

GERMAN DEVELOPMENT INSTITUTE
(GDI)

**Access and Benefit-Sharing (ABS):
An Instrument for Poverty Alleviation**
Proposals for an International ABS Regime

Gudrun Henne
Klaus Liebig
Andreas Drews
Thomas Plän

Bonn, November 2003

Contact data:

Dr. Gudrun Henne	 Institute for Biodiversity (IBN) Science and Business Experts Network Böckhstrasse 4 D - 10117 Berlin	gudhenne@aol.com
Klaus Liebig	German Development Institute (GDI) Tulpenfeld 4 D – 53113	klaus.liebig@die-gdi.de www.die-gdi.de
Dr. Andreas Drews	Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ) GmbH Project “Implementing the Biodiversity Convention” OE 4411 Postfach 5180 D – 65726 Eschborn	andreas.drews@gtz.de www.gtz.de/biodiv/english/index.html
Dr. Thomas Plän	 Institute for Biodiversity (IBN) Science and Business Experts Network Dr-Johann-Maier-Strasse 4 D – 93049 Regensburg	plaen@biodiv.de www.biodiv.de/index.html



Preface

This study is the result of a collaborative effort of German scholars and institutions. It has been prepared as a scientific contribution to the *Second Meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-Sharing*, which will be held in Montreal, Canada, from December 1 to 5, 2003. The authors take as their common starting point the view that the Contracting Parties of the Convention on Biological Diversity (CBD) should use the on-going process to develop and implement an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources with a view to increasing the effectiveness of Access and Benefit-Sharing (ABS) as an instrument of poverty alleviation. In 2002 the heads of state and government committed themselves in Monterrey to the Millennium Development Goals. As elaborated in this study, ABS can contribute to achieving these goals if the international community takes its political statements seriously and develops an ABS regime that simultaneously supports the goals of the CBD: conservation of biological diversity, sustainable use of its components, and the fair and equitable sharing of benefits.

The views expressed in the study do not necessarily represent the opinion of the various institutions involved. While the study is a joint effort by all authors, the main responsibilities of the different Chapters are as follows: Klaus Liebig has written Chapters 1 and 2. Chapter 3 has been co-authored by Andreas Drews, Gudrun Henne and Klaus Liebig. Gudrun Henne has contributed the core part of the study, Chapter 4, which contains detailed proposals for an international ABS regime. The policy recommendations in Chapter 5 have been prepared jointly by Gudrun Henne and Thomas Plän. The project has been coordinated by Klaus Liebig.

Bonn, November 2003

Contents

1	Introduction	1
2	Poverty, Biodiversity, and Access and Benefit-Sharing (ABS)	2
2.1	Concepts of poverty and poverty alleviation	2
2.2	Valuing biodiversity	4
2.3	Who benefits from biodiversity?	5
2.4	Potential of ABS agreements for alleviating poverty	7
3	Case studies on benefit-sharing	10
3.1	Selection of the case studies	10
3.2	The case studies	11
3.2.1	The Kani case (<i>Kani</i>)	11
3.2.2	The Kava case (<i>Kava</i>)	15
3.2.3	The Hoodia case (<i>Hoodia</i>)	17
3.2.4	The MSI anti-cancer agreement (<i>MSI-Cancer</i>)	21
3.2.5	The INBio-Merck agreement (<i>INBio</i>)	24
3.3	Conclusions from the case studies	27
3.3.1	Contribution to poverty alleviation	28
3.3.2	Legal conclusions for the design of a benefit-sharing regime	29
4	Provisions for an international ABS regime	31
4.1	The political landscape of the international regime	31
4.1.1	Policy call for an international regime	31
4.1.2	Poverty alleviation and benefit-sharing	32
4.2	Form, motivation and objectives of an international ABS regime	33
4.2.1	Definition of “regime”	33
4.2.2	Norm-setting options under the CBD	34
4.2.3	Political motivation for the international regime	36
4.2.4	Conclusion: which regime-building process?	38
4.3	International and national levels of ABS regulation	39
4.4	ABS provisions at international level	40
4.4.1	General provisions	41
4.4.2	Sovereign rights with respect to genetic resources	42
4.4.3	Rights of indigenous and local communities to associated knowledge of genetic resources	43
4.4.4	Prior informed consent	45
4.4.5	ABS agreements: benefit-sharing based on mutually agreed terms	45

4.4.6	Benefit-sharing – geographical indications	47
4.4.7	Harmonizing transactions: ABS certification	49
4.4.8	Mechanism to support verification, enforcement and compliance	49
4.4.9	International institutions of the ABS regime	53
4.5	ABS provisions at the national level	54
4.5.1	Provider situation	55
4.5.2	User situation	56
5	Recommendations for policy-makers	57
5.1	International collaboration	57
5.1.1	Building the international ABS regime	57
5.1.2	Institutional framework	58
5.1.3	Policies in related fields	58
5.2	Policy advice and support at national and regional level	59
5.2.1	User countries	59
5.2.2	Provider countries	60
5.3	Development cooperation	62
Annex I		67
Annex II		68

Executive Summary

This study endorses the call in the Plan of Implementation of the World Summit on Sustainable Development (WSSD) held in Johannesburg in 2002 to “negotiate within the framework of the Convention on Biological Diversity [...] an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources”. It is argued that an international ABS regime can and should be used as an instrument both to alleviate poverty and to protect biodiversity. Detailed proposals for the design of such a regime are put forward with the aim of stimulating the debate among governments and parties to the CBD.

Although poverty and biodiversity are linked, there is no clear-cut causal relationship between the two. Poverty may undermine biodiversity, but the poor may at the same time depend on biodiversity. On the other hand, while biodiversity loss may aggravate poverty, the conversion of land (the primary cause of biodiversity loss) may be necessary to induce economic growth and prosperity. To assess the potential of ABS agreements for alleviating poverty, it is necessary to recognize the multiple dimensions of poverty and of the values of biodiversity. Today, poverty is regarded as “pronounced deprivation in well-being”. This concept leads to a poverty alleviation strategy that encompasses three elements: promoting opportunities, facilitating empowerment and enhancing the security of the poor. ABS agreements can contribute most visibly to the first two elements of the strategy: monetary and non-monetary benefits promote *economic opportunities* for the poor as long as the government of the provider country ensures that some of the benefits go directly to local and indigenous communities. Empowerment is facilitated since ABS agreements redistribute *rights* to the custodians of biodiversity, giving them a say in the negotiations with users.

Theoretical analysis and the experience demonstrated in five case studies show that the benefits of ABS agreements flow through different channels. In some cases, monetary benefit-sharing is based on expectations for the future (“blockbuster-hope”). In other cases, benefit-sharing occurs in the short term by providing income-generating job opportunities for locals. For some marginalized communities, the empowerment effect is more important than the monetary benefit. Some provider countries concentrate more on technology transfer and the build-up of a biotechnology industry. As a rule, various stakeholders in provider countries benefit from the utilization of genetic resources under ABS agreements. The distribution of benefits may give rise to conflicts. The poverty-alleviating effect depends on the specific situation in each country, and especially on the scale of any pro-poor public policy.

An international ABS regime will help provider countries to implement their national ABS regulation and force users to abide by the rules agreed by the international community. There are various legal options for the construction of a regime, which is defined as a set of principles, norms, rules and decision-making procedures around which actors’ expectations

converge in a given area of international regulations. From a political and legal point of view, there are strong arguments for an ABS protocol since a protocol would provide the necessary political momentum for an ABS regime as well as a strong legal base. Political will, however, is the core requirement for any ABS regime, whether in the form of a protocol or any other document adopted by the Conference of the Parties.

This study proposes elements of an international ABS regime which seeks to alleviate poverty. The proposals are based on the Bonn Guidelines, the relevant literature and the theoretical and empirical parts of this study. They go beyond the Guidelines, especially with regard to institutional requirements for ensuring the implementation and monitoring of the regime. If policy-makers do not consider the concrete proposals helpful, they should at least take them as a starting point for the design of an effective regime. It would not be in the spirit of the WSSD or the decisions of the CBD's COP if Parties left it at a vague international ABS regime.

An international ABS regime will become effective only if it is implemented at national level. User countries should take the necessary measures to reduce implementation and control costs to provider countries. Providers should streamline procedures and legislation as far as possible in order to reduce transaction costs to users while ensuring effective benefit-sharing. Industrialized countries should support less developed countries with various forms of development cooperation.

1 Introduction

The Convention on Biological Diversity (CBD) is one of the international conventions that govern environmental resources. But it is more than that: drafted in the spirit of the World Summit held in Rio in 1992, the CBD is part of the international regime which seeks to foster development and environmental conservation. Ecological sustainability, economic growth and social and political development should go hand in hand in the quest for world-wide *sustainable development*.

This is, maybe, a utopian goal. But Rio rightly deserves praise for trying to frame this goal in various international conventions, thus forming the starting point for the construction of an international regime. At the World Summit on Sustainable Development held in Johannesburg in 2002, the heads of state and government took stock of the progress made since Rio. The general claim at Johannesburg can be summarized as the view that we need to proceed from policy formulation to implementation in order to come closer to the ideal of sustainable development. At the United Nations Millennium Summit in 2000 and again in 2002 at the ‘Financing for Development’ Conference in Monterrey, the international community committed itself to the Millennium Development Goals, thus refocusing political attention on poverty alleviation.

These important political statements call for a closer examination of the links between biodiversity conservation and poverty alleviation. This issue has also been included in the Multi-Year Programme of Work of the Conference of the Parties up to 2010. In the meantime, the CBD Member States are giving a great deal of thought to ways of making Access and Benefit-Sharing (ABS) more effective. Equitable sharing of the benefits arising out of the utilization of genetic resources is one of the three objectives of the Convention and has always been of great interest to the developing countries that harbour the bulk of the world’s species diversity.

This study brings together both strands of the debate. It backs the call in paragraph 44(o) of the Plan of Implementation of the World Summit for Sustainable Development for action to “negotiate within the framework of the Convention on Biological Diversity, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources”.¹ An international ABS regime can and should be used as an instrument both to alleviate poverty and to protect biodiversity.

The study is broken down into four parts. Chapter 2 provides a synopsis of the links between biodiversity and poverty so that the possible impact of ABS agreements on poverty and the

¹ WSSD (2002).

conservation of biodiversity may be assessed. It is suggested that ABS agreements can be used as an instrument for alleviating poverty, especially if the many dimensions of poverty are taken into account. Chapter 3 illustrates the theoretical analysis with five case studies of different types of ABS agreement. Chapter 4 contains some detailed proposals for a comprehensive ABS regime. The proposals are based on the Bonn Guidelines but go beyond them with a view to stimulating the debate among the Convention's Member States. Finally, Chapter 5 makes some policy recommendations as to how the regime-building process should be supported by the international community.

2 Poverty, Biodiversity, and Access and Benefit-Sharing (ABS)

Although poverty and biodiversity are linked, there is no clear-cut causal relationship between the two. Poverty may undermine biodiversity, but the poor may at the same time depend on biodiversity. On the other hand, while biodiversity loss may aggravate poverty, the conversion of land (the primary cause of biodiversity loss) may be necessary to induce economic growth and prosperity. This chapter differentiates the dimensions of poverty and the values of biodiversity in order to assess the potential of ABS agreements for alleviating poverty. It begins with concepts of poverty and poverty alleviation (2.1) and then presents the different values of biodiversity (2.2) and its many beneficiaries (2.3). Finally, the ability of ABS agreements to contribute to poverty reduction is discussed through an analysis of three important dimensions of ABS agreements: the expected level of monetary benefits, the types of benefits, and the possible beneficiaries (2.4).

2.1 Concepts of poverty and poverty alleviation

“Poverty is pronounced deprivation in well-being.”² Behind the word “deprivation” lie numerous mutually reinforcing dimensions of poverty: lack of income to meet basic needs, vulnerability to external shocks and the absence of opportunities to influence public institutions are the most important characteristics of the poor. Concepts of poverty alleviation should ideally tackle all dimensions of poverty if the Millennium Development Goals that the international community has set itself are to be achieved.

In recent decades concepts of poverty have been progressively broadened.³ In the 1970s poverty was interpreted basically as material deprivation and consequently measured in terms of the absence of income or consumption of the poor. The best-known measure in this context is the Headcount Index used by the World Bank, which classifies all people earning less than US\$ 1 a day as poor and relates the number of poor people to the total population.

2 World Bank (2001), p. 15.

3 For an overview see, for example, World Bank (2001) and Müller (2002).

Subsequently, lack of access to basic services (health and education) was included in poverty surveys. Today, it is common practice to include other dimensions of poverty that depart from income measures (and are more difficult to gauge): exposure to risk, voicelessness and powerlessness. Poverty in this broad sense restricts the “*capabilities that a person has, that is, the substantive freedoms he or she enjoys to lead the kind of life he or she values.*”⁴

What makes poverty reduction policies so difficult to conceptualize is the fact that all dimensions of poverty interact and frequently reinforce each other. Poverty reduction approaches have mirrored the broadening of the poverty concept. The World Bank has proposed a three-part strategy: promoting opportunity, facilitating empowerment, and enhancing security.

