hormones that prevent them from getting osteoporosis (brittle bones), with a view to developing a drug that could similarly protect humans
- bacteria in extreme environments such as the Arctic Ocean, with a view to developing new antibiotics
- spiders' webs, to learn how to produce stronger materials.
(See Rosendal and Schei, 2012.)

Much rewarding bioprospecting has been carried out. All the same, less than 1% of flowering plants, marine species and microbial diversity have been thoroughly examined for their chemical composition. This richness, and the fact that such a large part of it remains undiscovered, is one reason why biodiversity has been described as the life insurance of humankind (Rosendal and Schei, 2012).

The world's biodiversity is found mainly in the South, whereas the scientific and technological capacity to make use of its genetic resources is found mainly in the North, although this pattern is gradually changing, with some of the world's megadiverse countries also becoming emerging economies. The countries of the South saw the Convention on Biological Diversity as an opportunity to get the benefits derived from their genetic resources fairly and equitably shared. This is further discussed in this report's review of the various international regimes involved in ABS, followed by a review of the state of practical application of ABS.

2 State of the art in access to genetic resources and benefit sharing from their utilization (ABS)

2.1 The Convention on Biological Diversity (CBD)

The 'fair and equitable sharing of benefits arising out of the utilization of genetic resources' is the third of the three overall objectives of the Convention on Biological Diversity (CBD), along with the conservation of biodiversity and the sustainable use of its components. To give effect to this objective, the CBD includes provisions to regulate access to genetic resources and benefit sharing from their use.

The CBD establishes that states, as is the case for natural resources in general, have sovereign rights to genetic resources and that a person or institution seeking access to genetic resources in a foreign country shall apply for prior informed consent (PIC) of the country in which the

resource is located. Moreover, an agreement is to be made on mutually agreed terms (MAT) for access and use of the resource. This includes the sharing of any benefits with the provider as a prerequisite for access and use. Such benefits could include the sharing of results of research on the genetic resource, transfer of technologies which make use of the resource, and monetary benefits when products based on the resource are commercialized.

Provider countries are to create conditions to facilitate access to their genetic resources for environmentally sound use, and should not impose conditions that run counter to the objectives of the CBD.

The actual and potential values at stake are extremely high. The assumption is that well-established national implementation of the ABS regime could serve as an important incentive for conservation and sustainable use of biodiversity.

ABS has always been a controversial and politicized issue in the CBD, with major differences between North and South. Developing countries, often rich in biodiversity and genetic resources, have had high expectations of ABS as a means of avoiding the earlier situation where developed countries practised unrestricted and unrewarded access in order to exploit genetic resources. Developed countries, on the other hand, have seen ABS as an impediment to research and development (R&D).

In the run-up to the 1992 Earth Summit in Rio de Janeiro, most developed countries wanted the CBD to be a straightforward conservation treaty to protect wildlife fauna, flora and habitats by making use of similar approaches as earlier global nature protection treaties. Thus, the first drafts of the Convention text focused mainly on conservation tools such as protected areas and the targeted protection of threatened species. Developing countries, however, were not prepared to consider only conservation aspects in the strict sense. They saw the developed-country focus as a potential impediment to their national development needs and argued for a shift in focus: biodiversity should be viewed as a supplier of goods and services essential to meeting basic human needs – thus the need for including the sustainable use of the components of biodiversity as an objective of the Convention (Rosendal and Schei, 2012). Moreover, the developing countries, conscious of the benefits historically obtained by developed countries from the exploitation of the rich biodiversity of the developing world and aware that their rich biological resources represented a potentially significant basis for future national development, argued for a new regime that could level the playing field. In the early 1990s it was expected that industries in the economically and technologically-rich North – such as pharmaceuticals, agriculture, cosmetics, botanicals horticulture and biotechnology – would increasingly demand access to genetic resources in the biodiversity-rich South.

In parallel to the CBD negotiations, the playing field was becoming more uneven because of comprehensive developments in the law of intellectual property rights. The Agreement on Trade Related Aspects of Intellectual

Property Rights (TRIPS) was concluded as part of the establishment of the World Trade Organization (WTO) in 1993. TRIPS sets minimum standards of intellectual property protection; it also establishes that inventions to be patented will generally include both products and processes in all fields of technology.³ TRIPS *de facto* expands the scope for intellectual property on living material by specifying that plants and animals, but not micro-organisms, may be excluded from patenting, and that member states are required to protect plant varieties, by patents or by an effective *sui generis* system, or a combination of the two.⁴

The TRIPS negotiations did not seek to achieve coordination and mutually supportiveness with negotiations on the CBD regime on ABS. Therefore, the developing countries, concerned about how the extended rights to patent living material would affect their rights to benefit sharing, insisted on clear recognition of national sovereignty over genetic resources to level this asymmetry. In previous years, they had moved in the opposite direction, trying to maintain the ‘common heritage’ approach to genetic resources in the non-legally binding FAO 1983 International Undertaking on Plant Genetic Resources for Food and Agriculture, which specified that plant genetic resources should be available without restrictions for plant breeding, scientific and development purposes to all countries and institutions. This was, however, rejected by the developed countries through the reinterpreted Undertaking of 1989, which aimed at accommodating intellectual property rights and thus waiving the common heritage principle for systematically bred seeds (Pistorius, 1997; Pistorius and van Wijk, 1999; Raustiala and Victor, 2004; Rosendal, 2000).

The developing countries considered the arrangement to be unequal and unjust. Moreover, since they are home to the greater part of global biodiversity, it also reduced the incentive of biodiversity-rich developing countries to conserve and sustainably use their biodiversity (Prip et al., 2010).

By contrast, most developed countries long resisted the inclusion of ABS in the CBD, fearing that this would prevent them from enjoying their *de facto* free access to genetic resources in countries of the South.

In the end, the approach of the South largely prevailed. The CBD can be viewed as a paradigm shift in nature conservation – a change of focus from the protection of threatened species and habitats, towards the recognition of biodiversity as an important component of sustainable development. The Convention reflects several elements generally deemed important for sustainable development (Koester, 2006), including

³ TRIPS Article 27.1

⁴ TRIPS Article 27.3(b). Some felt that an effective *sui generis* system was provide for under the already existing Plant Breeders’ Rights established by the International Convention for the Protection of New Varieties of Plants adopted in 1961, which entered into force in 1969 and was revised in 1972, 1978 and 1991. The Convention also established the International Union for the Protection of New Varieties (UPOV) and is generally referred to as the UPOV Convention.

- sustainable use of natural resources (components of biodiversity) (second objective of the Convention and Article 10)
- integration of biodiversity concerns across economic sectors (Articles 6(a) and 10(a))
- inter-generational equity (included in the definition of ‘Sustainable use’ in Article 2⁵ and the Preamble)
- intra-generational equity (third objective and Articles 8 (j), 15, 16, 19, 20 and 21).

The intra-generational equity principle is particularly important in this context. It is directly reflected in the third objective of the CBD on fair and equitable benefit sharing, which has come to be perceived as not only serving equity in itself but also as a necessary incentive for achieving the first two objectives of conservation and sustainable use.⁶

This third objective is to be reached through reconfirmation of national sovereign rights to genetic resources and a requirement for PIC and MAT (Art. 15) coupled with the commitment of states to take steps to facilitate access.⁷ The third objective is further reflected in provisions for transfer of technology relevant for conservation and sustainable use of biodiversity on most favourable terms (Art. 16), access to the results and benefits of biotechnology (Art. 19(1 and 2)) and on the protection of traditional knowledge held by indigenous and local communities (Art 8(j)).

2.2 From the CBD to the Nagoya Protocol (NP)

ABS remained a controversial issue after the entry into force of the CBD in December 1993. Discussions under the CBD on how to follow up ABS provisions primarily centred on how to operationalize access (Wallbott et al., 2014). Little attention was paid to benefit sharing or to promoting compliance with countries’ access regulations, to the discontent of developing countries. Moreover, they were repeatedly unsuccessful in their efforts in the WTO TRIPS Council to obtain mutual supportiveness between the global ABS and IPR regimes through the imposition of requirements for disclosure of origin of genetic resource in patent applications as a tool for tracking compliance with provider-country access regulations. Developing countries reported many cases of alleged misappropriation of genetic resources (‘biopiracy’) – typically involving

⁵ ‘[...] use in a way that and at a rate that does not lead to the long-term decline of biological diversity, thereby maintaining its potential to meet the needs of present and future generations’.

⁶ The principle of intra-generational equity is also reflected in Articles 20 and 21 with commitment of developed countries to provide new and additional resources to the financial mechanism of the CBD for implementation of the CBD in developing countries. This again reflects another component of sustainable development, the principle of common but differentiated responsibilities.