- ***“Promoting opportunities:*** *expanding economic opportunity for poor people by stimulating overall growth and by building up their assets and increasing the returns on these assets, through a combination of market and nonmarket actions.*
- ***Facilitating empowerment:*** *making state institutions more accountable and responsive to poor people, strengthening the participation of poor people in political processes and local decision-making, and removing social barriers that result from distinctions of gender, ethnicity, race, and social status.*
- ***Enhancing security:*** *reducing poor people’s vulnerability to ill health, economic shocks, policy-induced dislocations, natural disasters, and violence, as well as helping them cope with adverse shocks when they occur.”*⁵

At the United Nations Millennium Summit in September 2000, the heads of state and government adopted the Millennium Development Goals (MDGs), thereby accepting that poverty reduction is the most important challenge of the 21st century.⁶ The German government has committed itself to a programme of action to help halve poverty by 2015.⁷ The programme of action identifies 10 priority areas of action, which follow the lines of the World Bank approach. This programme is only one example of how an industrialized country has tried to mainstream its global commitments into national political processes. Both policy programmes – the MDGs and the German programme of action – encompass dimensions of poverty that are influenced by biodiversity and genetic resources. Access and benefit-sharing agreements could be used as one means of maintaining sustainable livelihoods, promoting opportunities and facilitating the empowerment of the poor, as will be argued below.

4 Sen (1999), p. 20.

5 See World Bank (2001), p. 33.

6 See Annex I for the MDGs.

7 See BMZ (2001).

2.2 Valuing biodiversity

As biodiversity has many dimensions, it is extremely difficult to value it in economic terms. This is not a pointless exercise, however, since the conservation of biodiversity is costly. Humankind therefore has to balance the costs and benefits of conservation efforts to arrive at a rational decision. This section introduces a framework for assessing the total economic value of biological resources. The main advantage of such a framework is not that it enables the value of biodiversity to be expressed as a specific figure, but that it clarifies the prospects and limitations of an economic valuation of the many dimensions of biological resources.

In everyday parlance the term biodiversity is sometimes used as a synonym for nature. However, it is useful to distinguish between biodiversity and the abundance of living resources, which are two distinct qualities associated with biological resources.⁸ While *biodiversity* refers to the variety and variability of biological life at genetic, species and ecosystem levels,⁹ *bioabundance* focuses on the quantity of a particular living resource. Both qualities of biological resources impact on human life and generate different values. As a starting point, Table 1 presents the economic values and benefits of biodiversity and bioabundance. The study will then go on to focus on biodiversity in the narrow sense described above.

Table 1: The economic values and resulting benefits of biological resources				
Use values			Non-use values	
Direct use values		Indirect use values	Option values	Existence values
Consumptive	Non-consumptive			
<i>Definition:</i> goods for home consumption, manufacture or trade	Non-tradable or subtractive	Ecological functions for maintaining sustainability and productivity	Possible future use or serendipity	Satisfaction from knowledge of existence
<i>Example values from diversity:</i> mixed crop varieties; mixed food combinations	Aesthetic value of diverse landscapes; some birdwatching	Diversity of species assists ecosystem resilience and stability	Gene pool; potential medicines and drugs	Special concern for diverse species and ecosystems
<i>Example values from abundance:</i> food, fuel, fodder, raw materials	Birdwatching and recreation	Carbon storage, nutrient cycling, photosynthesis, waste assimilation	None identified	Cultural and spiritual assets
Source: Grimble / Laidlaw (2002), p. 8				

⁸ See Grimble / Laidlaw (2002), p. 5-6.

⁹ See in this vein the definition in Article 2.1 of the Convention on Biological Diversity: biodiversity means “the variability among living organisms from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems.”

The total economic value of biological resources is composed of use values and non-use values.¹⁰ Direct use values occur when biological resources are purposely used to gain some economic benefit. Indirect use values refer to the ecological functions that maintain the stability and productivity of the environment. But biological resources have a value even if they are not used for the moment. They may be used by future generations and so have an option value. Moreover, they are frequently esteemed for their mere existence, for example from an ethical or cultural belief in the inherent value of a specific resource. The further right one goes in Table 1, the more difficult it becomes to quantify the economic value of biological resources. Although there are techniques that seek to capture the total economic value, they run into theoretical and practical difficulties. One should therefore be aware of the limits to quantifying the total economic value of biological resources.

2.3 Who benefits from biodiversity?

Biodiversity performs different functions for nature and humankind and therefore generates different benefits. These benefits are distributed on a spatial and temporal scale among numerous users of biodiversity. Some of the benefits have the characteristics of public goods, which makes free-riding behaviour more probable. If biodiversity conservation and poverty reduction are to go hand in hand, it is imperative to examine the distribution of conservation costs and benefits. Only if incentives and property rights are structured in a way that local custodians of biodiversity benefit adequately from its use can a socially inefficient trade-off between conservation and poverty alleviation possibly be avoided.

The bulk of local benefits arise from direct use values of biodiversity (see Table 2). Rural people, especially the rural poor, benefit from mixed and well adapted crop varieties. Medicine men use the underlying genetic properties of herbs, combining them with traditional knowledge. In the tourism industry, poor locals may work as guides, while the more affluent may earn a living in the hotel business. From an economic point of view, it is important to note that most of these benefits are of a private nature, in that the consumption of the goods involved is exclusive and rival.¹¹ To some extent, then, market transactions reveal use values to the local population. At the same time, it is not surprising that this is not a situation of pure harmony: firstly, there are conflicts at local level between the poor and the more powerful groups over property rights, e.g. land rights. Frequently, the poor lack the necessary “voice” in the public systems, which are more receptive to powerful groups of large landowners, and they are consequently pushed into marginal regions. Secondly, even among the local poor there are different perceptions of the use value of biodiversity, and this generates conflict. Some species may be useful to a medicine man, while harmful to a farmer. Tourism may generate income for some, but limit the activities of hunters and farmers.

10 See Grimble / Laidlaw (2002), p. 7, and Liebig et al., pp. 9-10.

11 For a discussion of private and public benefits of biodiversity see Perrings / Gadgil (2003).

Table 2: Beneficiaries of biodiversity on a spatial and temporal scale		
	Local beneficiaries	Beneficiaries at the global level
Present	<u>Direct use value:</u> Poor rural people, farmers, medicine men Workers in the tourism industry	<u>Direct use value:</u> Consumers of herbal medicines and related industries, mostly in industrialized countries Tourists
	<u>Indirect use value:</u> Farmers (stability of local ecosystem)	<u>Indirect use value:</u> Upstream users of land and energy in developing countries; world community (e.g. through carbon storage function)
	<u>Existence value:</u> Local communities and indigenous peoples owing cultural beliefs	<u>Existence value:</u> Environment lobbies and concerned people
Future	<u>Existence value:</u> Local communities and indigenous peoples owing to cultural beliefs (heritable value)	<u>Existence value:</u> Environment lobbies and concerned people (heritable value)
	<u>Indirect value:</u> Future farmers using a stable environment	<u>Indirect value:</u> Future generations using ecosystem functions
		<u>Option value:</u> Future consumers interested in the global gene pool, mostly in industrialized countries
Source: Own compilation		

Moreover, local people benefit from the indirect use value and from the existence value. However, most of the benefits derive from public goods, since they are non-exclusive and non-rival in nature. It is important to remember this since, with the attributes of a public good, the danger of free-riding behaviour increases: while it is beneficial for all farmers to work in a stable ecosystem, it may be more profitable for the individual farmer to grow a high-yielding

Table 3: Values of biodiversity as a private and public good		
	Local beneficiaries	Beneficiaries at the global level
Private	Direct use value	Direct use value
Public	Indirect use value	Indirect use value
	Existence value	Existence value Option value
Source: Own compilation		

variety, thus marginally reducing biodiversity in the region. The same problem may arise with respect to the existence value as long as spiritual beliefs do not completely rule out the possibility of “using” a given resource.

On a global scale, people benefit from the same types of values but in different ways. Consumers of herbal medicines and tourists use biodiversity directly. They benefit – as do the industries providing the respective goods and services, most of which are based in industrialized countries. Again, these are private goods. However, three types of values attach to public goods: indirect use value, existence value and option value. These three values are at the heart of the international debate on biodiversity conservation: the vast majority of beneficiaries do not live in biodiversity-rich areas, many of the benefits will accrue in the future (especially the possible benefits derived from conserving the gene pool), and most of them are non-rival in nature. The market cannot therefore capture the benefits, free-riding behaviour occurs, and this results in too few resources being transferred to the custodians of biodiversity to cover the opportunity costs of biodiversity conservation. For locals it is therefore frequently a rational decision to convert land and so to diminish biodiversity. As described above, however, the decisions are frequently taken not by the local poor but by powerful local groups. Property rights and incentives need to be restructured to increase the benefits to the local poor. The next section considers how ABS agreements can be useful as a complement to a set of policy measures.

2.4 Potential of ABS agreements for alleviating poverty

The Convention on Biological Diversity lays down a range of provisions for national legislation to regulate access to genetic resources and to ensure the fair and equitable sharing of benefits derived from their commercial use. The hope was that ABS agreements would lead to an appreciation of biodiversity and facilitate a “grand bargain”, with genetic resources from the South traded for money, technology and knowledge from the North. This “bargain”, it was hoped, would provide incentives to conserve biodiversity, to use it sustainably and to ensure fair and equitable benefit-sharing.

Poverty alleviation was not the policy-makers' primary concern when the relevant parts of the Convention were drafted. Nevertheless, it seems obvious that an additional transfer of resources to the South will contribute to poverty alleviation. There are at least three reasons why the relationship is not that simple: the poverty-alleviating effect of ABS agreements depends, firstly, on the volume of monetary benefits transferred, secondly, on the types of benefit and, thirdly, on the beneficiaries. This section uses the differentiations presented above to outline the prospects of ABS agreements contributing to poverty alleviation and their limits in this respect. It will be argued that ABS agreements can help to foster the opportunities and empowerment of the poor, even if the volume of monetary benefits is limited. However, the concrete effect of ABS agreements depends on the public policies of the providing country.

Volume of monetary benefits

ABS agreements are contracts that regulate a bundle of rights between two (or more) parties (access and use rights). Since these access and use rights determine the outcome of a market transaction, ABS agreements can be regarded as an instrument for redistributing a share of the total economic value generated by biodiversity. As ABS agreements are geared to the use of genetic resources, they can cover only some of the values of biodiversity. Basically, they may redistribute a part of the (consumptive) direct use value and of the option value occurring in industrialized countries. Industries (and ultimately consumers) using genetic resources are forced to pay higher research and development costs than in a situation where there is no arrangement for some of the value added to genetic resources to be transferred to developing countries. This can be interpreted as a tax levied on a private good (e.g. a herbal medicine) in an attempt to overcome the free-rider problem inherent in the financing of the global public good known as ‘maintenance of the global gene pool’.

The volume of monetary benefits therefore depends on the size of the market in products based on genetic resources, on the willingness of consumers to pay for those products and on their willingness to pay for the maintenance of the global gene pool. There are some estimates regarding market size, the best known being based on a large industry survey by ten Kate and Laird, who calculate the size of the market at between US\$ 500 and 800 billion.¹² Moreover, forecasts of market development are usually optimistic. While these numbers indicate the consumptive direct use value in industrialized countries, they do not permit a reliable appraisal of consumers’ willingness to pay for genetic resources incorporated in end products, this being even more difficult where genetic resources are intended for future use. Empirical and anecdotal evidence suggests that willingness to pay is not very pronounced, since industry prefers to substitute synthetic inputs for genetic resources. The few reports of ABS agreements refer to no more than small amounts of monetary transfers being received and to future royalty commitments ranging between 1 and 5% of product sales.¹³ Apart from isolated success stories, monetary benefits will therefore be sufficient neither to compensate provider countries for the opportunity costs of biodiversity conservation nor to increase the economic capabilities of the poor more than marginally.

Types of benefits

The Bonn Guidelines provide an indicative list of possible types of benefits arising from an ABS agreement.¹⁴ Structured along the lines of the World Bank concept of poverty alleviation (see 2.1), some benefits increase *opportunities* for the poor, while others contribute to their *empowerment* (benefits geared to enhancing *security* are harder to identify). Opportunities

¹² See ten Kate / Laird (2000).

¹³ See also Chapter 3 of this study.

¹⁴ See Annex II.

may be increased by direct monetary transfers, by investment in capital and – probably more important – by generating additional investment in the most important asset, human capital (e.g. through training). Positive as this is, it should be noted that transfers of this sort may well give rise to conflict at local level, since many of them generate private (exclusive) benefits rather than public goods. The more valuable genetic resources become, the greater is the danger that the local poor will be deprived of the private benefits that could enhance their opportunities.¹⁵

ABS agreements can generate non-monetary benefits that empower the local poor. If properly designed, the contracts involve local and indigenous communities. The important point here is that an agreement gives them a *right* to participate, thus making their voice heard by the political system of the provider country. ABS agreements may thus contribute to the political capabilities of local and indigenous communities.

Beneficiaries

ABS agreements can benefit different stakeholders in providing countries: local and indigenous communities, governments, industry, and researchers. Some of them are poor, others are not. However, in all cases ABS agreements may contribute to the reduction of poverty if they include all stakeholders and if the general public policy of the providing country is pro-poor.