⁷ While developing countries rejected that biodiversity should be considered as the ‘common heritage’ of humankind, they accepted that conservation of biodiversity is of ‘common concern’ for humankind, implying common responsibility for the issue because of its paramount importance to the international community as a whole (Glowka et al., 1994).

inventions based on genetic resources and associated traditional knowledge that were patented without the prior informed consent of the provider country and/or the community holding the knowledge (Oberthür and Rosendal, 2014).

The level of national implementation of ABS remained low. Nearly all domestic implementation steps actually taken were provider-country measures to regulate access to their genetic resources (Greiber et al., 2012). Very few countries took steps to ensure that genetic resources utilized within their jurisdiction were accessed in accordance with prior informed consent and mutually agreed terms – steps mostly relevant for developed countries as users of genetic resources. For these reasons, developing countries argued for a protocol to complement the CBD, with clear legal obligations for ‘user countries’ to take measures to support compliance with provider-countries’ access regulations (Wallbott et al., 2014). The developed countries resisted; as a compromise, a set of voluntary guidelines, ‘the Bonn Guidelines’, was adopted in 2002.

Later that year, the newly founded group of ‘Like-Minded Megadiverse Countries (LMMC)⁸ – still dissatisfied with the Guidelines’ non-binding nature and limited attention to user-country measures – succeeded in getting the World Summit on Sustainable Development (WSSD) in Johannesburg to adopt a recommendation to ‘negotiate within the framework of the CBD an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources’⁹ (Wallbott et al., 2014).

The Johannesburg commitment was taken up by the CBD. There ensued a long and complicated negotiating process that was not completed until the final hours of CBD COP 10 in Nagoya 2010, when the Japanese COP Presidency presented a ‘take it or leave it’ compromise text of a Protocol. The Parties adopted the Protocol¹⁰ as part of a ‘Nagoya Package’ including also the CBD Strategic Plan 2011–2020, the ‘Aichi Targets’¹¹, and a global strategy for resource mobilization for biodiversity.¹² The package not only balances the interests of developing and developed countries (with developing countries demanding the NP for ABS and the resource mobilization strategy, and developed countries demanding the Aichi Targets), it also places ABS and the third objective of the CBD as integrated with the other objectives instead of having a separate life.

The North–South (provider–user) controversy was less explicit during later NP negotiations. This reflected a trend towards increased *multi-polarity* that characterizes other areas of global environmental politics as well. In the NP negotiations, the Global South split into four coalitions, although their interest structures were predominantly the same (Wallbott

⁸ The group consists of Bolivia, Brazil, China, Colombia, Costa Rica, Democratic Republic of the Congo, Ecuador, India, Indonesia, Kenya, Madagascar, Malaysia, Mexico, Peru, Philippines, South Africa, Venezuela,

⁹ Johannesburg Plan of Implementation, para 44(o).

¹⁰ UNEP/CBD/COP/DEC/X/1

¹¹ UNEP/CBD/COP/DEC/X/2

¹² UNEP/CBD/COP/DEC/X/3

et al., 2014).¹³ Possibly as a result of this lack of unity, the countries of the Global South played a lesser role than in the negotiations of the CBD and were less successful in achieving their main objectives in the NP than in the CBD. The Protocol appears to reflect to a rather large degree the preferences of ‘moderate’ developed countries, represented mainly by the EU (Oberthür and Rabitz, 2014) and Switzerland (Hufty et al., 2014), although the final outcome can still be described as a mixture of wins and losses for developing (provider) and developed (user) countries.

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

The Protocol entered into force 14 October 2014 and to date has 55 Parties. The key elements of the Protocol are examined in the following.

Until the very end of negotiations, the *scope* of resources to be covered remained a controversial issue – particularly the question of how *derivatives* should relate to prior informed consent and mutually agree terms. Examples of derivatives are aromas, biochemicals in cells, and snake venoms – compounds that are the basis of a wide range of medicinal, food and cosmetic products and are often the real source of benefits (Greiber et al., 2012). The developing countries insisted that the Protocol should apply not only to the genetic resources themselves but also to their derivatives, whereas the developed countries resisted an expansion of the CBD scope. It is generally held that establishing that the Protocol applies to ‘utilization of genetic resources’ (Art. 3, 5(1), 6(1) and 17(1)) combined with the definition of the term in Article 2(c) (‘to conduct research and development on the genetic and/or chemical composition of genetic resources, including through the application of biotechnology as defined in Art. 2 of the Convention’) has placed provider countries in a position to regulate R&D on both the genes themselves and what could be derived from them.¹⁴

The developing countries were also successful in resisting the strong developed-country position to exclude one particular type of genetic resources, *pathogens*, from the scope of the NP. Based on the halt from Indonesia in providing access to avian influenza virus to be used for vaccine development (unless they would also have access to the resulting vaccine), the developed countries feared that the approach to ABS in the Protocol could undermine effective responses to health concerns, particularly in situations of pandemic threats. The compromise reached

¹³ The four groups were the Like-Minded Megadiverse Countries (LMMC), the Like Minded Asia-Pacific Countries (LMAPC), the African Group and the Group of Latin American and Caribbean Countries. While their main positions were generally aligned, they had slightly different priorities. LMAPC, for example, was deeply concerned with indigenous and local communities and their traditional knowledge, whereas the African Group strongly advocated for a global multilateral benefit-sharing mechanism that should receive the benefits from the use of genetic resources for which PIC was not available. (Walbott et al., 2014)

¹⁴ Article 2(e) defines the term “derivative”. However, it does not appear in the Protocol outside the definition.

involves the obligation for countries to pay due regard to such situations in developing and implementing domestic ABS frameworks (Art. 8(b)), by providing for differentiated procedures in case of pathogens: simplified access to the material and also simplified access to the resulting vaccine.

Closely linked to scope, another controversial issue was whether the NP should allow for the establishment of *sector-specific ABS regimes* like the FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) (Oberthür and Rosendal, 2014). This core demand by developed countries was accepted, with the qualification that such alternative ABS regimes are consistent with and do not run counter to the objectives of the NP and the CBD (Art 4.3). When a specialized ABS instrument is in place (like the ITPGRFA with its multilateral ABS system) that instrument is to prevail over the NP (Art.4.4).

As noted, the developing countries saw provisions to support *compliance* with domestic ABS legislation as the cornerstone of a Protocol to prevent and react to future cases of misappropriation of genetic resources and associated traditional knowledge. The NP includes an obligation for Parties to take measures, providing that genetic resources have been accessed in accordance with PIC and MAT if this is required by the providing country (Art. 15.1) thereby expanding and reinforcing the requirements under the CBD. Parties are furthermore required to address non-compliance with these user measures (Art.15.2).

To support compliance, countries shall designate one or more *checkpoint(s)* for collecting relevant information on PIC and MAT (Art 17.1). Further, the Protocol establishes an internationally recognized certificate of compliance to serve as evidence that genetic resources have been acquired legally (Art. 17.2 and 3).

In the NP negotiations, provider countries failed once again to achieve recognition of their long-standing demand for a mandatory *disclosure* requirement regarding genetic resources in patent application as a tool for enhancing compliance.

In return for accepting the obligations to support compliance, the developed countries insisted that provider countries should be obliged to ensure the *legal certainty* of their access legislation and procedures. A Party providing genetic resources must take various measures ('access standards'), as appropriate, to provide the user with clarity as to the requirements and the various steps involved in the process of obtaining access (Art. 6.3).¹⁵

Concerned that the NP could create burdens and obstacles to conducting research related to genetic resources, developed countries also achieved the inclusion of a provision for *simplified measures* on access for non-

¹⁵ The Nagoya Protocol Art. 6(1) as well as the CBD Art. 15(5) of the CBD give Parties the option *not* to regulate access to domestic genetic resources. Several EU member States are likely to make use of this option.

commercial research ‘taking into account the need to address a change of intent for such research’ (Art. 8a).

Besides user-country measures to support compliance, the provisions on *traditional knowledge* associated with genetic resources are probably the most innovative. The Protocol significantly enhances the protection of the holders of traditional knowledge in international law (Buck and Hamilton, 2011). Parties are required to take measures aimed at ensuring that traditional knowledge associated with genetic resources and held by indigenous and local communities (ILCs) is accessed with their PIC and with MAT (Art. 7). Parties are also obliged to consider the role of customary law and community protocol in their implementation of the NP (Art. 12.1), and to take measures to enable the sharing of benefits from the use of traditional knowledge with the holders (Art. 5.5). Finally, in parallel with user-country measures on compliance with national access legislation, Parties shall also take measures to support compliance with PIC and MAT from ILCs if this is required by domestic legislation (Art. 16.1).

2.4 Interaction and complexity: ABS and other international regimes

The CBD/Nagoya Protocol ABS cuts across several other international regimes. These often have sectoral approaches, with other ministries/agencies as national competent authorities having other interests to defend and often with more power than the environment ministries normally responsible for the CBD/Nagoya Protocol. This has led to turf battles between the regimes themselves and between and within countries as to which regime is to prevail. Still, the general CBD/NP regime may also have advanced an ABS approach in other forums and sectors (Oberthür and Pozarovska, 2014).

In the following we examine some of the international regimes most relevant to ABS.

2.4.1 The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)

ITPGRFA came into force in 2004 and is administered by FAO. It has 134 Parties and provides for a specialized ABS instrument in accordance with Article 4(4) of the NP, and thus prevails over the Protocol.

ITPGRFA was developed as a result of and with objectives mirroring the CBD – the conservation and sustainable use of plant genetic resources for food and agriculture (PGRFA), and the fair and equitable sharing of benefits derived from their use. However, it differs from the CBD/NP approach by introducing a Multilateral System (MLS) under which over 64 major crops and forages are regarded as a common pool from which genetic resources may be freely accessed. The Treaty is meant to provide for benefit sharing through information exchange, access to and transfers of technology, capacity building and voluntary monetary benefits – the latter either in the form of voluntary contributions to a benefit-sharing fund, or compulsory contributions in certain cases of commercialization

and restriction of the use of a product derived from MLS material.¹⁶ The obligation to share benefits is not in favour of the provider, but of the multilateral system, and the free exchange of genetic resources is viewed as a benefit in itself. (Chiarolla et al., 2013; Dedeurwaerdere et al., 2013.)

The background for the FAO system with free access is the important role of plant genetic resources in providing food for a growing world population. The rationale for decoupling benefit sharing from the provider and the resources accessed stems from the incremental improvement and multiple sources characterizing seeds and plant breeding; this means that there is high interdependence among providers and users in plant breeding (Morgera et al., 2012). Incremental improvement, multiple sources and interdependence all indicate that there is not one, single, end-product linked to the accession and that it is hard to identify a source country: a provider may become a user, and vice versa (Schloen et al., 2011; Chiarolla et al., 2013). PGRFA have been widely exchanged across communities, countries and regions, leading to a situation in which a significant part of the genetic resources used in food and agriculture are of exotic origin. This makes it difficult to draw a clear line between provider and recipient countries, and providers are seen as gaining more by having access to all the resources than by restricting access to their own (See Chiarolla et al., 2013; Dedeurwaerdere et al., 2013.) Thus, a need was seen for a regime to promote exchange of crops and their genes with as few restrictions as possible. For plant genetic resources for food and agriculture not covered by the MLS, the CBD/Nagoya Protocol provisions on access and benefit sharing apply.

ITPGRFA recognizes ‘Farmers’ Rights’ – the invaluable contributions that farmers and their communities have made and continue to make to the conservation and development of plant genetic resources. This includes the protection of traditional knowledge and the right to participate equitably in benefit sharing and in national decision-making about plant genetic resources.

The Multilateral System is generally considered to be functioning well as regards the free exchange of PGRFA. Statistics from March 2015 show that approximately two million samples of material have been transferred through the system using its Standard Material Transfer Agreement (SMTA).¹⁷ However, as of 2013 the MLS had received no money from benefit sharing – voluntary or compulsory – from companies (Chiarolla, 2013).

The relationship between the main ABS regime under the CBD/NP and the ITPGRFA remains controversial. Developed countries actors view the Treaty as a clear success and have been seeking to extend the scope of the Multilateral System (MLS) to include *in situ* material as well as wild relatives of listed plants, and to increase the number of species on the list.

¹⁶ ITPGRFA 13.2(d) and Standard Material Transfer Agreement (<ftp://ftp.fao.org/ag/agp/planttreaty/agreements/smta/SMTAe.pdf>).

¹⁷ ITPGRFA website: <http://www.planttreaty.org/news/statistics-germplasm-flows-multilateral-system-go-online>

By contrast, several developing countries and NGOs are concerned: the benefit-sharing arrangement of the MLS is decoupled from the provider, and apparently very few monetary benefits have been generated through the System (Chiarolla, 2013). Moreover, they consider ‘free’ access to PGRFA to be rather illusive as long as the system allows private appropriation of resources through intellectual property rights.

2.4.2 *FAO Commission on Genetic Resources for Food and Agriculture (CGRFA)*

Article 4(2) of the NP allows for the development of specialized ABS agreements in the future, as long as they are supportive of and do not run counter to the NP. If the international community agrees to develop such agreements, these are likely to emerge under the auspices of CGRFA and cover all or some of the genetic resources for food and agriculture (GRFA) not already covered by the ITPGRFA, including animal genetic resources. The CGRFA has concluded that the time is yet not ripe for such agreements and has instead developed guidelines to support countries in designing national measures that implement ABS for GRFA.¹⁸

Also on this topic opinion is divided. A general argument is that the diversity in types of genetic resources and their uses is so great that a ‘one size fits all’ approach to regulatory frameworks may be difficult to implement, and could have negative consequences for providers and users alike (Laird and Wynberg, 2012). It is held that a common-pool approach to ABS applied to plant genetic resources in the ITPGRFA that differs from the provider–user approach of the CBD/NP regime may be equally important for also other GRFA from a food-security perspective (Chiarolla et al. 2013). Against this, it is argued that jumping quickly to specialized ABS agreements would be ‘throwing the baby out with the bathwater’ and would lead to fragmentation of what is covered by the general ABS rules even before the Nagoya Protocol has had a chance to work in practice (Tvedt, 2014). Viewing ABS a mechanism to counterbalance intellectual property rights, some fear that the balance would tip in favour of IPRs and thereby in favour of powerful developed-country actors seeking to circumvent benefit sharing and challenge the existing ABS regime (Rosendal and Andresen, 2014.). Moreover, the utilization of genetic resources in farm animals, forest trees, aquatic, micro-organisms, and invertebrates follows different patterns from plant seeds: there is less or no incremental improvement involved (particularly not for micro-organisms and invertebrates), and generally far less dependency on multiple sources or interdependence among users (Medaglia et al., 2013).

¹⁸ See Earth Negotiations Bulletins report from the CGRFA meeting 19–23 January 2015. <http://www.iisd.ca/download/pdf/enb09650e.pdf>.

2.4.3 *World Health Organization (WHO)*

As noted, a controversial question during the NP negotiations was whether genetic resources in the form of pathogens should be exempted from the Protocol. Citing the halt on the part of Indonesia in providing access to avian influenza virus to be used for vaccine development, some developed countries feared that the bilateral approach to access and benefit sharing in the NP could undermine effective responses to health concerns particularly in situations of pandemic threats. Indonesia was the first country to report human infections with this particular virus strain and had previously shared virus samples with the WHO for surveillance and research purposes. However, after learning that an Australian company was applying for a vaccine patent developed on the basis of these samples, Indonesia refused to submit further samples (Wilke, 2013).

Pathogens are not exempted from the scope of the Nagoya Protocol, but countries are to pay due regard to such situations in developing and implementing domestic ABS frameworks (Art. 8(b)). Also, the NP is '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' (Nagoya Protocol, Preambular para. 17).

In parallel to the NP negotiations on whether to exempt pathogens from the scope, the Indonesian refusal to submit viruses led to accelerated work in the WHO to develop a new global mechanism for virus sharing in cases of global pandemic influenza, a mechanism that would be fairer to poorer countries (Greiber et al., 2012). This resulted in the Pandemic Influenza Preparedness (PIP) Framework for the Sharing of Viruses and Access to Vaccines and Other Benefits in 2011, aimed at better protection against pandemic influenza by improving and strengthening the WHO global influenza surveillance and response system. Further, the objective of the PIP Framework is a fair, transparent, and equitable system for sharing influenza viruses with human pandemic potential, and for access to vaccines and the sharing of other benefits. The PIP Framework is an example of the CBD/NP ABS approach 'spilling over' to a particular sector regime, with scope for mutual supportiveness with the NP rather than turf battles and forum shopping.

2.4.4 *International fora on intellectual property rights (TRIPS, WIPO and UPOV)*

The connection between the ABS regime and intellectual property rights (IPR) regimes is a particularly controversial issue. The reinforcement of national sovereignty to genetic resources as a backbone of the ABS regime was largely to counterbalance the rapid evolution in modern biotechnology and with that patenting of living material at a time where the question of access to genetic resources had otherwise moved in the direction of a 'common heritage of mankind' approach with open access. Developing countries saw patents and other IPRs as enabling firms in the developed countries to access their genetic resources without compen-

sation, while also imposing a high price for ‘reintroduction’ of the patented products based on the resources.