Local and indigenous communities: This group of stakeholders will probably form part of the poorer segments of the providing country. Benefits that are directly targeted at this group are therefore likely to have a poverty-alleviating effect by directly increasing their economic opportunities. Income generation may be possible through the sharing of monetary benefits or through short-term monetary benefits (e.g. for guides or for the cultivation of biological resources that are traded for their genetic properties). Future assets could be improved through investment in training or basic infrastructure. ABS agreements can empower local and indigenous communities if the national governments of providing countries give them a say in the negotiation of the contract (e.g. by requiring the prior informed consent of those communities).

Government: Most governments in provider countries will be interested in monetary benefits as a source of income for the national budget. In this case, it is quite obvious how the effect of ABS agreements is determined by the public policies of the government: if they are pro-poor, additional government spending is most welcome as a means of improving services for the

15 This is not an argument based on empirical facts but an assumption which it may be important to bear in mind. It takes account of the fact that in most societies the poor lack the voice and power to assert their economic and political rights. ABS agreements can help to empower the poor. But – given the existing power asymmetries – genetic resources which may yield a high level of monetary benefits are prone to being misused by the powerful groups in a country or region.

poor. If they do not concern themselves with the poor, the sharing of monetary benefits will contribute little to poverty reduction.

Industry and science: Most providing countries seek to develop their own industrial or scientific capacities to benefit from their genetic resources. They are therefore interested in technology transfer and capacity-building. Although this will primarily benefit the middle class in the short run, the strategy may help to increase the economic opportunities of the poor in the long run, firstly, by fostering economic growth and, secondly, by increasing the national market in biodiversity-related products. However, it is important that the poor have the necessary assets (especially human capital) to benefit from economic growth. Again, we see that the concrete effect of ABS agreements on the poor depends on the complementary public policies.

3 Case studies on benefit-sharing

This chapter analyses experience of benefit-sharing as an empirical basis for the norm-setting proposed in Chapter 4. It gives an account of the criteria for the selection of the case studies (3.1) and provides a brief description of each case (3.2) and an analysis of the contribution made to poverty alleviation and of its legal implications (3.3).

3.1 Selection of the case studies

The number of case studies on access to genetic resources and benefit-sharing is steadily growing.¹⁶ For the purpose of this study, five case studies have been selected to illustrate the breadth of current benefit-sharing approaches in terms of the type of genetic resource, the range of actors involved, how the genetic resource is used, whether or not legislation and an ABS agreement exist, what benefits accrue, what contribution is made to poverty alleviation and whether use is made of traditional knowledge.

Regarding the status of legislation on access and benefit-sharing, the selection encompasses cases with already existing and carefully drafted access and benefit-sharing legislation in the country of origin (case study No 4: *MSI-Cancer*; case study No 5: *INBio*),¹⁷ an ABS agreement drafted while legislation is being developed (case study No 3: *Hoodia*) and cases where there is no legislation or ABS policy in the country of origin (case studies No 1: *Kani* and No 2: *Kava*). As regards ABS agreements governing the use of resources, three cases are based on an ABS agreement (*MSI-Cancer*, *INBio*, *Hoodia*) and one on a voluntary agreement

¹⁶ See www.biodiv.org/doc/case-studies.

¹⁷ For ease of reference, an abbreviated form of the title of each case study is used in *italics*. For full titles and descriptions see 3.2 below.

(*Kani*), while one is not backed by an ABS agreement at all, providing a classic example of trade in a biological material (*Kava*). The actors are extremely varied: pharmaceutical companies, companies dealing in herbal medicines, universities and biodiversity research institutions, indigenous and local communities and government agencies. Traditional knowledge is involved in *Kani*, *Hoodia* and *Kava*, not relevant in *INBio* and not a specific focus in *MSI-Cancer*. How the resource is used also varies considerably: while research in *INBio*, *MSI-Cancer* and *Hoodia* is targeted on blockbuster discoveries for major diseases of western civilization, the focus in *Kava* and *Kani* is currently on the use of the biological material itself.

The biological resources used range from plants (*Kava*, *Kani*, *Hoodia*, *INBio*) to insects (*INBio*), marine invertebrates (*MSI-Cancer*), microorganisms (*InBio*) and market herbal botanicals for health care (*Kava*, *Kani*, *Hoodia*), with the lead substances being further optimized for use as biopharmaceuticals (*Hoodia*) or directly screened for biopharmaceutical leads (*INBio*, *MSI-Cancer*).

The five cases show a wide variety of benefits in both cash and kind: from funds for the communities involved (*Kani*, *Hoodia*) to potential or current employment opportunities (*Kani*, *Hoodia*, *Kava*, *INBio*); from the strengthening of the community's cultural identity and self-governance (*Kani*, *Hoodia*) to percentage-based options some time in the future (*INBio*, *MSI-Cancer*, *Hoodia*), technology transfer and research cooperation, awareness creation and biodiversity inventories (*MSI-Cancer*, *INBio*). All cases show that ABS has the potential to bring the achievement of the Millennium Development Goals closer.

3.2 The case studies

3.2.1 The Kani case (*Kani*)¹⁸

Type of genetic resource: *Trichopus zeylanicus* spp. *travancoricus* (Trichopodaceae), a herbaceous, perennial, rhizomatous plant (local name: *argyapaacha*) found in the Agasthyar Hills of the Western Ghats (in Kerala and Tamil Nadu, India) that produces a rosette of 10 to 15 evergreen leaves weighing 100 to 200 g, with 2 or 3 flushes every year. It seems that only the subspecies found in Agasthyar has the claimed medicinal properties, although the species (*Trichopus zeylanicus*) is also found in the Malay peninsula and Sri Lanka.

Actors involved

- 1) The Kani people, originally a semi-nomadic tribal community, who now lead a largely settled life in the forests of the Thiruvananthapuram district of Kerala in the Western

¹⁸ See Anuradha (2000); Gupta (2002); Moran (2002).

Ghats: the customary rights to transfer and use certain traditional medicinal knowledge are held by tribal healers, known as *Plathis*. This knowledge is traditionally passed on from one generation to another, for the most part orally.

- 2) The Tropical Botanic Garden and Research Institute (TBGRI), an autonomous institution set up in 1979 by the government of Kerala for research and development. It has the largest botanical garden in Asia, with a wide collection of tropical plant species. One of the Institute's main aims is to carry out botanical, chemical and pharmacological research for the development of scientifically validated and standardized herbal drugs.
- 3) Arya Vaidya Pharmacy Ltd (AVP), a private company based in Coimbatore, which has been engaged in manufacturing high quality Ayurvedic drugs since 1948.

How the genetic resource is used

The plant is eaten by the Kani people to suppress fatigue and reduce stress. On the basis of this traditional knowledge, which was revealed by a number of Kani guides to members of a TBGRI expedition in 1987, the TBGRI spent seven to eight years carrying out all the investigations, toxicity tests and clinical trials needed to complete the formulation of *Jeevani*, a herbal drug consisting of four compounds. Subsequently, the TBGRI obtained a national process patent for *Jeevani* and licensed the product in November 1995 to Arya Vaidya Pharmacy Ltd for seven years at a licence fee of US\$ 25,000 and a 2% royalty on ex-factory sales for ten years from the date on which commercial production began.

In 2000, NutriScience Innovations LLC, a US-based supplier of nutritional and functional food ingredients registered the trademark *Jeevani* for the sale of the same drug in the USA. *Jeevani* is also an ingredient of the energizer Adrenerlin and is included in such Chinese/Japanese medicines as “Shosaikoto” to considerable clinical effect. *Jeevani*, based, as it is, on the Kani tribe's traditional knowledge, seems to have tremendous potential in the global natural health care product and sports medicine markets.

ABS agreement

The idea of sharing the licence fee and royalties obtained from AVP was developed by the TBGRI with a view to recognizing Kani's contribution, rather than as a result of any legal obligation to enter into such a benefit-sharing arrangement. At the time, there was no defined structure or policy in India for the sharing of benefits between originator communities and other bodies involved in the use of traditional community knowledge. In 1997, with the help of the TBGRI, NGOs and local government officials, the Kerala Kani Samudaya Kshema Trust was founded to represent Kani communities and promote local development in a unique and unprecedented benefit-sharing arrangement in India.

Implementation and compliance instruments

As the benefit-sharing agreement with the Kani is voluntary and based on a decision of the TBGRI Board of Directors, there are no legally binding instruments to ensure implementation and compliance by the TBGRI. The licence agreement between the TBGRI and Arya Vaidya Pharmacy Ltd is governed by Indian civil law.

Benefits

The TBGRI agreed to give to the tribal community 50% of the licence fee and 50% of the royalties obtained by AVP from the sale of Jeevani.

Benefits realized to date: In March 1999, the amount due to the Kerala Kani Samudaya Welfare Trust by that time (US\$ 12,500, i.e. its 50% share of the licence fee) was transferred to the trust on the understanding that only the interest accruing from this amount would be used for the welfare activities of the Kani tribe.

It has been impossible to realize any further benefits in the meantime, since the Forest Department, which has jurisdiction over the forest areas in which the Kani have settled, does not allow the plant to be collected or cultivated, even though cultivation methods allowing sustainable harvesting have been developed by the TBGRI together with the Kani. The Kani are thus prevented from delivering sufficient plant material to Arya Vaidya Pharmacy.

Indirect benefits: The TBGRI has also trained dozens of tribal families to cultivate the plant around their dwellings in the forest. In the first year of cultivation, before cultivation of the plant was stopped by the Kerala Forest Department in late 1999, each family earned about Rs 8,000 (about US\$ 180) from the sale of *arogyaapacha* leaves. Representing over 700 families, the Trust began to provide a critical source of employment for tribal people as cultivators and processors of the plant, while ensuring that harvesting techniques were sustainable.

Direct contribution to poverty reduction

So far, the Trust has supported poor members of the community, provided insurance for pregnant women and assisted when accidents have occurred.

As soon as the Kerala Forest Department approves the cultivation of *arogyaapacha*, the Kani will be able to develop a regular source of income based on the sustainable use of the natural resources of the forests they inhabit. This will help to empower communities to become involved in the conservation and development of the natural resources for their own benefit and that of the wider world.

The agreement between the TBGRI and the Kani triggered a discussion among the Kani themselves on the inherent value and custodianship of their traditional knowledge, and this

has led to self-organization and a general recognition of the individual responsibility of tribal members for the welfare of the whole community.

Lessons learnt to date

The Kani, who number about 17,000, live in different areas and have differing opinions on the arrangement with the TBGRI, which in the early stages in particular interacted primarily with the Kani from one area. This group of Kani supports and appreciates the TBGRI's role. However, Kani in other areas were offended by the restriction of the TBGRI's cooperation to one group – the one which revealed the knowledge considered sacred by some members of the community. The TBGRI acknowledged that it had not reached out to or communicated with all members of the Kani tribe, and the Trust was therefore established and registered with initially about 500 members. Today it represents over 700 families with a much broader regional coverage than at the outset.

The TBGRI process for the sharing of benefits with the Kani evolved in a policy vacuum, well before the CBD was introduced. The lessons learnt from mistakes made in this case did not have the luxury of a precedent or of guiding legislation passed by the national government. Instead, procedures were developed gradually in an *ad hoc* manner over the years. This occurred despite the fact that all project participants were nationals, with no international trade, companies or institutions involved. From the TBGRI's perspective, the whole effort was based on mutual trust and benefit between itself and the Kani. The ratification of the CBD by the Government of India in February 1994, however, helped to implement the benefit-sharing scheme with the Kani despite the efforts of the Tribal Welfare Department of India to block it.

This case highlights the need for multi-stakeholder frameworks to discuss the scale of access, value addition and benefit-sharing. If the Forest Department has jurisdiction over a territory, it must be included in the stakeholder discussions while benefit-sharing mechanisms are being established. Under the existing IPR regime, the scale of the benefits to be shared could have been much wider if:

- international patent applications had been filed under the Patent Cooperation Treaty administered by WIPO, to protect formulation in countries other than India,
- product patents rather than mere process patents had been available in India for pharmaceutical products,
- trademarks had been registered to protect the features that distinguish this product from those of other undertakings.

3.2.2 The Kava case (*Kava*)¹⁹

Type of genetic resource: *Piper methysticum* (Piperaceae), a perennial shrub growing to 3 m, with bright green, heart-shaped leaves about 15 to 20 cm in length.

Kava is the ceremonial and social drink of several Pacific island nations, and its cultivation, properties and uses have become a central part of Pacific island traditional knowledge. The plant has also been the subject of research and commercialization by Western researchers and firms since the middle of the 19th century. The medicinal and sedative properties of kava are well documented, and today there are a growing number of kava-based preparations in the European and US markets, some of which have been patented.

Actors involved

- 1) Traditional and commercial kava growers in the Pacific islands.
- 2) Numerous companies in the herbal industry, which have filed patent claims relating to the processing, preparation and use of kava. They include the French companies L'Oréal (EP 0672046) and Sederma S.A. (WO 9925369), Germany's Willmar Schwabe (DE 4028945) and Japan's Lion Corp (JP 1007464) and Shiseido (JP 09067238).

How the genetic resource is used

Kava plays an important role in the culture and social customs of the region. It has been cultivated for over 3,000 years and is used by Pacific islanders in religious ceremonies, in courtship rituals and at social gatherings. More than 118 cultivars are known to have been developed by farmers. It is a mood-altering substance, inducing relaxation, peace of mind and contentment, as well as a sharpening of the senses. Herbalists have traditionally used kava as a remedy for nervousness, urinary problems, asthma, whooping cough, stomach ache and headache. It is also used as a muscle relaxant for the relief of spasms and cramp. Kava kava is traditionally used in herbal medicines in non-standardized preparations, and no negative effects are reported.

The active compounds of kava are found in the rootstock. They consist primarily of the kavalactones, fifteen of which have been isolated. To date, scientific studies have identified three as responsible for a range of medicinal activities: dihydromethysticin (DHM), dihydrokavain (DHK) and kavain. Demonstrated activities include the inducement of sleep, painkilling, local anaesthetic, anti-convulsive, and anti-bacterial activity.

19 See Downes/Laird (2000); GRAIN/The Gaia Foundation (2000); WWF (2000).

The activity of kava is determined by the kavalactone content and absorption, which depend on the variety and maturity of the plant, how it is prepared and processed and how it is consumed.

ABS agreement: none.

Implementation and compliance instruments: not relevant.

Benefits

Benefits realized to date: not relevant.

Indirect benefits: Kava is among the ten best-selling herbs globally. A boom in 1998 saw sales surge to an estimated US\$ 50 million. While only about 100,000 kg was shipped to Europe in the whole of 1996, Fiji alone exported 50,000 kg of dried roots every week in 1998. In 1997, kava extract was sold by processing companies to manufacturers for US\$ 100 per kg, compared to US\$ 250 to 300 per kg in 1998.

The dramatic increase in the popularity of kava during the second half of the 1990s caused demand temporarily to outstrip supply. Good-quality material has usually sold out within a few days. A recent downturn in demand in the US and European herbal markets, influenced by adverse media coverage, led to a drastic slump, with unfavourable effects on local economies and growers, who had been increasing the acreage under cultivation. Marketing and export businesses have suffered. One small consolation for farmers is that the domestic market is strong and expanding and that the use of kava for traditional purposes and its cultural symbolism have grown. There are now kava bars, and kava is used symbolically in Christian atonement.

Direct contribution to poverty reduction

The use of kava by the herbal industry has the potential to contribute significantly to poverty reduction. Small farmers could earn substantial income from the cultivation of kava. However, market structures and marketing channels stand in the way of small farmers obtaining a fair share of the end product's value. This is true not only of kava but also of many other botanical resources of the herbal industry, such as devil's claw, *Harpagophytum procumbens* and *Harpagophytum zeyherii* (Pedaliaceae), from southern Africa and cohune, *Orbignya cohune* (Arecaceae), from Central America.

As the kava case demonstrates, international recognition of a local natural resource may lead to its local recognition and so to increased local demand, thus ensuring additional employment and income possibilities for local growers.

Lessons learnt to date

Kava is a major cash crop in the Pacific islands. However, substantial cultivation may eventually be developed elsewhere. World Botanicals (US) and others are looking at kava cultivation in the US state of Hawaii, the French colony of New Caledonia, Queensland in northern Australia and even Mexico. Kava from Hawaii is beginning to come on to the market in significant quantities, and as countries with a far larger acreage to sow than the small Pacific islands emerge with their kava harvests, the premium currently enjoyed by a few states seems certain to disappear.

US and European companies have trademarked a number of terms related to kava, including the names “Kava Pure” and “Kavatrill.” There are also at least five patents on kava extracts and active compounds. At least one company has obtained a patent on a combination of kava and other herbs, “Kavatrol”.

Kava appears to be a product with significant potential for the use of trademarks or geographical indications. An appropriate trademark, particularly a certification mark that reflected standards of environmental and socially responsible sourcing and processing of raw materials, might very well increase the Pacific growers’ market share if they could identify or develop suitable local cultivars that could be marketed as “True Kava”^(TM). This would be similar to the *Appellation of Origin* (DOC) label attached to some European wines and cheeses, which gives recognition to long histories of community-based innovation and experimentation that have resulting in the products we buy today. Measures needed to secure such an appellation for kava might include the use of clearly defined varieties and processing methods, all adequately monitored, with labelled products for each country. This may go some way to encourage quality control and social and environmental standards.

3.2.3 The Hoodia case (*Hoodia*)²⁰

Type of genetic resource: *Hoodia gordonii* (Asclepiadaceae), a succulent plant about 45 cm tall and indigenous to southern Africa.

20 See Wynberg (2003).

Actors involved

- 1) The San (Kalahari bushmen), one of the most poverty-stricken and marginalized communities in the region, live in Angola, Namibia, Botswana and South Africa and are organized in the Working Group of Indigenous Minorities in Southern Africa (WIMSA) and the South African San Council.
- 2) The Council for Scientific and Industrial Research (CSIR), a South African-based statutory board which represents one of the largest research organizations in Africa, responsible for 12% of all industrial research and development on the continent.
- 3) Phytopharm plc, a small British pharmaceutical company, specializing in the development of phytomedicines, founded 1990.
- 4) Pfizer Inc., a US-based multinational life science corporation.

How the genetic resource is used

The Hoodia cactus has long been used by the San to stave off hunger and thirst. In 1995 the CSIR patented Hoodia's appetite-suppressing element (P57). In 1997 it licensed P57 to Phytopharm. In 1998, an exclusive world-wide licensing agreement was signed by Phytopharm and Pfizer for the development and global commercialization of P57 as an oral prescription drug for the treatment of obesity (a market worth more than US\$ 10 billion). Phytopharm will receive up to US\$ 32 million in royalty and milestone payments. P57 is considered to have the potential to become a "blockbuster" drug and is likely to be commercialized as a prescription medicine with an estimated market potential of US\$ 1 to 8 billion.

ABS agreement

With the consent of the Department of Environmental Affairs and Tourism (DEAT), the CSIR has developed a bioprospecting agreement with Phytopharm under the law of contract with a view to providing DEAT with case studies as a basis for future policy development.

Under a 2002 Memorandum of Understanding with the South African San Council, the CSIR has formally recognized the San as the originators of traditional knowledge associated with the human use of Hoodia.

March 2003 saw the conclusion of negotiations between the San and CSIR on the specifics of a mutually acceptable benefit-sharing agreement. In the event of successful commercialization, the potential income stream will be deposited in the San Hoodia Benefit Sharing Trust, established by the CSIR and the South African San Council to improve the standard of living and well-being of the San peoples of southern Africa. The Trust will

include representatives of the CSIR, the =Khomani, !Xun and Khwe, other San stakeholders in southern Africa, the WIMSA and the Department of Science and Technology, with strict rules determining the distribution of funds to beneficiaries. The agreement commits the parties to conserving biodiversity, requires the CSIR to grant the San access to existing study bursaries and, significantly, lays the foundations for further collaboration in bioprospecting.

Implementation and compliance instruments

A contract governed by South African law.

Benefits

Benefit-sharing is agreed in the contract as a two-step procedure. As the first step, the CSIR receives milestone payments and royalties from Pfizer and Phytopharm. By licensing the technology, the CSIR is likely to earn US\$ 10 million in milestone payments, linked to the success of the drug at different stages of the clinical trials. The specific royalty percentage has not been made public, but is considered by the CSIR to be substantial by international standards. Typically, royalty percentages for pharmaceuticals range from 0.5% to 5% of total sales. If successful, the commercialization of P57 is likely to bring in tens of millions of US\$ p.a. in royalty income for the CSIR during the life of the patent (15 to 20 years).

As the second step, the CSIR will pay the San 8% of all milestone payments it receives from its licensee, as well as 6% of all royalties that the CSIR receives once the drug is commercially available. Milestone payments are subject to agreed technical performance targets for P57 during its clinical development over the next three to four years, and royalties are based on sales, which are not scheduled to begin before 2008. The San will thus receive only a very small proportion – less than 0.03% – of net proceeds from the sale of the product.

Owing to this two-step procedure, Pfizer and Phytopharm are exempted from sharing the benefits directly with the San. As the CSIR acts as an intermediary, the San depend on its negotiating strategy for their share of the benefits. Moreover, the agreement stipulates that the companies are protected against any further financial demands from the San. It also explicitly prevents the San from using their knowledge of Hoodia in any other commercial applications.

Benefits realized to date: So far, US\$ 33,000 has been paid into the San Hoodia Benefit Sharing Trust as the San's share of the milestone payments received by the CSIR.

Indirect benefits: Two of the more significant indirect benefits to emanate from the agreement have been the construction of a medicinal plant extraction facility at the CSIR, which requires the approval of the US Food & Drug Administration and manufactures material used in P57 clinical trials, and the establishment of a Botanical Supplies Unit – each the first of its kind in the world.

Where the San are concerned, what is most remarkable is that the benefit-sharing agreement covers not only the San living in South Africa but the San community throughout southern Africa. This strengthens the cross-border identification of the San as an indigenous people of southern Africa and may do a great deal to improve the position of San communities in some of the other countries, where they are even more marginalized than in South Africa and Namibia and are fighting for recognition by the various national governments.

Direct contribution to poverty reduction

The funds received by the trust will be used to improve the general living conditions of the marginalized San communities in southern African countries through the development of health care, infrastructure and social security. In the long term the benefit-sharing agreement will help to further the recognition of the San as an indigenous people not only in South Africa but in the region as a whole.

Currently, commercial farmers in the Northern Province and Northern Cape are undertaking cultivation trials. Further cultivation represents an obvious development opportunity for the San and other marginalized communities, although the technical challenges associated with the plant's cultivation are reportedly considerable. The scarcity of water also constrains cultivation in the parched areas of the Kalahari, where many of the San live. Successful cultivation will not only contribute to sustainable resource use but also provide income for local communities. Trade in herbal Hoodia products is growing, and demand will most probably increase in the coming years.

Lessons learnt to date

Many consider South Africa to have reached an important turning point in bioprospecting. Patent rights to the active constituents of Hoodia responsible for suppressing appetite have been successfully retained by South Africa through the CSIR (although other Hoodia-related patents remain foreign-owned), with foreign drug firms obtaining licences for the further development and commercialization of the drug.

The 2002 Memorandum of Understanding between the CSIR and the South African San Council recognizes the San as the originators of the relevant knowledge. However, the agreement is almost entirely confined to monetary benefits, which hinge on product sales and successful commercialization. Yet commercialization is far from certain: Phytopharm announced on 30 July 2003 that it had been notified of Pfizer's decision to discontinue the clinical development of P57 for the treatment of obesity and to return the rights to Phytopharm. Following the closure of the Natureceuticals group within Pfizer, the company has decided that P57 may best be developed by another organization. As a result, Phytopharm is now free to license P57 to other parties. Pfizer also stated that clinical data on P57 in

patients indicate the wisdom of further study of the use of the natural material in the treatment of obesity.

3.2.4 The MSI anti-cancer agreement (*MSI-Cancer*)²¹

Type of genetic resource: Marine organisms as a source of extracts and compounds with potential anti-cancer activity, originating from specific areas within the Philippine archipelago.

Actors involved

- 1) Marine Science Institute of the University of the Philippines (UP-MSI) – co-collector.
- 2) University of Utah, USA – principal collector.
- 3) Philippine Department of Agriculture (DA).
- 4) Wyeth-Ayerst, formerly American Cyanamid, USA – receives under a transfer agreement materials from the University of Utah for further research and commercialization.

How the genetic resource is used

The commercial research agreement (CRA), which is entitled “Anticancer Agents from Unique Natural Product Sources”, allows the parties “to collect from certain areas in the Philippines marine organisms as a source of extracts and compounds with potential anti-cancer activity, which shall be exported to the United States for evaluation of the presence of the stated medicinal or pharmacological content.”

ABS agreement

The CRA 98 – based on Presidential Executive Order 247 (EO 247) – between the Marine Science Institute of the University of the Philippines, the Department of Agriculture of the Philippines and the University of Utah, USA, was approved for three years in July 1998. The main objectives of the CRA 98 are: (1) to collect marine organisms from different habitats within the Philippine archipelago; (2) to isolate active metabolites and to determine their structure and (3) to perform systematic inventories of the biodiversity of the various habitats

21 See Columbia University (1999), Liebig et al. (2002) and Concepción (2003).

within the Philippine marine ecosystem. The agreement expired in 2001 and was renewed for another three years in 2002.

Implementation and compliance instruments

EO 247 became law on 18 May 1995 in response to a non-governmental initiative aimed at implementing the Convention on Biological Diversity. It provides a legal framework for bioprospecting and is one of the first attempts by a nation formally to regulate access to biological diversity. In June 1996, the Department of Environment and Natural Resources issued Department Administrative Order No 20 (DAO 96-20), which sets out the rules and regulations governing the implementation of EO 247.

The joint obligations of CRA 98 require the collectors to comply with all the applicable laws and regulations of the Republic of the Philippines and the United States of America. Any controversy or dispute related to the agreement which cannot be settled by mutual accord between the parties must be settled by arbitration.

The Department of Agriculture's obligations include the monitoring of the research activities to ensure compliance with the provisions of EO 247, DAO 96-20 and CRA 98. The collectors must submit a copy of the collection reports to the field office of the Department's Fisheries Office nearest the collection site. They must also provide the Department with a complete list of institutions, gene banks and other depositories where materials, data and documents have been placed. The Department of Agriculture has reserved the right to suspend or stop any collection or research activity if the collectors do not follow the prescribed Prior Informed Countries (PIC) process.