The IPR development was enshrined in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), one of the pillars of the World Trade Organisation (WTO). Leading developed countries were reluctant to address the interrelationship between the ABS regime and TRIPS both in the CBD and the NP negotiations and vice-versa in the TRIPS Council. Except for a very general and qualified stipulation in the CBD that IRPs should support and not run counter to the objectives of the CBD,¹⁹ there are no provisions in the CBD, NP or TRIPS to the effect that patents or other IPRs shall respect prior informed consent and mutually agreed terms for access to genetic resources.

Developing countries in the TRIPS Council have attempted to promote mutual supportiveness between the two regimes by proposing an obligation to disclose the country of origin of genetic resources and associated traditional knowledge in patent applications. This is meant to serve as a tool for tracking compliance with provider-countries’ access requirements; however, despite increasing support from developed countries, other countries – mainly the USA – have obstructed adoption of the proposal. On the other hand, this has not prevented countries like Norway, Switzerland, Denmark and Belgium from introducing such a disclosure requirement in their national IPR legislation.

Plant Breeders’ Rights is another type of IPR that has been widely discussed in relation to ABS. It derives from the emergence of breeders as a profession distinct from farmers and the fact that plant material is self-replicating, making it easy to use breeder-innovated plant varieties freely. The Union for the Protection of Plant Varieties (UPOV) was established in 1961 with a Convention that created a new form of IPR, intended to provide breeders with exclusive rights to the propagating material of new plant varieties such as seeds.²⁰ A breeder’s exemption allows access to protected material for research, for further breeding and for non-commercial use by farmers. Under the original UPOV Convention farmers were allowed to retain seeds for their own use and for non-commercial exchange (Farmers’ Privilege). However, the 1991 revision of the UPOV Convention brought a strengthening of breeders’ rights in the direction of patent protection, creating similar conflict points with the ABS regime as those created by TRIPS.

The UN World Intellectual Property Rights Organisation (WIPO) is a third IPR forum relevant in this context. In 2000, WIPO established the Intergovernmental Committee on Intellectual Property and Genetic Resources (IGC)²¹. For many years mainly a forum for policy dialogue, in 2009 the IGC was mandated to begin formal negotiations aimed at

¹⁹ CBD Art. 16.5: ‘The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.’

²⁰ <http://www.upov.int/portal/index.html.en>

²¹ <http://www.wipo.int/tk/en/igc/>

reaching agreement on one or more international legal instrument(s) to ensure the effective protection of genetic resources, traditional knowledge and traditional cultural expressions. Such an instrument or instruments could range from a recommendation to WIPO members to a formal treaty that would bind the countries that ratified it. However, progress has been limited, due to the division of opinions between typical provider and user countries – as in the CBD/NP context (Vivas-Eugui, 2012).

2.4.5 *United Nations Convention on the Law of the Sea (UNCLOS)*

Marine genetic resources found in areas beyond national jurisdiction (ABNJ) are outside the scope of the CBD and the NP. The legal framework to regulate activities in ABNJ is the UN Convention on the Law of the Seas (UNCLOS) which entered into force in 1994. Since UNCLOS itself does not specifically address genetic resources, the issue has been taken up in several UN General Assembly resolutions and is also discussed under UNCLOS by an ‘Ad Hoc Open-ended Informal Working Group to study issues relating to the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction’. At its meeting 20–23 January 2015, the group decided on a recommendation to UNGA to develop a legally binding instrument on the conservation and sustainable use of marine biological diversity in ABNJ²², and 19 June 2015 UNGA followed the recommendation.²³ Although this general mandate reflects only the two first objectives of the CBD, the recommendation specifies that genetic resources, including questions of benefit sharing, are also included (Para. 1(f)).

The interaction between the CBD/NP ABS regime and the above-mentioned international instruments and processes to enhance policy coherence has been extensively examined by many scholars.²⁴

2.5 **Perceptions of ABS by the business sector and other non-state actors**

Non-governmental actors have played a prominent role in ABS negotiations, as has generally been the case in the CBD – also when compared to other international environmental negotiations (Orsini, 2014).

Throughout the ABS negotiations, as well as in related international arenas such as WIPO and WTO, the business sector was influential in affecting the positions of the developed countries. Its overarching objective was to minimize legally binding requirements as much as possible, including the Nagoya Protocol as such (Orsini, 2014). However, with growing awareness of the ABS concept (which for many years had

²² http://www.un.org/depts/los/biodiversityworkinggroup/documents/ahwg-9_report.pdf

²³ UNGA/RES/69/292.

²⁴ Generally, see: Rosendal, 2001 and Rosendal and Andresen, 2014. On ITPGRFA and sector approaches to ABS, see: Pistorius, 1997; Chiarolla et al., 2013; Dedeurwaerdere et al., 2013, Medaglia et al., 2013; Tvedt, 2014. On WHO: See Wilke, 2013. On IPRs: Posey and Dutfield, 1996; Rosendal, 2006; Swanson, 1995; Medaglia, 2010; Tvedt, 2010; Pavoni, 2013. On UNCLOS: See Salpin, 2013.

been quite low in the business sector), increased naming and shaming by NGOs of ‘biopirates’ and greater consumer demand on business to perform according to socially and environmentally responsible standards, the sector has gradually become more mindful of and receptive to ABS. An indicator of this is the emergence of the Union for Ethical Bio Trade (UETBT), launched in 2007 as a non-profit association, to promote the ‘Sourcing with Respect’ of ingredients that come from biodiversity.²⁵ The UETBT has set a positive business tone, which indicates that, by providing a clearer and more level playing field, the Protocol does not only create burdens for companies, but also opens up opportunities for companies already working towards ethical practices in their sourcing of biodiversity.²⁶ The UETB also sets some basic conditions for supportive involvement of business. Legal clarity is a key condition that ranks low in existing national ABS frameworks, according to the UETBT; differentiation in the ABS frameworks between various uses of genetic resources is another.²⁷ Generally, the business sector has favoured flexibility and minimal bureaucracy in national ABS frameworks.

Indigenous peoples and local communities (ILCs) were another non-state actor highly influential in the negotiations (Orsini, 2014). ILCs traditionally have a standing in the CBD that is much higher than under other multilateral environmental agreements because of the close interdependence between ILC livelihoods and biodiversity. The ILCs succeeded in shifting the legal fence poles in the NP and gaining new recognition of their rights as holders of genetic resources and associated traditional knowledge. Other NGOs – including big international NGOs like the IUCN and the WWF – played a more modest role in the process.

The scientific community was less vocal in the ABS negotiations than the two other non-state actors even though it may have had the most critical perception of ABS, with serious concerns about the implications for non-commercial research. In the end this community was influential in introducing NP Art 8(a) on simplified procedures on access for non-commercial research purposes (Burton, 2013).

²⁵ <http://ethicalbiotrade.org/>

²⁶ UEBT briefing note on the Nagoya Protocol. <http://ethicalbiotrade.org/dl/benefit-sharing/UEBT-ABS-Nagoya-Protocol.pdf>

²⁷ Discussion note prepared by UEBT, 2014: “Business perspectives on ABS implementation: Key challenges and possible approaches” for the ABS dialogue seminar, “Key challenges and practical ways forward for the implementation of the Nagoya Protocol”, 4 to 6 August 2014, Goa.

3 ABS in practice

3.1 Background

From the entry into force of the CBD, much of the focus on ABS has been on clarification and interpretation of the concept and on addressing disagreements in this interpretation, mainly a North/South divide. This has also been the primary perspective of researchers. From around 2000 most efforts concerned negotiating ABS follow-up frameworks – first the Bonn Guidelines, followed by the ‘international regime’ mandated by the Johannesburg Plan of Action in 2002, which became the Nagoya Protocol adopted in 2010. Limited attention was paid to whether and the extent to which ABS has been applied in practice and with what impacts. Lately there has been increasing research interest in this area, an interest likely to grow further with the entry into force of the Nagoya Protocol and the focus on its implementation.

The following will attempt to provide an overview of ABS implementation and application based on the relatively limited sources available.