Wilful violation by the collectors of the terms and conditions of the agreement will result in its cancellation, the confiscation of the materials by the Philippine government and the imposition of reasonable penalties as provided under Section 10 of EO 247. The principal collector may rescind the agreement in the event of bankruptcy, security problems and *force majeure*, provided that, in the case of bankruptcy, all bonds are forfeited and all equipment and materials and related documents transferred to the co-collector and other Philippine institutions.

Benefits

An annual bioprospecting fee of PhP 10,000 (about US\$ 200) payable to the Interagency Committee for Biological and Genetic Resources for the duration of the agreement. Additionally, a minimal performance bond no greater than PhP 10,000, which will be returned upon the termination of the agreement on condition that none of the provisions of the agreement has been violated.

Five per cent of the net revenue received by the collectors in respect of any invention, licence, royalty or other commercialization of any material will be paid to the Department of Agriculture (the Integrated Protected Areas Fund, if the materials come from a protected area, the indigenous people or local community who gave the PIC or the individuals who provided such materials from private property). The two collectors have agreed in a memorandum to share equally (50/50) the intellectual property rights and any ensuing material benefits from discoveries made during this project.

The UP-MSI is also required to help train government representatives in taxonomy or natural products chemistry under short-term internship programmes. The systematic inventories of the biodiversity of the various habitats within the Philippine marine ecosystem will increase knowledge of the biodiversity and conservation status of marine organisms. A complete set of all specimens is to be deposited at the UP-MSI, which will make arrangements with the National Museum of the Philippines regarding the requirement for holotypes.

To provide benefits for the communities, the UP-MSI must conduct an information campaign on the protection/conservation of coastal resources and their value. In addition, if inventions are derived from the use of the materials, the collectors must provide training in a marine-related discipline if there is a qualified candidate from the community.

Benefits realized to date: So far, only UP-MSI has received any substantial benefits through its close academic collaboration with the University of Utah. The Philippine government has received only negligible benefits in the short term, i.e. the annual bioprospecting fee (about US\$ 200). Long-term benefits have not yet materialized, since none of the compounds isolated from the samples has yet been considered promising enough for international patenting and licensing.

Indirect benefits: The PIC procedure stipulated in EO 247 has been followed by the collectors, although it has not been easy to identify the local communities concerned in the case of marine resources. Nevertheless, with the help of NGO advisory services the communities have begun to exercise the rights they enjoy under EO 247. Furthermore, the consultation process has given communities the feeling that they are being taken seriously as users of regional marine biodiversity.

Direct contribution to poverty reduction

The direct contribution to poverty reduction is unpredictable because significant revenues will flow back to the Philippines only if a commercially successful product is developed from the materials collected. Furthermore, the benefits will depend on the result of the negotiations between the collectors and the party that commercializes the product. The CRA stipulates only that the Philippine government is to receive 5% of the revenues received by the collectors. How these revenues are channelled back to the indigenous or local community that originally granted the PIC has still to be defined.

Lessons learnt to date

This CRA is one of the few negotiated under EO 247, the first legislation anywhere in the world to implement Article 15 of the CBD on access and benefit-sharing at national level. The agreement provides for administrative fees to be paid to the Philippine government. Further benefits, which may flow back to indigenous and local communities or be used for conservation purposes in protected marine areas, can be generated only on the basis of patentable inventions that can be successfully commercialized. This focus in the benefit-sharing agreement on successful commercialization is the weak point of the agreement, since in the short term only MSI profits from the close academic collaboration between the two institutions until a promising compound can be identified.

3.2.5 The INBio-Merck agreement (*INBio*)²²

Type of genetic resource: Plants, insects and environmental samples to be evaluated for potential pharmaceutical and agricultural applications.

Actors involved

- 1) National Institute of Biodiversity of Costa Rica (INBio), a non-profit association established under Costa Rican law in 1989. INBio has a formal agreement with the Ministry of the Environment, allowing it to undertake specific activities relating to the national inventory and the utilization of the biodiversity in the protected areas.
- 2) Merck & Co., Inc.

How the genetic resource is used

A predetermined (confidential) number of processed plants, insects and environmental (micro-organism) samples are initially extracted and processed by INBio, and their pharmaceutical properties are explored at Merck facilities in Spain and the United States.

ABS agreement

The INBio-Merck agreement was signed in 1991, before the Convention on Biological Diversity was established, and renewed in 1994, 1996 and, for the last time, 1998.

22 See Columbia University (1999); Government of Costa Rica (1999).

Implementation and compliance instruments

A contract governed by Costa Rican law. Explicit compliance mechanisms entail only the payment of royalties. Article 3(d) states that, if an audit reveals an unfair payment in excess of 10%, the offending party must pay the full cost of the audit and correct the amount paid as soon as possible.

Benefits

Merck will provide INBio with a research fund of US\$ 1million during the first two years of the agreement and contribute the laboratory equipment and materials needed by INBio to operate the laboratories for the processing of the samples at INBio and the University of Costa Rica. Merck will provide an additional fund to support INBio's work during any extension of the agreement.

Merck agrees to pay royalties to INBio for any pharmaceutical product for human or animal use or for any product that can be used in agriculture that has been initially isolated or produced from any sample sent by INBio to Merck. The royalties will also apply to any product derived from or analogous to these compounds and to chemical compounds derived from living microorganisms isolated from environmental samples or from samples of dead tissue. The royalty percentage is considered to be confidential information and will not be divulged. It is within the range of percentages usually granted under this type of agreement.

INBio will establish the necessary facilities in Costa Rica for the collection and processing of plants, insects and environmental samples. It will hire and train the personnel needed for the collection and processing of the samples. Merck agrees to provide training in its laboratories for INBio's personnel or whomever INBio appoints.

The samples of plants and insects will be processed in a laboratory established by INBio at its own facilities and under a service subcontract at the University of Costa Rica.

Benefits realized to date: During the first two years of the agreement Merck paid INBio US\$ 1 million in advance and provided an additional US\$ 130,000 worth of laboratory equipment and material. Part of the money was allocated to the Costa Rican government's conservation programme, part was used by INBio for a complete inventory of the country's biological resources. No other information on the specific benefits of this agreement has been published.

In the years after the trail-blazing Merck contract, INBio signed more agreements with other companies and scientific institutions. As of 2002, INBio's biodiversity prospecting agreements has generated almost US\$ 600,000 for the Ministry, more than US\$ 790,000 for conservation areas and US\$ 1,000,000 for public universities, as well as US\$ 740,000 to cover INBio activities, particularly the national biodiversity inventory.

Table 4: Contributions and payments by INBio's Bioprospecting Unit from 1991 to 2002, in US\$							
	1991 - 1993	1994	1995	1996	1997	1998 - 2002	Total
Ministry of Energy and Environment	100,040	43,400	66,670	51,092	95,196	242,057	598,455
Conservation Areas	86,102	203,135	153,555	192,035	126,243	29,579	790,649
Public Universities	460,409	126,006	46,962	31,265	34,694	337,692	*1,037,028
Other groups at INBio	228,161	92,830	118,292	172,591	129,008	0	740,882
Total	874,712	465,371	385,479	446,983	385,141	609,328	3,167,014
* Includes the value of INBio's equipment located at the University of Costa Rica. Source: INBio (2003).							

Indirect benefits: The agreement with Merck has triggered a number of cooperative projects involving INBio and other private sector companies and scientific institutions in the bioprospecting of Costa Rica's natural resources. A cooperation agreement signed in 1994 by INBio and the Ministry of the Environment and Energy governs INBio's responsibilities in the area of bioprospecting and specifies how it is to use the payments it receives. The agreement is valid for five years and is automatically renewed for the same period. It requires that the equivalent of at least 10% of the budget of each bioprospecting venture be used to support the management and protection of conservation areas and that 50% of any economic and material benefit (e.g. royalties) which INBio derives from the conclusion of bioprospecting contracts be transferred to the Ministry, which uses the money for the management and protection of conservation areas.

Direct contribution to poverty reduction

INBio has signed agreements not only with the industrial sector but also with the academic, non-governmental and governmental sectors. However, local communities have not yet shared in the economic benefits to any great extent. Men and women from the rural communities of Costa Rica, near protected areas, attend an intense, 6-month vocational course to become parataxonomists. The course covers the fundamentals of biology, ecology, taxonomy, evolution, collection and preservation techniques, techniques in data and information handling, equipment maintenance and administration, and everything that an individual has to know to combine individual fieldwork with teamwork. The employment of local residents is one of the direct benefits of conservation to the rural communities of the areas concerned. In addition to fieldwork and investigation, the parataxonomists disseminate their knowledge and impart the value of biodiversity to their own communities and parks

through educational programmes aimed at their colleagues, neighbours, relatives and local schools.

Compared to other forest income activities in Costa Rica, such as forestry (which generates US\$ 28 million p.a.) and tourism (US\$ 421 million), the contribution made by the initial bioprospecting activities has been fairly small. However, a number of drugs are likely to be developed from Costa Rican genetic resources in the medium term. According to the World Resources Institute, even if INBio received only 2% of royalties on the sale of pharmaceuticals developed from Costa Rica's biodiversity, it would take "only" 20 drugs for INBio to be able to earn more funds than Costa Rica currently obtains from coffee and bananas, two of its major export crops.

Lessons learnt to date

The lack of transparency and information does not make it easy to evaluate the INBio-Merck agreement. Furthermore, the agreement does not provide for any measures to ensure the participation and compensation of all the stakeholders, especially the local and indigenous communities, or respect for their property rights.

While not necessarily a model for other countries in itself, INBio is a very interesting example of how a particular bioprospecting effort – structured, designed and implemented before the CBD entered into force – has enabled a small biodiversity-rich country to enhance its national research capacities and establish a specific benefit-sharing arrangement that satisfies national interests. The INBio-Merck case is only one current institutional activity and is promoting further understanding of and research into Costa Rica's biodiversity, particularly in protected areas, where INBio undertakes the bulk of its activities. INBio's institutional policies are focused on adding value to national biodiversity by carrying out specialized research in the country and supplying potential academic and commercial users with information and initial products. In the case of the INBio-Merck deal not only are raw samples being supplied: they are also classified and pre-screened. Furthermore, passport information is coded in order to ensure that, if there should be any interest in future research and development processes, users are forced to return to INBio to obtain further materials or information.

3.3 Conclusions from the case studies

The case studies provide major insights into how genetic resources and the sharing of the benefits arising from their use can contribute to poverty alleviation (3.3.1) and what this means for a legal regime (3.3.2).

3.3.1 Contribution to poverty alleviation

According to the overall concept of poverty alleviation presented in Chapter 2, any measures taken should seek to promote opportunities, facilitate empowerment and enhance security for the poor. The diverse benefit-sharing approaches revealed by the five case studies show that ABS policies can contribute to the first and second elements of the concept. The implications for the third element remain rather more speculative, although not necessarily unrealistic.

Opportunities for the poor are promoted in at least three ways. At the most general level, ABS policies can foster economic growth, which in the long run could benefit the poor, if the policy framework is supportive. Of the cases presented, *INBio* is most obviously pursuing this goal. It is the clear objective of *INBio* and its political supporters to increase the value added to genetic resources in Costa Rica. A similar idea can be identified in *Hoodia* and *MSI-Cancer*, although the respective countries of origin seem to be pursuing a less stringent policy to achieve the goal. *Kani* and *Kava* are still at the stage where the region produces the raw material, while the value is added elsewhere. In the medium and long run, this strategy offers less prospect of economic growth since the suppliers of raw material are likely to lose market shares if more competitive substitute suppliers emerge or demand falls.

On the other hand, *Kani*, *Kava* and, to some extent, *Hoodia* are promoting short-term opportunities for the local poor directly by providing employment opportunities. This is the most visible way for the local poor to share in the benefits derived from the use of biodiversity. It should be noted, however, that the local poor benefit by collecting or cultivating the biological resource. This approach to benefit-sharing is therefore similar to conventional trade in biological resources (e.g. timber). The difference from conventional trade lies in the genetic properties of the biological resources that are of interest to the user of the final product.

Finally, opportunities for the poor could be promoted in the future through long-term benefit-sharing. *MSI-Cancer*, *INBio* and *Hoodia* include agreements on future benefit-sharing and represent cases of “blockbuster-hope”. All cases show that it is too early to assess the amount of monetary and non-monetary benefits that may accrue in the future. Consequently, it is not yet possible to discuss the scale of the poverty-alleviating effect. But three points can already be made: first, agreements about long-term benefit-sharing increase the credibility of bioprospecting for the local communities since they will share in any future profits. Second, funds seem to be an appropriate avenue for the distribution of monetary benefits in the region. Third, if locals have only insecure benefits to look forward to (as in *MSI-Cancer* and *INBio*), an ABS agreement is hardly likely to materialize, since the values of biodiversity for the local population will not increase in the short term.