3.2 Trends in use of genetic resources

Some detailed studies of the actual use of genetic resources in various sectors have been conducted: ten Kate and Laird in 1999 published *The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit-Sharing*, with a comprehensive study of industrial sectors using genetic resources. The 2008 CBD report *Access and Benefit Sharing in Practice: Trends in Partnership across Sectors* by Laird and Wynberg includes an overview of key industry sectors and several case studies. In 2012 the CBD Secretariat issued a series of reports titled *Bioscience at a Crossroads: Implementing the Nagoya Protocol on Access and Benefit Sharing in a Time of Scientific, Technological and Industry Change*, again authored by Laird and Wynberg. In addition to a report on general trends, the series consists of reports on six sectors: cosmetics, industrial biotechnology, botanicals, agriculture, pharmaceuticals, and food and beverage. In the following some trends are summarized:

The intense attention paid to ABS during the CBD negotiations was closely related to the demand from pharmaceutical companies for collecting large numbers of plant and other samples in nature for mass screening, with that an expectation of huge benefits to be shared. However, in the following decades significant changes in science and technology led to a declining interest in field-based bioprospecting for pharmaceuticals and other industries. Most pharmaceutical companies terminated their internal natural products programmes. This development – combined with a surge in the patenting of biological products and processes and the proliferation of mergers and acquisitions, changing how genetic resources were owned and accessed by industry – resulted in less substantial benefit sharing than expected (Laird and Wynberg, 2012). Some have also seen the CBD ABS regime in itself as a deterrent to

bioprospecting, as users perceive it as cumbersome and bureaucratic (Robinson, 2015: 16).

On the other hand, it has been estimated that more than 50% of pharmaceutical products today are derived from genetic resources or inspired by natural compounds – indicating that pharmaceutical products may still hold a great potential for benefits to be shared (Pisupati and Bavikatte, 2014).

Extensive *ex-situ* collections have been developed (for instance as gene banks or herbariums) with material collected over a very long time but with no or unclear access regulations, thus also reducing the demand for access to field collections.

Another trend is the increasing role of universities and the decreasing role of industry in preliminary research. This means that industry may decide to leave the risks and costs of bioprospecting to the public sector, becoming involved through licensing and purchasing only when interesting compounds have been identified. (See Robinson, 2015; Prip et al., 2014.)

Finally, mention should be made of the shift in research attention towards micro-organisms in industries such as pharmaceuticals, agriculture, biotechnology and food. Genomes of micro-organisms can be more easily sequenced than those of plants or insects; moreover, micro-organisms share considerable genetic material, so that an interesting compound found in one location may be found also in micro-organisms on the other side of the world. (See Laird and Wynberg, 2012: 5.)

The cosmetics and personal care sector is an example of an industry with expanding ABS potential due to the significant growth of natural ingredients in its products, where traditional knowledge is often involved. That also makes the sector highly vulnerable to allegations of biopiracy (Laird and Wynberg, 2012).

3.3 ABS case studies

For many years, ABS case studies were very few, and the same cases were quoted again and again. Laird and Wynberg (2008) presented seven cases; recently a series of eight new case studies has been presented in Robinson (2015). Some of the best known and most cited cases are:

3.3.1 The Merck/InBio agreement

In 1991 the US multinational company, Merck & Co Pharmaceutical and the Costa Rican National Institute of Biodiversity (InBio) entered into an agreement. InBio was to provide genetic resources for drug research for which Merck would have exclusive rights to develop. In return, Merck would pay approx. USD 1 million as well as royalties for any drug developed. The establishment of protected areas, training local parataxonomists and institutional capacity building was also part of the deal (Rosendal, 2000). The case has been seen as a clear example of how bioprospecting contracts can help to conserve biodiversity and promote

sustainable development by empowering the local workforce and creating well-established mechanisms for distribution of funds. However, the ‘blockbuster’ drug was never found – the drug that could have generated large monetary benefits to be shared. This case is also an example of the trend towards less dependence on bioprospecting and natural products in pharmaceuticals, as discussed above: in 2008, Merck abandoned its search for new drugs in nature, shifting its attention to synthetic compounds and vaccines instead (Conniff, 2012).

3.3.2 *The Teff case*

The cereal crop teff is one of Ethiopia’s most significant crop species. The grain is gluten-free and has various other attributes of interest to the food industry. In 2005, a ten-year ABS agreement for the further breeding and development of teff was made between the Ethiopian-based Institute of Biodiversity Conservation, the Ethiopian Agricultural Research Organisation, and the Netherlands-based company Health and Performance Food International. In return, the Dutch company was to share substantial benefits with Ethiopia. The agreement was hailed as one of the most advanced of its time. However, Ethiopia received practically no benefits, since the company was declared bankrupt in 2009 – and also transferred a patent obtained on the processing of teff flour in Europe to new companies set up by the same owners. (For details, see Andersen and Winge, 2012.)

3.3.3 *The Hoodia case*

This case from the early 2000s involves the commercial development of the succulent plant Hoodia as an appetite suppressant, and the range of ABS agreements involving the multinational consumer company Unilever, the British phyto-medicine company Phytopharm, the South African Council for Scientific and Industrial Research, commercial Hoodia growers, and the indigenous San peoples of southern Africa. Hoodia has long been used by the San to stave off hunger and thirst, but this knowledge was not acknowledged in the initial patent application for the appetite suppressant. However, two benefit-sharing agreements (BSAs) have subsequently been developed for sharing profits with the San. The Hoodia case demonstrates the importance of prior informed consent, the complexities of regulating ABS when the resource is used both as a genetic resource and as a raw material, and the difficulties of implementing benefit sharing in marginalized communities that lack institutional capacity. The case has been a success in the sense that it has aroused wide-ranging interest about the importance of protecting traditional knowledge and ensuring that the holders of such knowledge receive fair compensation. At government level, the case has led directly to a greater focus on biodiversity and its potential value – and in South Africa, to the inclusion of prior informed consent and benefit sharing within new biodiversity legislation and the requirement of disclosure of origin prior to the granting of patents. At the international level, the case is widely seen as having set precedents for compensating holders of traditional knowledge (Laird and Wynberg, 2008).

3.4 ABS domestic legislation

The ABS regime will not function unless the parties enact legal measures to fulfil their treaty obligations at the national level and capacity built to manage these measures. Such measures need to address access as well as benefit sharing and compliance. Users need legal certainty in provider countries when accessing genetic resources and provider countries need effective legal measures in user countries to ensure that they comply with benefit-sharing and otherwise do not misappropriate or misuse genetic resource or associated traditional knowledge. This has been the case ever since the CBD entered into force in 1993,²⁸ and is unambiguously established by the Nagoya Protocol.

At the time of entry into force of the Protocol, 57 countries (40 developing countries and 17 developed countries) had enacted some kind of domestic legal ABS measures, according to the CBD Secretariat.²⁹ Here it should be noted that the emerging economies and megadiverse countries Brazil, China, India and South Africa have all enacted fairly comprehensive ABS legislation (see below on Brazil, India and South Africa).

The arguably low level of national implementation can be attributed largely to the complex subject matter of ABS, its potentially far-reaching impact on uses of genetic resources, as well as the arguable lack of detail in CBD provisions on ABS (Buck and Hamilton, 2011). The ongoing ABS negotiating process after the CBD entered into force may also have postponed national implementation in anticipation of a more detailed international ABS regime to come. Moreover, the developing countries became de-motivated in their implementation efforts because of the longstanding reluctance of the developed countries to apply user-country measures in support of compliance. The developed countries have argued the converse: that their reluctance was influenced by the lack of access legislation in provider countries which user-country legislation could relate to (Prip et al., 2010).

The first instances of domestic access legislation were generally considered to be bureaucratic, with a protectionist approach aimed at preventing biopiracy rather than incentivizing bioprospecting. The early ABS legislation of the Philippines is often cited as an example of this approach – but the Philippines is also a country that amended its legislation in a more flexible direction on realising that this legislation had a deterrent rather than an incentive effect on bioprospecting activities and was restricting the prospects of benefit-sharing (ten Kate and Laird, 1999; Smagadi, 2005).

The restrictive conditions for access to genetic resources imposed by some countries could be explained as a reaction to the reluctance of

²⁸ According to CBD Article 15.7 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.”

²⁹ <http://www.cbd.int/abs/measures/groups.shtml>

developed countries to adopt user-country measures to support effective benefit sharing and compliance in provider countries by researchers and companies under their jurisdiction (Morgera et al., 2013, Introduction). Before the entry into force of the NP, only a very few countries had enacted such user-country measures and these mainly pertained to disclosure of origin of genetic resources (and in some cases also associated traditional knowledge) in patent applications. Only one country – Norway – moved beyond disclosure and actually prohibited the import and utilization of genetic resources acquired without or in violation of prior informed consent of the provider country. The Norwegian legislation is further described below.

In preparation of their ratification of the NP, more countries have now enacted user-country measures – most notably the EU on behalf of its 27 member states, as described below.