As meagre as the monetary benefits have hitherto been in the five case studies, they nevertheless point in the right direction. Benefit-sharing agreements are used to transfer a certain amount of the present direct use value of genetic resources to the local poor. This is achieved primarily through the provision of employment opportunities. Long-term benefit-

sharing is intended to transfer a share of the option value which the global gene fund has for humankind. Little has so far been achieved, but *INBio*, *MSI-Cancer* and *Hoodia* at least reveal the potential of ABS agreements in this respect. However, the *Kani* case also provides an example of how benefit-sharing may give rise to conflict even within an indigenous community. The agreements should therefore be drafted in a participatory process in order that they may take account of different perceptions within the local and indigenous communities and avoid treating them as a “black box”.

Empowerment of the poor has been facilitated in some of the cases, most obviously in *Kani* and *Hoodia*. Both these cases provide potential turning points for indigenous communities from dependence on government welfare to self-governance. It has been the negotiation process rather than the benefits themselves that has facilitated this process. Similarly, in *MSI-Cancer* it is the PIC process that has been instrumental in empowering local and indigenous communities.

Security has not yet been enhanced by benefit-sharing in any of the cases. This does not come as a surprise, however, since all the cases are still relatively recent. Security may be enhanced if the stability of the local ecosystem is increased by benefit-sharing. This may be the case if benefit-sharing leads to a greater appreciation of the functions of biodiversity compared to substitutive land uses. A share of the indirect use value of biodiversity thus needs to be transferred to the local population. The five cases show a certain potential in this respect, but an assessment of any concrete effects would be premature.

3.3.2 Legal conclusions for the design of a benefit-sharing regime

Neither the existence of a national ABS regime nor a carefully negotiated ABS agreement is a guarantee of a fair distribution of benefits among the stakeholders in the provider country. It is especially worrisome that the local poor do not always benefit from the agreements, at least not in the short term. This handicaps the functioning of an ABS agreement since the whole idea of a win-win solution implies that the custodians of biodiversity benefit from the use of genetic resources. From the experience gained in the case studies it is fair to say that, without clear guidance for negotiators of ABS agreements, short-term benefits for the local poor are left to the benevolence of the main actors (*Kani*), occur only as a side-effect (*MSI-Cancer*, *INBio*) or have not even been considered (*Kava*). *Hoodia* is a laudable exception that comes as no surprise. The design of the ABS agreement in this case is due to several factors in the country of origin that establish the right policy environment: a clear biodiversity policy, strong encouragement from the South African government to support communities and alleviate poverty, an advanced stage in the drafting of legislation on ABS with the main actors involved from the outset and thus a general awareness of the issue certainly had a decisive impact on the negotiations and the agreement.

The legal implications are thus twofold: firstly, governments need to establish a **broad participatory process** when drafting legislation to make sure that everybody is on board and

that awareness is raised to a level where it impacts on the outcome of ABS negotiations. Secondly, legislation or policy should stipulate **explicitly that benefits for the local poor** are to be addressed when benefits are being negotiated.

The case studies hint at options for the innovative use of intellectual property rights in the interests of achieving the objective of poverty alleviation in benefit-sharing agreements. *Kava* appears to be a product with significant potential for the use of trademarks or geographical indications. Growers in the Pacific may be able to secure for themselves a measure of protection against competitors in industrialized countries if they are able to identify or develop suitable local cultivars which can be trademarked as “True Kava”^(TM). This would be similar to the *Appellation of Origin* (DOC) label attached to some European wines and cheeses, giving recognition to long histories of community-based innovation and experimentation that have resulted in the products we buy today. Measures needed to secure such an appellation for kava could include the use of clearly defined varieties and processing methods, all adequately monitored, with labelled products for each country. This may go some way to encourage quality control and social and environmental standards.

What the case studies could not show, but what constitutes a problem for the international community, is the distinct possibility that today’s benefits are so meagre because users are employing substitution strategies to circumvent provider countries with stringent ABS regimes. In this case, users may still resort to free-rider behaviour, resulting in an inadequate share of the value of biodiversity being transferred to provider countries. If this is so, the “grand bargain” of the CBD will not materialize, and neither environmental protection nor poverty alleviation will be achieved through ABS agreements. The international community should therefore adopt legislation to prevent the users of genetic resources from pursuing inefficient substitution strategies.

4 Provisions for an international ABS regime

This chapter discusses the political motivation of and suggests provisions for an international regime on ABS with the focus on benefit-sharing as a poverty alleviation tool. The first section provides an overview of the international political landscape that calls for an international regime (4.1). This is followed by a discussion of its form, motivation and objective (4.2). The third section provides the theoretical background for the level of regulation on the regime – national or international (4.3). Section 4.4 is the core section of this chapter: it proposes key substantive, procedural and institutional provisions for the international ABS regime. This is complemented by a final section on implementation at national level (4.5.).

4.1 The political landscape of the international regime

4.1.1 Policy call for an international regime

The main provisions of the CBD that concern ABS are Articles 15, 16.3, 19.1 and 19.2 in conjunction with Article 8(j) and other articles. These provisions establish the framework for ABS. Since the CBD entered into force, the Conference of the Parties (COP) have discussed the question of ABS at every meeting.²³ At its sixth meeting, the COP adopted in decision VI/24 A the Bonn Guidelines on access to genetic resources and the fair and equitable sharing of benefits arising out of their utilisation.²⁴ In paragraph 6 of the decision the COP “recognizes that the Guidelines are a useful first step of an evolutionary process in the implementation of the relevant provisions of the Convention ...”, thus accepting that the Bonn Guidelines are not in themselves equal to the task of implementing the provisions of the Convention that concern ABS. Nor are ABS regimes yet in place at regional level. The European Community’s 1998 Biodiversity Strategy notes the need for the Community to promote appropriate multilateral frameworks for ABS and states in its Second Report to the COP that it has “yet to introduce comprehensive legislation governing ABS and related traditional knowledge”.²⁵

In September 2002, six months after the adoption of the Bonn Guidelines, paragraph 44(o) of the Plan of Implementation of the World Summit on Sustainable Development called for action to “negotiate within the framework of the Convention on Biological Diversity, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources”.²⁶ Heads of

²³ Decisions II/11; III/15; IV/8; V/26; also III/5; III/14; IV/13.

²⁴ CBD/COP/6/20/PART2, see www.biodiv.org.

²⁵ EC (2001), p. 2.

²⁶ WSSD (2002).

state and government recognized the current absence of an international regime on benefit-sharing. Not only the COP itself but the international community is of the view that the text of the CBD together with the Bonn Guidelines do not yet constitute a benefit-sharing “regime” at international level. The COP has been clearly charged by the WSSD to develop such a regime.

The Inter-Sessional Meeting that discussed the Multi-Year Programme of Work of the Conference of the Parties up to 2010 reinforced this approach in March 2003. The meeting recommended that “the Ad Hoc Open-ended Working Group on Access and Benefit-sharing should, in its consideration of other approaches [...] consider the process, nature, scope, elements and modalities of an international regime and provide advice to the Conference of the Parties at its seventh meeting on how it may wish to address this issue”.

4.1.2 Poverty alleviation and benefit-sharing

The WSSD not only provides policy guidance on the regime as such but, indirectly, also gives indications for its content. The Millennium Development Goals were adopted by the UN General Assembly in September 2000.²⁷ The first MDG is to eradicate extreme poverty and hunger by 2015 (“halve the proportion of people living on less than a dollar a day and those who suffer from hunger”). Paragraph 7 of the Plan of Implementation of the WSSD underlines this goal and specifies ways and means of eradicating poverty, including the improvement of access by indigenous people and their communities to economic activities (paragraph 7(e)) and the building of basic rural infrastructure, the diversification of the economy and the improvement of access to markets (paragraph 7(i)). The WSSD also sets a target for biodiversity conservation. Paragraph 44 calls for a “significant reduction in the current rate of loss of biodiversity” by 2010. This will require the provision of new and additional financial and technical resources, and action *inter alia* aimed at “poverty eradication, including initiatives which promote community-based sustainable use of biological diversity” (paragraph 44(d)).

The question is, therefore, whether the CBD supports poverty alleviation as an aspect of benefit-sharing. The CBD itself has little to say about poverty. It is explicitly mentioned only in paragraph 19 of the preamble: “Recognizing that economic and social development and poverty eradication are the first and overriding priorities of developing countries [...]” However, the CBD makes specific reference to developing countries in many of its operational provisions (e.g. Articles 16.3, 17.1, 18.2) and thus indirect reference to poverty alleviation.

On the other hand, poverty alleviation is one of the purposes of the Bonn Guidelines: “to contribute to poverty alleviation and be supportive to the realization of human food security, health and cultural integrity (paragraph 11 k of the Annex to decision VI/24 A).

²⁷ See UNDP (2000).

In his statement at the Open-ended Inter-Sessional Meeting held in March 2003 to discuss the Multi-Year Programme of Work of the COP up to 2010 the Mexican representative, speaking on behalf of the Group of Like-Minded Megadiverse Countries, pointed to “the sad paradox that those living in the most biologically diverse regions of the world also lived in conditions of unacceptable poverty.... The loss of biological diversity could be reversed only if the developing countries which were the countries of origin of biological diversity, and the indigenous and local communities that acted as the custodians of biodiversity resources were given a fair and equitable opportunity to benefit from the conservation and equitable use of biological diversity” (UNEP/CBD/COP/7/5, paragraph 32).

Contributing to poverty alleviation through benefit-sharing goes hand in hand with the implementation of Article 8(j). The stakeholders, indigenous and local communities having traditional knowledge, are too often prone to poverty. But the addressees of poverty alleviation in the context of benefit-sharing are not only those who have traditional knowledge for which they receive benefits: ABS can provide income opportunities for local people, as the cases of *INBio* (parataxonomists), *Kava* and *Hoodia* (cultivation for internal and external markets) show. Moreover, ABS agreements can help to facilitate the empowerment of the poor.

4.2 Form, motivation and objectives of an international ABS regime

When the task of developing an international regime is undertaken, one question that needs to be asked is what “regime” means. What is the nature of the regime? In what form should it be constructed? What is meant to be developed? As the WSSD’s instructions do not provide any guidance, the CBD offers policy-makers considerable scope.

4.2.1 Definition of “regime”

The term “regime” may reveal what the legal and structural implications of the international rule-making process are. Based on their analysis of international treaties and policy fields, regime theorists in political science define the term “international regime” as “a set of principles, norms, rules and decision-making procedures around which actors’ expectations converge in a given area of international relations”.²⁸ “Regime” also implies “some minimal effectiveness which can be measured by the degree of rule-compliance”.²⁹

This definition does not state whether the principles, norms, rules and procedures are legally binding or whether some parts of the regime should be legally binding. It reveals that “regime” entails not only substantive provisions but also procedural provisions relating both

²⁸ Krasner cited in UNEP/CBD/MYPOW/6 para 19.

²⁹ List/Rittberger cited in UNEP/CBD/MYPOW/6 para 19.

to decision-making and implementation/compliance. Embedded in the WSSD's call for the "development of an international regime" lies the implicit acknowledgement that the Bonn Guidelines do not meet the benchmark of what a "regime" entails. It does not, however, give any further information on the legal quality of the regime.

4.2.2 Norm-setting options under the CBD

Voluntary guidelines such as the Bonn Guidelines do not suffice for an international ABS regime. For a decision to be taken on the nature of the regime, the norm-setting options offered by the CBD will need to be analysed. As a treaty governed by public international law, the CBD provides several tools that can be used either together or separately to support the implementation of its provisions: COP decisions, amendments, annexes and protocols to the Convention.

COP decisions

COP decisions are the most direct means of creating a benefit-sharing regime. They are binding interpretations of the Convention. As the CBD is a multilateral treaty governed by public international law, its norms are subject to the rules and principles of interpretation in public international law. States are bound by the rules of customary international law on treaty interpretation (see Article 38.1(a) of the Statute of the International Court of Justice). The Vienna Convention on the Law of Treaties (VCLT) of 1969 codifies authoritatively the principles of treaty interpretation. Its principles are generally accepted as reflecting customary international law and are therefore binding on matters falling within the realm of public international law.³⁰ According to the rules of interpretation, any interpretation of a treaty should take into account "any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions." (Article 31.3(a) of the Vienna Convention).³¹ When taken unanimously, COP decisions are subsequently (after agreement on the text of the CBD) agreed interpretations. If the meaning of a COP decision is clear and unambiguous, it can be a good tool for implementing the CBD, e.g. in the case of litigation between Parties, COP decisions would be used to determine whether a CBD norm had been violated. One example of such a clear interpretation is to be found in paragraph 2 of decision II/11, ("The COP reaffirms that human genetic resources are not included within the

³⁰ International Court of Justice (ICJ), Competence of the General Assembly for the Admission of a State to the United Nations, Advisory Opinion of March 3, 1950, ICJ Reports p. 8; ICJ, Case Concerning the Arbitral Award of July 21, 1989, judgement of November 12, 1991, ICJ Reports 1991, pp 69, 72; Bernhardt (1995), pf. 1421. Cf. Articles 31 and 32 of the Vienna Convention on the Law of Treaties between States and International Organizations or between International Organizations of March 20, 1986 (UN Doc. A/Conf. 129/15, March 20, 1985), which are identical with Articles 31 and 32 of the Vienna Convention on the Law of Treaties.

³¹ <http://www.un.org/law/ilc/texts/treaties.htm>.

framework of the Convention”). If COP decisions are clear, non-contradictory and explicit in their wording, forged with legal understanding and do not contain “escape qualifiers” such as “as appropriate” and “as necessary”, they provide a useful tool for designing a regime. What appears to be a good solution at theoretical legal level, however, may prove not to be practicable.

If an international ABS regime is to be of greater use to Parties than what voluntary guidelines provide, COP decisions establishing the regime need to be clear and precise, leaving no room for interpretation *ad libitum*. Unfortunately, there must be serious doubts about the COP having the necessary discipline to take a stringent decision. Of the 143 decisions so far taken by the COP, very few of those concerning substantive issues meet these requirements. While COP decisions may be the easiest and also the most flexible way to establish a regime – it can be amended by superseding decisions – it is very doubtful whether the regime would have much strength.

Another aspect of COP decisions to be considered is their relationship with other international treaties. While they have exclusive interpretative power over the text of the CBD and are thus legally binding in the context of the CBD, they carry less weight in relation to other international treaties, such as the TRIPs Agreement.

Amendments

Another approach to the construction of an ABS regime is the adoption of amendments. Amendments can be adopted by the COP under Articles 23.4(d) and 29. They are adopted by consensus at a meeting of the COP. When every effort to achieve a consensus has been made, the amendment may be adopted as a last resort by a two-thirds majority of the Parties present (Article 29.3). As amendments require ratification, acceptance or approval, the Parties have to undertake the same national legislative procedure as when adopting a protocol. Amendments are binding only on those Parties who submit their instruments of ratification, acceptance or approval to the Depositary. As an amendment has no advantage over a protocol, the latter may be preferable since it leaves the text of the Convention unaltered.

Protocols

Article 23.4(c) empowers the COP to adopt protocols. They are a stronger means of specifying a set of obligations, normalizing practices and facilitating harmonized approaches than COP decisions. Protocols are separate legal instruments and Parties to the CBD are not obliged to become Parties to protocols. The text of the CBD implies that any matter it covers may be covered by a protocol (see Article 30). A protocol typically contains additional substantive obligations or rules and, if necessary for the promotion of particular goals, may actually exceed the scope of a convention. It may provide for its own international bodies, such as a conference of parties or, as in the Biosafety protocol, a meeting of the parties.

The problem with a protocol that provided for an ABS regime is that negotiations would require considerable time and effort. Once adopted, changes to the protocol would require its amendment, similar to an amendment of the text of the CBD (see above). The protocol would not make for flexibility. On the other hand, a clear and concise protocol with clear provisions and a mechanism for facilitating the conclusion of ABS agreements and for ensuring compliance might be the appropriate way to introduce the regime.

Annexes

Annexes form an integral part of the CBD. As a result, the COP would have oversight over the implementation of an annex, and the CBD's financial mechanism could support its implementation. However, creating new substantive obligations or rules in an annex may not be possible as its content would be restricted to procedural, scientific, technical and administrative matters (Article 30.1). Annexes would enter into force for all CBD parties except those which had deposited a declaration of objection within one year of adoption by the COP (Article 30(c)).

4.2.3 Political motivation for the international regime

Neither the definition of "regime" nor the analysis of the norm-setting options provides an answer as to the form the regime should take. The political motivation, the formulated need underlying the request for the regime, may reveal some characteristics the regime should have and help to determine its form.

At government level an international biodiversity-related regime was first proposed by the Group of Like-Minded Megadiversity Countries (LMMC)³² in their inaugural Cancún Declaration, which called for a regime "to effectively promote and safeguard the fair and equitable sharing of benefits arising from the use of biodiversity and its components".³³

The decision stemmed from concern about the limitations of the ability of existing international instruments effectively to protect the legitimate interests of the countries of origin of biodiversity.³⁴ Biological diversity is being progressively integrated into the global economy through trade in biological material, the direct and indirect use of ecosystems and intellectual property rights to life forms and processes without the country of origin receiving sufficient benefits in return. On the one hand, benefits provide incentives to conserve biodiversity and, on the other hand, they are what is to be expected in all fairness.

³² The group of LMMC comprises: Bolivia, Brazil, China, Costa Rica, Colombia, Ecuador, India, Indonesia, Kenya, Mexico, Malaysia, Peru, Philippines, South Africa and Venezuela; see www.megadiversity.org.

³³ LMMC (2002), paragraph h.

³⁴ LMMC (2002), preamble, paragraph 7.

Countries are concerned that their sovereign rights over their biological resources are not being respected internationally³⁵ and that fairness is lacking in a broader context. It seems at first sight to be contradictory for an international regime to be needed to support national sovereignty. However, sovereignty also involves the right to regulate at international level, thus exercising this very sovereignty. In the establishment of certain rules that must be respected internationally, the norm protects the object of regulation in international relations, e.g. the genetic resources of nations. Several concerns are associated with this need for international regulation to ensure national protection. One is the lack of capacity of developing countries that an international regime can help to alleviate. LMMC and developing countries in general have limited capacity to negotiate successful terms for ABS agreements. A clear international framework removes a considerable burden from countries. National implementation is much easier if international standards have been set, especially for those countries that currently have less interest in ABS regulation, i.e. countries which are not “biodiversity-rich”. Although biodiversity-rich countries may have the bulk of species diversity,³⁶ genetic resources of interest for biotechnological development may be found in places that are biodiversity-poor. For example, endemites and extremophile microbes may contribute to revolutionary technology in the future and may possibly be found in a biodiversity-poor country with a very arid climate. The CBD did not, in its wisdom, limit the ABS framework to any specific notion of biodiversity. For countries with unknown genetic resources and limited capacity a regime will mean that translating the provisions into national law may be fairly easy – designating responsible institutions and referring to the international ABS regime as the regulatory framework for ABS may often be sufficient to impose legal constraints on free riders and prevent them from going to the country where access is easiest. International norms oblige countries to eliminate “free rider” situations. This was one of the reasons for the establishment of the TRIPs Agreement: it forces countries where the protection of intellectual property has been lax or non-existent to introduce legislation to protect IPR. While intellectual property rights can be protected and asserted globally (albeit by complicated procedures with often unclear outcomes), rights over genetic resources are not (yet) as secure and effective.³⁷

Similar to the free-rider syndrome is the facilitation of compliance. Genetic resources are easy to access, and controlling their flow is quite difficult.³⁸ Genetic resources can be easily acquired illegally. Tracing their use outside the country of origin is nearly impossible. The legal system of the country of origin can easily be circumvented unless there are clear provisions applicable to all countries to ensure compliance.

³⁵ LLMC (2002).

³⁶ See www.megadiversity.org.

³⁷ See von Hahn (2001), p. 17.

³⁸ See Caillaux/Ruiz (2002), p. 11.

With regard to users, more and more institutional policies and codes of conduct are being developed, but they lack consistency.³⁹ However, it is not only countries providing genetic resources or countries of origin that will benefit from an international regime that standardizes ABS. A user faces a wide range of ABS regulations that vary considerably from one country to another.⁴⁰ This increases the transaction costs of ABS, leads to legal insecurity and a lack of transparency and ties up resources. An ABS regime should therefore be absolutely unambiguous, very strict, precise and clear.⁴¹

Fairness and effectiveness are further concerns. If set up properly, the regime will facilitate fairness in trade. Those currently in a weaker position will be protected by the regime since it will subject everyone to the same rules, which, it is hoped, will also be fair in themselves. Free riders and economically stronger stakeholders must abide by the rules and will thus be “tamed” and subjected to the law. Effectiveness will be relevant for those interested in using genetic resources: a clear regime will save time and energy. Legal certainty, clear competencies etc. are essential if transaction costs are to be kept down and business is to be done successfully.

4.2.4 Conclusion: which regime-building process?

The starting point for a regime-building process is the political objective that ABS agreements need a stronger international legal basis than they currently have. Deciding on the form that the international regime should take is not easy and this paper will not give an answer to that question. Advantages and disadvantages must be carefully weighed in the balance; they cannot be assessed from a legal angle, but require a political decision. Starting discussions on the substance while considering the form may be a way to save time in the process. From a political point of view, it would be desirable to have a separate mandate within the CBD for negotiating an international ABS regime in order to induce the necessary dynamics in the negotiating process. From a legal point of view, a negotiated protocol with clear and concise norms and appropriate institutions is the preferable solution. As experience shows, however, negotiating a protocol on ABS will be an arduous and possibly tedious and expensive undertaking, for which many parties may still lack the political will. Instead, a COP decision on the regime, with clear provisions on substance and the establishment of an effective body for facilitation and implementation, may be an elegant solution. But again: is the COP able to deliver? If an ABS regime is constructed as a COP decision, there is a danger that during the negotiations ABS will be linked to other CBD issues and – in the worst case – misused as a bargaining chip. Hence, from a political and legal point of view, there are important arguments for an ABS protocol; nevertheless, practical result will depend on the political will of CBD members.

³⁹ See overview at EC (2002), p. 30.

⁴⁰ See Glowka (1998).

⁴¹ See Caillaux/Ruiz (2002), p. 11

4.3 International and national levels of ABS regulation

Whatever form the regime on ABS may take in the context of the CBD, it will be binding only on the Parties, i.e. States and the EU. Any international norm that is not self-executing (i.e. that gives direct rights on the Parties and imposes obligations on them, such as the Vienna Convention on the Law of Treaties) needs to be implemented through international or national law and policy.

International norms can be so designed that they do not need any further interpretation, only translation into national law. Other norms are framework regulations that need to be implemented through adaptation to the specific national situation, both factual and legal. In some countries this may require the amendment of existing national legislation.

The first question to arise in the design of the international ABS regime is: what should or needs to be regulated at international level and what should or needs to be regulated at national level? In some respects, the text of the CBD provides part of the answer in that it delegates the decision to one level or the other. The regulation of traditional knowledge, for example, is a matter for national legislation (Article 8(j)); Article 15.1 states that determining access to genetic resources is subject to national legislation.

However, this is only part of the answer. As mentioned above, Parties may well agree on framework conditions or harmonizing standards at the international level, thus using their sovereignty to agree on international rules that guide national legislation. Secondly, the CBD establishes a framework for a new international regime on genetic resources that seeks to enshrine the principle of equitable sharing.⁴² The key pillars of the regime, Articles 15, 16.3, 19.1, 19.2 and 8(j) of the CBD require further elaboration at international level before they provide a clear set of norms and measures to ensure compliance can be taken and monitored. An international discussion is needed to arrive at a common interpretation, so that Parties may agree on what is sufficient for the implementation of the various norms. There is a need for integration, i.e. an agreement on what are the minimum standards and norms if the requirements of the Convention are to be met. Parties that deliberate on these issues at the COP meetings use the regime-building framework to define these norms and standards. In so doing, they impose certain obligations on the Parties by agreement. This is the key to the whole idea of regime-building, which is the cornerstone of the Convention.⁴³

Regime-building is needed if it is to be possible for these provisions to be implemented. The concepts of “mutually agreed terms”, “prior informed consent” and “sharing [benefits] in a fair and equitable way” are such provisions. Implementation can be considered at several levels. From a legal point of view, an international treaty with broad obligations is implemented at international level if its norms are specific enough to allow for

⁴² See Henne/Fakir (1999), p. 324.

⁴³ See Henne/Fakir (1999), p. 327.

implementation by the Parties.⁴⁴ The international regime must provide sufficient detail to give clear guidance for national implementation, while remaining flexible enough for adaptation to the national legal, political and factual situation. It should stipulate the standard and boundaries required by the CBD with respect to related international policy and law under which the objectives of the CBD can best be realized.

The following criteria may help when it comes to deciding whether the various norms need to be specified and interpreted at international level or can be left to national discretion: issues that require further interpretation without which it will be impossible to assess the implementation of the provision (principle of clarification); issues that require a harmonized approach to implementation in order to make the ABS framework meaningful (principle of harmonization). International regulation (in a legal or other form) is needed to the extent that individual countries cannot regulate the issues themselves to ensure adequate implementation of the Convention (principle of subsidiarity). International regulation is also needed where there is an international mandate that may otherwise be forgotten (principle of integration of issues of international concern). These principles are general in nature. Considerable progress may be made if *common sense* and an attitude of fairness are applied when the ABS regime is being negotiated.

4.4 ABS provisions at international level

The international regime sets the framework for national legislation. Based on the suggestions in the Bonn Guidelines (Dec. VI/24 A), which provide sound foundations for the drafting of a more thorough ABS regime, the following elements are suggested as a minimum requirement.⁴⁵ Irrespective of the legal nature of the international regime, the language used should be clear, concise and unambiguous. The sentences in *italics* are proposals for provisions of the international regime. While it is obvious that the regime will be established by means of negotiations aimed at finding compromise solutions, the clear language used here may be helpful as a starting point. As the principal issue in this study is poverty alleviation, the various elements focus on this aspect of the regime.⁴⁶

⁴⁴ See Henne/Fakir (1999) p. 355.

⁴⁵ The suggestions have also been based on the experience gained in the case studies presented in Chapter 3 and on the relevant literature, e.g. Caillaux/Ruiz (2002), Columbia University (1999), Stoll/Wolfrum (1999), Glowka (1998), Henne (1998) and Liebig et al. (2002).

⁴⁶ The following is not meant as a comprehensive proposal for a regime but to set out the elements that are critical if the regime is to address poverty alleviation in a serious manner.