Generally, the adoption of the NP in 2010 has created a momentum that has speeded up national implementation efforts – with the growing recognition that all countries are actually or potentially both providers and users of genetic resources and thus need legislation to cover both aspects. Several ABS capacity-building initiatives have been initiated to support the early entry into force and national implementation of the Nagoya Protocol. These include Global Environment Facility (GEF) financed regional and sub-regional projects in Latin America and South East Asia, and the ABS Capacity Development Initiative, a multi-donor initiative targeted at the African continent and the Caribbean and Pacific Group of States.³⁰

Limited research has been conducted on the state of implementation of ABS at the national level, although there have been studies by the Fridtjof Nansen Institute of ABS in some African countries (Ethiopia by Andersen and Winge, 2012; Ghana by Rosendal et al. 2012; Cameroon by Rosendal, 2012) and also Australia (Prip et al. 2014). Studies have also been conducted of the ABS frameworks of the three megadiverse countries, Brazil, India and South Africa by the GIZ ABS Capacity Development Initiative in 2014³¹ (further presented below), and a general overview of national and regional measures on ABS has been prepared by the Centre for International Sustainable Development Law (Medaglia et al., 2014). The following will provide some examples of provider as well as user-country legal measures:

3.4.1 Examples of national legislation to regulate access to genetic resources

India

Access to India's biological resources and associated knowledge is regulated by the Biological Diversity Act of 2002 and the Biological

³⁰ <http://www.abs-initiative.info/>. The Initiatives started already in 2006.

³¹ See <http://www.abs-initiative.info/countries-and-regions/global/india/second-abs-dialogue-on-key-challenges-and-practical-ways-forward-for-the-implementation-of-the-nagoya-protocol/>.

Diversity Rules of 2004. Subject to prior approval by the National Biodiversity Authority (NBA) are commercial utilization, research, bio-survey or bio-utilization and applications for intellectual property rights based on biological resources. The obligation to obtain approval for these activities applies, with some exceptions, to non-Indians and not to domestic citizens and companies. Approval takes the form of a contract between the NBA and the bioprospectors, with agreed formats for specific uses. The NBA consults with the relevant State Biodiversity Board, which is also to consult with the relevant Biodiversity Management Committee (BMC) at the village level. With monetary benefit sharing, the NBA may direct the amount to a National Biodiversity Fund or, in the case of resources provided from specific individuals or groups, directly to them.

Most of India's ABS Agreements have been for non-commercial utilization of genetic resources. In the few commercial cases, the users have generally shared benefits with the National Biodiversity Authority (NBA). By August 2013, NBA had entered into 117 ABS agreements, out of 844 applications received – quite a large bulk of applications for the NBA to handle (GIZ, 2014). The NBA has received approximately Rs. 4.3 million, of which 90% comes from one case: PepsiCo India Holdings Pvt. Ltd for seaweed export. Cases have also been reported where, although the NBA had directed payment of monetary benefits, no actual payments have been made (India, GIZ report, 2014).

India's system has been criticized for being overly centralized and bureaucratic with too little consultation and benefit sharing with the local Biodiversity Management Committees (India, GIZ report, 2014). However, it is important to note that this criticism concerns the domestic distribution of benefits from use of genetic resources and does not really pertain to the international ABS regime, which addresses international distribution. The NBA has also been criticized for applying a standardized rule-of-thumb approach in determining the size of benefits to be shared rather than a case-by-case approach which could better break down bioprospecting processes into discovery and commercialization phases (Bavikatte and Tvedt, 2014).

Australia

In the ABS context, Australia is a special case: an industrialized country that is also megadiverse and a large provider of genetic resources. Australia's federal ABS legislation applying to Commonwealth areas, adopted in 2006, is relatively advanced and pioneering in giving national effect to the third objective of the CBD. Commonwealth areas include land owned or leased by the Commonwealth including several national parks and the waters of the Exclusive Economic Zone. The Environmental Protection and Biodiversity Conservation Act 1999 and subsequent regulations require permits for all bioprospecting activities (termed 'biodiscovery') using native biological resources, and mandatory BSAs for bioprospecting with commercial intent. To obtain a permit for non-commercial biodiscovery, the researcher must sign a legally binding statutory declaration that the resources are to be used solely for non-commercial purposes. In case of change to commercial intent, the user

must obtain a new permit and establish a BSA with the access provider. There are also requirements in the Commonwealth legislation for prior informed consent when access is sought for biodiscovery on indigenous peoples' lands and/or when associated traditional knowledge is used.

As under other countries' ABS legislation, most permits issued have been for non-commercial use. Only very few commercial permits have been issued – and only to one institution.³² The difficulty of tracing biological/genetic material through a bioprospecting development process has been argued as a reason for the surprisingly low number of commercial cases in a country with a large natural products industry. Natural product biodiscovery (particularly in pharmaceuticals) is increasingly undertaken by universities and in non-commercial contexts, but with the potential to become commercial if something of interest is found. Patent applications and their disclosure could be a suitable trigger for determining when a biodiscovery process enters into a commercial phase and thereby for establishing benefit-sharing arrangements (Prip et al., 2014). Also a reason for the low number of commercial permits could be 'access shopping'. There is ready access to material from locations in Australian states and territories that are not part of the Commonwealth and that hence do not require a permit. Areas under Commonwealth jurisdiction are limited, and only two of Australia's states and territories – Queensland and Northern Territory – have ABS legislation in place (Prip et al. 2014; Robinson, 2015).

Although commercial benefit-sharing has been largely illusive in Australia, there is one well-known example of a private–public non-monetary benefit-sharing arrangement discussed in detail by Laird et al. (2008): Griffith University in Brisbane and the pharmaceutical company, Astra Zeneca established a partnership between 1993 and 2007 in which the company invested more than AUD 100 million. The partnership allowed for advanced testing of an extensive array of genetic resources, an activity that Griffith University has continued at a high technical level after the end of the partnership. The agreement also provided for monetary benefit sharing in case the screening should lead to commercialization of pharmaceutical products. However, as yet no commercialization has emerged as a result of the partnership. Concerns have been voiced about the partnership, including the 'locking up' of Australian biological resources by one multinational company, and the lack of consideration for traditional knowledge and resources accessed on indigenous peoples' lands (Prip et al. 2014; Robinson, 2015).

Brazil (based on Brazil GIZ report, 2014.)

In 2001 Brazil enacted a Provisional Act to regulate access to components of 'genetic heritage' and associated traditional knowledge for the purpose of scientific research, technological development or bioprospecting and the fair and equitable benefits from its use. The competent authority for issuing authorization is the Genetic Heritage Management Council (CGEN), under the Ministry of the Environment (GIZ, Brazil

³² The Australian Institute of Marine Science (AIMS)

2014:4). Access can be authorized only for domestic institutions – not for individuals or for foreign institutions. The latter are required to enter an association with a Brazilian institution if they wish to obtain access (National ABS Study of Brazil, 2014).

While Brazilian biological resources are considered collective goods, the 2001 Provisional Act recognizes property rights to the resources by private landowners, indigenous peoples and local communities and others. For government authorization for access to the material, the applicant is required to provide evidence of prior approval by the property rights holder/provider.

The legal system operates with three categories of ‘access’, distinguishing between scientific research for non-commercial activities, technological development aimed at economic gains, and bioprospecting with potential for commercial use. Non-commercial scientific research requires only permission from landowners (with some exceptions), whereas technological development and bioprospecting require authorization from the CGEN (GIZ, Brazil 2014:5). As of March 2012, there were 25,000 researchers registered in the system, which is online, with a maximum of 60 days for authorization. In the event of a change of intent (shift from non-commercial to commercial), the institution authorized must inform CGEN and obtain a new access authorization (PIC) and benefit-sharing contract. Such PICs are provided for a period of two to five years (GIZ, Brazil 2014:14–15).

Access activities under the categories of bioprospecting or technological development require an agreement with the competent authority on benefit sharing and other matters. Benefit sharing may take the form of profit sharing, royalties, access to and transfer of technology, free licensing of products and processes or capacity building, and should preferentially contribute to the conservation and sustainable use of biodiversity in the country.

Applicants for patents must disclose the origin of the genetic material and/or associated TK.

By 2013, 1314 authorizations for access had been issued, predominantly for scientific research purposes. In all, 103 BSAs had been approved. Typical are community associations, private individuals or companies, while the main uses dealt with in the agreements are cosmetics (79) and to a lesser extent pharmaceutical development. A further 79 included mixed monetary and non-monetary benefits, 15 only monetary, and 12 potential (agreed but not yet occurred) monetary benefits. The majority of monetary benefits were agreed on a percentage (varying from 0.05% to 5%) of net earnings. One third of the BSAs involve socio-economic or conservation objectives (GIZ, Brazil 2014:24).

The Brazilian ABS legislative framework is widely viewed as an example of the first generation of defensive and protective access regulation aimed at preventing biopiracy rather than enabling R&D. This is expressed particularly in the general ban on foreigner users to access, but also domestic users have expressed dissatisfaction and have often conducted

activities in violation of the Provisional Act (GIZ, Brazil 2014:26). 20 May 2015 a new Biodiversity Law was signed by the President of Brazil to regulate access to genetic heritage components, protection and access to associated traditional knowledge and the fair and equitable sharing of benefits for preserving and sustaining Brazilian biodiversity. The law that enters into force 17 November 2015 is intended to simplify and accelerate the process for scientific research with respect to native plants, animals, microbes and other materials containing functional units of heredity. It also seeks to facilitate the process for economic exploitation of biodiversity resources and to innovate and develop scientific and technological research.³³ At the moment, the Law is not available in English.

South Africa (based on South Africa GIZ report, 2014)

South Africa ranks among the top megadiverse countries and hosts a particularly rich diversity of flowering plants (Huntley, 1988). Like Australia, South Africa operates with the concept of 'indigenous biological resources' in its ABS legislation.

Authority for issuing bioprospecting permits lies with the Department of Environmental Affairs (DEA) as the competent authority. The legislative instrument governing bioprospecting is the Biodiversity Act of 2004. In addition, there are the Bioprospecting, Access and Benefit Sharing Regulations (BABS) of 2008, which govern the commercialization phase of bioprospecting through permits, based on PIC and MAT. Triggers for commercialization are defined and linked to the Patent Amendment Act of 2005 through disclosure.

Although the South African state is the trustee of biological diversity, legislation does not vest ownership of genetic resources in the state unless they occur on state land. Landowners own both the biological and the genetic resources on or under their property (SA, GIZ report 2014:4).

While non-commercial research can be conducted without a permit, the commercialization phase of bioprospecting requires a permit which will be granted only in the interest of those who own and provide the resources and the associated knowledge including indigenous communities. MTAs and BSAs are required for access to indigenous knowledge associated with genetic material. The PIC and MAT processes depends on building trust; the average time for obtaining a permit is reported to be about four months (SA, GIZ report 2014:9).

As in Brazil, individual foreigners may not apply for access, but must apply for export permits or bioprospecting jointly with South African institutions. The permit holder is to submit an annual status report; offences are liable to prison sentence or fines. Monetary benefits do not go directly to the providers/communities from the users, but are channelled through a Bioprospecting trust Fund.

³³ Federal Law N° 13.123/2015.

<http://www.lexology.com/library/detail.aspx?g=17a10533-609f-4023-9736-75b1deedc55e>

The greatest demand has been for access to genetic resources in plant material, including wild, harvested and cultivated, and most cases refer to *ex situ* collections. South African intermediaries are most often universities or research institutions. In the case of wild material, biotradors play a role, engaging with landowners with genetic resources on their land.

As of 2014, 17 permits had been issued for commercialization, only one of which concerned a foreign company. Another 60 applications for commercialization are in the review and approval phase, while 81 notifications have been sent to DEA for the discovery phase. Moreover, 72 MTAs have been issued and 32 BSAs approved by the Ministry of Water and Environmental Affairs, recorded by DEA. All of these (17 + 72 + 32) are for commercialization of bioprospecting; both monetary and non-monetary benefits have been derived from these agreements. South Africa is reportedly experiencing a surge in the use of natural products in the cosmetics, nutraceutical, agricultural and pharmaceutical industries that may lead to further ABS arrangements.

3.4.2 Concluding remarks on domestic access legislation

The presentation above has described the experiences of four particularly important countries in relation to ABS and national regulatory and institutional frameworks for access to genetic resources. Their experiences are important lessons for the many countries that are yet to take action in this field.

A first lesson is that having a functional, national ABS system is necessary if a country and its communities are to partake in the benefits from the value of genetic resources – which is the whole idea behind the ABS concept. A study of a biodiversity-rich country with no such legal and institutional framework, Cameroon, showed clearly that without such a framework (including the capacity to know who is actually conducting bioprospecting in one's country), the prospects of benefit-sharing agreements are quite remote (Rosendal, 2010a).

Also noteworthy are the sizable differences in the legislation of the four big ABS countries presented here: Australia, Brazil, India and South Africa. Below are some comparisons in selected fields:

- All four have legislation that covers a broader topic than the CBD/NP subject of 'genetic resources' ('biological resources' or 'genetic heritage').
- Brazil and South Africa regulate access of domestic and not foreign users (the latter are generally not allowed access unless in association with a domestic user), India regulates foreign and not domestic users (the latter are generally allowed access), while Australia regulates the two on an equal footing.
- Australia and India generally require permits for using biological resources for both commercial and non-commercial research, which is normally not the case in Brazil or South Africa.

- Only in India is ownership to biological resources vested in the state: the state is the Party in BSAs with users, but can extend benefits to ‘conservers’. In the three other countries, rights are vested in the owners of the property where the biological resources occur, making the property owners the provider party in BSAs.
- All countries except Australia require disclosure of origin of biological resources in patent applications.

Further, the national frameworks have provided a fairly large number of bioprospecting activities, many of them with benefit-sharing arrangements, but – apparently – few with commercial intent and thus with few examples and low amounts of monetary benefits shared. South Africa seems to have the highest share of commercial ABS arrangements.

It is particularly noteworthy that Australia, a megadiverse developed country with pioneering ABS legislation (also as regards benefit sharing with indigenous peoples) and a well-developed national products industry has had so little to offer in this field. How can this be explained? Do bioprospectors deliberately fail to comply with their obligations to seek a permit or to obtain a new permit when the intent changes? Is it perhaps not possible to determine when such change happens? Is the value chain from collection in nature to a manufactured product so complex, with resources going through so many steps and so many intermediaries, that the legal frameworks simply do not fit the realities? (See Table 2.) Or, finally, is ‘traditional’ bioprospecting – screening wild plants and animals in the South for bioactive compounds suitable for industrial use – an outdated activity because these compounds can already be found in *ex-situ* collections or in micro-organisms in one’s own backyard? These are questions that call for further research on the ABS regime and its objectives against the actual supply chain as regards the manufacture of natural products.

Table 2 Complexity of Possible ABS Circumstances

Attributes	Characteristic	
Source of supply	<i>Ex-situ</i>	Non-commercial (botanical gardens, gene banks, etc.)
		Commercial (broker companies)
	<i>In-situ</i>	One source country
		Several source countries
Purpose of usage	Commercial	Development of end-products
		Development of intermediate products
	Non-commercial	Basic non-commercial research with option to transfer material to commercial users.
		Basic non-commercial research with material kept for conservation
Relationship between genetic resources and product	Closely related	Chemical molecule found in the plant serves as prototype for an active compound in the product (pharmaceutical utilization)
		Extracts (raw material) of the plant are substance of the content in the product (natural medicine, natural cosmetics, dietary supplement) NOTE: no genetic resource according to CBD definition, but different views possible in national ABS laws
	Not closely related	Molecule found in the plant needs to be modified in many steps to be included in the product (derivative in pharmaceutical utilization)
		The function of an organism or its parts serve as a model (e.g., mimics in material research, biotechnology)
Characteristics of material identifiable before utilization	Identifiable	Material obtained from <i>ex-situ</i> collections, further information included
	Partly identifiable	Material acquired by bioprospecting activities, type of related knowledge
	Not at all identifiable	Material obtained by wide-scale, random bioprospection; no further information available/acquisition of sample of completely unidentified resources
<p>Source: Greiber et al. 2012, based on S. Täuber, K. Holm-Müller and U. Feit (2008). <i>An Economic Analysis of New Instruments for Access and Benefit-Sharing under the CBD – Standardisation Options for ABS Transaction, Interim Report.</i> (Bonn/ Bad Godesberg: BfN).</p>		

3.4.3 *Examples of national legislation to regulate users of foreign genetic resources under the country's jurisdiction*

Norway

The Norwegian Nature Diversity Act (2009) directly addresses user-measure obligations in ABS (Sections 57 to 60). The import of genetic material into Norway from a provider state that requires prior informed consent may take place only in accordance with such consent. So far, no cases of alleged misappropriation have been brought before the Norwegian competent authority.

When biological material is utilized for research or commercial purposes in Norway and patented, 'the patent application shall include information on the country from which the inventor collected or received the material or the knowledge (the providing country). If it follows from the national law in the providing country that access to biological material or use of traditional knowledge shall be subject to prior consent, the application shall state whether such consent has been obtained' (Patent Act (Section 8b, of 2003)).³⁴ Moreover, any person receiving genetic material from a public collection shall refrain, in Norway or abroad, from claiming intellectual property rights to the material, unless the material has been modified in a way that results in a substantial change. Contrary behaviour is subject to sanctions through legal action (see also Medaglia 2013; Tvedt 2010).

EU

Through its Regulation No 511/2014 of 16 April 2014, the European Union on behalf of its 27 member states has implemented the Nagoya Protocol in terms of user-country measures – and only of such measures. It is left to member-state discretion to decide if and how to regulate access to domestic genetic resources.

Users of genetic resources are required to exercise due diligence 'to ascertain that genetic resources and traditional knowledge associated with genetic resources which they utilize have been accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements, and that benefits are fairly and equitably shared upon mutually agreed terms, in accordance with any applicable legislation or regulatory requirements' (Article 4.1). Users shall seek, keep and transfer to subsequent users an internationally recognized certificate. If this is not available, similar detailed information shall be kept about the transaction, including as regards prior informed consent, mutually agreed terms and the presence/absence of rights and obligations pertaining to genetic resources in the provider country (Art. 4.3(b)).

The EU Commission shall establish a register of collections within the Union (Art.5). Member states are to designate competent authorities and focal points (Art 6) and two checkpoints for monitoring compliance:

³⁴ As is the case of similar disclosure requirements in legislation of other European countries, requirement does not affect the validity of the patent.

when receiving research funding, and at the time when a final product is developed (Art. 7). Member states shall also carry out checks on user compliance with due diligence and lay down rules on penalties (Art. 11).

The Regulation has been criticized for being too cumbersome for industry. The German seed industry has announced that it will bring its legality with EU law before the European Court of Justice.³⁵ From the provider side, the Regulation has been criticized mainly for its temporal scope: it applies to ABS transactions only after the entry into force of the Nagoya Protocol, and thus does not support compliance with access legislation enacted on the basis of the CBD (as the legislation of the four megadiverse countries referred to above). Moreover, for transactions actually covered by the Regulation, the trigger is the time of access and not utilization, thereby excluding large amounts of genetic resources and traditional knowledge acquired before the Nagoya Protocol but still waiting to be utilized (United Nations University et al., 2014). The reason stated by the EU for this temporal scope is the principle of non-retroactivity in legislation.

3.4.4 Concluding remarks on user-country legislation

The above presents two models of user-country legislation for inspiration for the many countries that do not have such measures in place as required by the Nagoya Protocol: A broad conduct-based requirement of ‘due diligence’; and a result-based more tangible, direct requirement of users to comply with provider-country legislation.³⁶ EU legislation also gives rise to the question, important for other countries, as to the time from which these legal measures are to be applied. Should they support compliance with access regulations according to the obligations of the CBD? or only the Nagoya Protocol? And should the trigger be solely access, or also utilization?

3.5 ABS between equity and ecosystem services

The ABS regime has a dual foundation. Fairness and equity are the explicit concerns of the third CBD objective in respect of countries sovereign rights over biodiversity and – reinforced by the Nagoya Protocol – the rights of indigenous peoples and local communities (ILCs). Equity and fairness were seen implicitly as serving the other foundation – the creation of an incentive for conservation and sustainable use – although in practice there may not always be a causal link between the two sets of concerns. Hence, perceptions have differed along the familiar South/North lines on their weighting. With the Nagoya Protocol, the link between fairness and equity on the one hand and conservation and sustainable use on the other has become explicit.³⁷

³⁵ See <http://ipkitten.blogspot.no/2014/08/german-plant-breeders-challenge-eu.html>.

³⁶ Prior to the EU Regulation, Denmark had enacted legislation with user requirements very similar to that of Norway. This legislation is deemed legally compatible with the EU Regulation. Switzerland has enacted legislation very similar to the EU Regulation.

³⁷ Nagoya Protocol Article 1: Objective.

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

As discussed above, the ABS thinking on fair and equitable sharing of benefits has influenced work under other international regimes such as the WHO and the UN Convention on the Law of the Seas. Moreover, it is likely that the UN Declaration on the Rights of Indigenous People (UNDRIP) adopted by the UN General Assembly in 2007 was deeply influenced by the CBD discourse on ILCs and their traditional knowledge and customary use of biodiversity. UNDRIP went beyond CBD in recognizing the rights of indigenous peoples to genetic resources and associated knowledge,³⁸ in turn laying the foundations for the far-reaching provisions of the Nagoya Protocol, which can be seen as an advancement of human rights (Savaresi, 2013).

As to the conservation foundation, it is widely held – especially by user countries – that the ABS regime has not been able to stimulate conservation and sustainable use of biodiversity significantly. This, however, can be attributed mainly to the lack of implementation of ABS measures at the national level, including user-country measures. It can further be argued that lack of tangible benefits for biodiversity is not a valid argument against the equity dimension of the ABS regime, and that ABS was never meant to carry the sole responsibility for biodiversity conservation. (See Oberthür and Rosendal, 2014.)

In any case, examples of conservation and resource mobilization benefits from ABS remain scarce. The 2014 report to the CBD COP 12 of the High Level Panel on Global Assessment of Resources for Implementing the Strategic Plan for Biodiversity 2011–2020 offers few reflections on this topic. In annexes to the report with concrete examples of various ecosystem services and benefits of achieving the Aichi targets, only two are ABS related – one on crop genetic resources in Nepal, and another on traditional knowledge of medicinal plants in South Africa.³⁹

That said, in the wake of the Nagoya Protocol and the other parts of the ‘Nagoya package’, there is movement towards viewing ABS in the context of payment for ecosystem services and as a source of resource mobilization. In India the National Biodiversity Authority has initiated work on developing an appropriate method/model for valuation of bio-resources for operationalization of the ABS mechanism (Nellyiat and Pisupati, undated).

Pisupati and Bavikatte (2015) argue for national regulatory ABS systems that are facilitative rather than protectionist, to promote effective use of ABS as an innovative financial mechanism for biodiversity. That would mean approaching ABS as a business model that could generate a steady

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.

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.

³⁸ UNDRIP, Art. 31.

³⁹ UNEP/CBD/COP/12/INF/4 p. 120 – 124.

<http://www.cbd.int/doc/meetings/cop/cop-12/information/cop-12-inf-04-en.pdf>

stream of revenues to incentivize conservation and sustainable use of biodiversity, rather than understanding ABS solely as a regulatory system for preventing biopiracy.

Robinson (2015) presents several new ABS cases with promising contributions to biodiversity conservation. Clearly, there is scope for more research in this area.

3.6 Benefit sharing beyond genetic resources

As noted, some countries have chosen not to limit their ABS coverage to the concept of ‘genetic resources’ in the CBD but to cover biological resources as such. Also beyond the biodiversity agenda (but probably inspired by it), the idea of benefit sharing has been seen as holding promise for greater equity and thereby addressing the green-economy equity deficit.⁴⁰ Benefit sharing has been described as a way ‘to *frame* equity issues by emphasizing the advantages (the positive outcomes and or implications) of tackling global challenges so as to help motivate participation by different stakeholders’ (Morgera, 2014). The concept appears to be expanding to areas such as the international law on shared natural resources (like shared watercourses) and to the international climate-change regime. There it is has been discussed whether benefit sharing could address equity concerns in connection with the Clean Development Mechanism and REDD+. Benefit sharing might serve to deliver global benefits arising from environmental protection efforts that remain under the individual country, but have become a common concern of mankind – very much as in the biodiversity context.

A wide research gap exists also in this field.

4 General concluding remarks

ABS has often been described as the ‘great bargain’ between the biodiversity-rich developing countries and the economically and technologically-rich developed countries – with the former providing access to their genetic resources, and the latter providing benefits in return to promote equity and incentives for conservation and sustainable use. The ABS regime has existed from more than 20 years now, but it does not seem to have generated the types and amounts of shared benefits that were expected. The complexity of the ABS concept, rapid technological developments, low capacity in the developing countries and lack of commitment from developed countries have often been cited as reasons for the limited progress. Another obvious reason is that the ABS issue has been constantly evolving. The 2002 decision to develop a more detailed and functional ABS regime and the ensuing years of negotiations leading up to the Nagoya Protocol in 2010 have inevitably postponed national implementation efforts. Today there are signs of emerging

⁴⁰ See website of the of the Benelex project. http://www.benelex.ed.ac.uk/about_us

progress, mainly in the form of ABS capacity building in many developing countries and growing awareness and appreciation of ABS from the user side. In assessing how far progress has come, some see the glass half full, others as half empty. Widespread commitment to make ABS a success will depend very much on which of those two approaches prevails.

The ABS concept has generated considerable academic interest for its innovation in creating new rights and obligations for states and indigenous and local communities, and for its noteworthy interaction with other international regimes. Also beyond the context of genetic materials, ABS is becoming an increasingly used term that often refers to the equity dimension in natural resource management (Morgera, 2014). However, research has tended to be in the form of theoretical analyses of the concept and studies of the negotiations. Despite an increase in recent years, there is still a lack of research on how and the extent to which ABS is applied on the ground, its consequences for equity and conservation, and the impediments to making ABS function.

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