4.4.1 General provisions

(a) Scope

The international regime covers genetic, biochemical and related biological resources and associated traditional knowledge, innovations and practices (TK).

Although the international community has limited the development of the regime to benefits arising from genetic resources, the distinction between genetic resources governed by an ABS agreement and biological material not covered by the ABS framework is not always clear. In *Kava*, biological material is being exported, but intellectual property rights relating to certain characteristics of the resource have been claimed without the holders of the knowledge or those living where the resources originate being involved. In nutraceuticals and herbal medicine, the resource base is used as biological material, but biochemicals may be extracted and research on genetic properties may be undertaken simultaneously by the same user.

If the regime is limited to genetic resources as defined in the CBD, the potential for poverty alleviation will be limited. It is often the trade in biological material that harbours income opportunities for the local poor. Limiting the regime to the narrow definition of genetic resources would limit its scope in a way that would not do the political mandate justice. On the other hand, an ABS regime cannot be designed for all trade in biological resources. This would exceed its scope and not enjoy much support. In the search for a solution, the spirit of the CBD and the WSSD regarding ABS may provide some guidance: measures which contribute to conservation, sustainable use and poverty alleviation should be rewarded. It is proposed above that genetic and biochemical resources should form the “entry point” of the scope of the regime and also cover “biological resources related” to them. “Related” resources are resources cultivated and harvested with the objective to use their genetic or biochemical properties.

(b) Use of terms

1. *The terms defined in Article 2 of the CBD apply to the regime.*
2. *Traditional knowledge means “knowledge, innovations and practices of local and indigenous communities embodying lifestyles relevant to the conservation and sustainable use of biological diversity”.*

(c) National institutions: National Focal Point and Competent National Authority

- 1 *Each Party designates one national focal point for access and benefit-sharing.*
2. *It makes information available on national policy and law, case studies on benefit-sharing, institutional competences and related information through the clearing-house mechanism. It provides both provider- and user-related information on all available aspects of genetic resources related to access and benefit-sharing (tenure rights,*

ownership, communities with associated knowledge, law on intellectual property rights etc).

3. *It acts as the competent national authority in respect of all aspects of access to and the sharing of benefits derived from genetic resources (e.g. the negotiation, processing, monitoring, evaluation, implementation and enforcement of and dissemination of information on ABS agreements).*
4. *Clear and transparent delegation to other entities is possible.*

Parties to the ABS regime will be required to establish a competent national authority. To streamline competencies, only one institution should act as the contact point for issues related to ABS. As this may not be practical for various reasons (size of country, how genetic resources are used, etc.), delegation to other entities needs to be absolutely transparent. Not only countries of origin and provider countries should have such competent national authorities: user countries/countries with users under their jurisdiction also need to establish a competent national authority to be kept informed by the provider country of ABS negotiations and agreements. This will give the provider country an opportunity to join in with poverty alleviation measures to back up the ABS agreement, such as supporting capacity-building in the provider country, expanding national markets, or creating consumer awareness.

4.4.2 Sovereign rights with respect to genetic resources

(d) Clarification of genetic resource rights

Parties specify rights with respect to genetic and biochemical resources at national level with the involvement of all relevant stakeholders, especially indigenous and local communities having traditional knowledge. Unless national law and policy have been established, genetic resources are owned by the government, and associated traditional knowledge is owned by the holders of such knowledge.

Article 15.1 leaves it to the sovereign state to determine how to define and assign what internationally represents the sovereign claim to genetic resources, this being limited only by Article 15.2. States are charged to specify rights relevant to the uses of genetic resource. Such regulation probably needs to address two different aspects:

From the point of view of substance, what needs to be clarified is how such rights as land use rights and rights on tangible property will be related strictly to a title to genetic resources. In this regard, States may pass on any title to resources to holders of specific rights, such as land use rights. On the other hand, it may be possible for States or public entities to retain some distinct and special title to genetic resources. In this case, there would be a need to clarify how such an entitlement of the State would be in conformity with more specific rights of individuals. Conflicting exercise of those rights and the proper attribution of a claim to negotiate and participate in benefit-sharing are questions which have to be considered in this

regard. While the CBD does not confer any rights on indigenous and local communities at international level, it does request governments to respect, preserve and maintain traditional knowledge. Its wider application requires the approval of the holder of the knowledge (Article 8 (j)). The use of this knowledge is often related to genetic resources. In such cases, the right to use the genetic resource *per se* may be different from the right to use a genetic resource in accordance with traditional knowledge.

As not all Parties have the capacity to legislate on rights to genetic resources or are currently interested in doing so, an international “safety clause” assigning this right to the government should prevent confusion and avoid “free-rider excuses”. As has become evident from the case studies, awareness of stakeholders is an important requirement for ABS agreements that take poverty concerns into account. In the case of legislation, wide-ranging consultations with stakeholders are a vital means of creating awareness and “buy in” of all actors potentially involved in ABS negotiations. They will also improve the legislation since greater account will then be taken of the needs and constraints of those concerned.

4.4.3 Rights of indigenous and local communities to associated knowledge of genetic resources

(e) Rights to traditional knowledge

1. *Holders of traditional knowledge must consent to the use of their knowledge.*
2. *Benefit-sharing should focus on ways to alleviate poverty that empower and strengthen the communities holding such knowledge and provide them with longer-term income opportunities.*
3. *Parties should develop and adopt rights to traditional knowledge as soon as possible. Once these rights are in place, the use of knowledge without approval shall be declared illegal. Related ABS agreements are invalid. Applications on intellectual property rights using such knowledge without consent by the holders of such knowledge will not be granted. Until such rights are recognized, the international ABS Advisory Body will negotiate a fair benefit-sharing mechanism between representatives of the holders of traditional knowledge, the user of such knowledge and the Party having jurisdiction over the user. The state of the negotiations will be reported regularly through the Clearing-House Mechanism.*

Article 8(j) of the CBD requires the Parties, subject to national legislation, to “promote the [...] wider application [of traditional knowledge] with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices”.

To make absolutely sure legally that the wider application of such knowledge occurs only with the approval of its holders, it needs to have legal protection. Concrete, discernible rights

should be attributed to the holders of traditional knowledge so that it can be ensured that wider application occurs only with their approval and that benefits are always shared. Designing such rights is not an easy undertaking. How the consent of the group to the use of their traditional knowledge and the conclusion of agreements can be achieved through appropriate structures within such a group needs to be clarified, for example. It is not always clear who or what can be deemed competent to receive information, to be a party to negotiations and to conclude agreements. It also has to be decided what form legal protection should take, how extensive the rights afforded by that protection should be and what specific elements or expressions of traditional knowledge are protected by distinct legal rights.

At present, national law often fails to recognize, or lends no more than weak support to, claims by local and indigenous communities regarding their traditional knowledge.⁴⁷ This is especially true where communities or individuals have lost exclusive control over such knowledge. If the information has become known to the public at large, proprietary claims are forfeited. New legal mechanisms have to be created to permit the implementation of Article 8(j). In a number of countries, legislation to that effect is being enacted or pending. The protection of knowledge under Article 8(j) may overlap protection in other areas of traditional knowledge. As the same knowledge may serve different functions, it may need to be protected by different, overlapping rights.

The issue of the protection of traditional knowledge is currently being analysed and discussed in great depth in WIPO. The Intergovernmental Committee on the Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore has analysed forms of defensive protection (preventing others from asserting or acquiring intellectual property rights to traditional knowledge)⁴⁸ and experience of positive protection of traditional knowledge.⁴⁹ Where the latter is concerned, WIPO categorizes different mechanisms: existing intellectual property systems applied to traditional knowledge; adaptations and *sui generis* elements of existing systems to ensure their application to traditional knowledge; stand-alone *sui generis* intellectual property systems. Several legal instruments for the protection of traditional knowledge are currently being tried out, examples being community intellectual rights, a community register, trade secrets and know-how licenses.⁵⁰

Discussing and proposing mechanisms for the legal protection of traditional knowledge would exceed the scope of this study. Justice could not be done to this rather complex issue. WIPO will shortly be reporting on its findings to the COP. A debate on the ABS regime for the protection of traditional knowledge should thus await the outcome of the deliberations within WIPO. However, it is important for some kind of “interim” protection of traditional knowledge to be introduced since its exploitation continues unabated. For the time being, a

⁴⁷ The term “traditional knowledge” is defined in provision (b) above.

⁴⁸ See WIPO (2002).

⁴⁹ See WIPO (2003a,b,c).

⁵⁰ See Glowka (1998), p. 38; WIPO (2003b,c).

policy solution is proposed that at least helps to negotiate benefit-sharing for traditional knowledge holders. It is proposed that the use of traditional knowledge by outsiders, which is not yet illegal, but is certainly unethical and unfair, should be widely publicized and that and that the Party having jurisdiction over the user should be involved in the negotiations.

4.4.4 Prior informed consent

(f) Prior informed consent

The system of prior informed consent includes the following:

1. *The PIC procedure involves all potential partners in a process of negotiation for an ABS agreement. Depending on the type of resource, its location and the rights to the resource or the knowledge, these partners are: research institutions, local and/or indigenous communities, farmers, protected area management authorities and landowners.*
2. *Information is provided on currently intended potential uses of the genetic resource/traditional knowledge, time, place, method of collection, method of research, expected results, benefits for the user, potential benefits for the provider and confidentiality.*
3. *Clear and comprehensive information is provided in a language understandable to the stakeholder early enough for consultations among groups of stakeholders.*

Questions that need to be clarified are: what stakeholders have a right to know before giving their prior informed consent, who has to be informed and how this information should be communicated to ensure that everyone is informed. PIC precedes negotiations on an ABS agreement. Only if all parties share an adequate level of information can negotiations take place among equal partners. The chances of fair and equitable benefit-sharing under the ABS agreement as called for by the Convention and the WSSD increase with the level of shared information. Moreover, “knowledge is power”. In this sense PIC is instrumental in facilitating the empowerment of local and indigenous communities. All in all, PIC is thus a key requirement for poverty alleviation.

The Bonn Guidelines refer to some more specific items that should be included in PIC. For the purpose of legislation, the language should be shortened and streamlined.

4.4.5 ABS agreements: benefit-sharing based on mutually agreed terms

Mutually agreed terms are the result of negotiations following PIC. Basically, “mutually agreed terms” are the content of the ABS agreement and another word for “contract” or

“treaty”.⁵¹ The international regime must provide the framework for the negotiations, so that the end result conforms to the provisions of the Convention, its objectives and the larger policy regime within which the CBD is embedded. The international regime should specify the “bottom-line” requirements for the contractual agreement.

(g) Invalidity

ABS agreements are invalid if they

1. *have significantly adverse effects on the conservation and sustainable use of biological diversity,*
2. *provide for the use of traditional knowledge without ensuring respect for the rights of the holders of such knowledge.*

These provisions protect the underlying principles of the ABS regime. They are provisions similar to those in civil law which protect morals or other basic values of society. A contract that undermines its very reason for existence – the objectives and the spirit of the CBD – cannot be valid. In stipulating the invalidity of such ABS agreements, the ABS regime prevents parties to the contract from seeking to comply with the contract despite its violation of the CBD. The clause on traditional knowledge refers to “rights of the holders” because legal protection is feasible only if identifiable rights are granted to an identifiable subject of law (this can be an individual or a group) who, in theory at least, can defend such rights in a court. Answers have to be found to many questions on how to afford legal protection to traditional knowledge, which constitutes an amorphous body of information throughout the world, as discussed in section 4.4.3 above. The rights have to be clearly defined to enable the invalidity of a contractual arrangement to be invoked as and when necessary.

It is very unlikely that much advantage will be taken of this clause. Nonetheless, it is important to provide such a last-resort clause so that it is absolutely clear what is allowed under an ABS regime.

(h) Mutually agreed terms – access

As they are based on the PIC procedure, the ABS agreement consists of mutually agreed terms. The material and information to which access is permitted includes at least the following: stakeholders involved, type and quantity of genetic resources, geographical area of activity, general description and limitations of the use of the material, conditions for renegotiations, third-party conditions, use of traditional knowledge, confidentiality.

⁵¹ See Henne (1997).

(i) General benefit-sharing requirements

1. *An ABS agreement shall cover the conditions, obligations, procedures, types, timing, distribution and mechanisms relating to the benefits to be shared.*
2. *Benefits should be shared, as the case may be, among those who contribute to resource management, scientific and/or commercial process, holders of associated traditional knowledge and poor people living in the geographical area of origin of the resource.*
3. *Benefits should contribute to the conservation and sustainable use of biological resources as well as to poverty alleviation. It should involve technology transfer and joint research. Priority in benefit-sharing should be given to measures contributing to alleviating poverty, such as the creation of income opportunities for local people and markets for products. Biological material should be cultivated in the areas of origin of the genetic resource. Benefits should include the empowerment of local people and the strengthening of self-governance, cultural identity and self-confidence.*
4. *Benefits should include advance and milestone payments sufficient to contribute to poverty alleviation in the short term and to create an incentive for the conservation and sustainable use of biodiversity. Appropriate institutions should be set up to ensure that payments are used efficiently (e.g. trust funds).*

As the Bonn Guidelines rightly point out, benefits to be shared “vary depending on what is regarded as fair and equitable in light of the circumstances” (paragraph 45). Many interests are involved, and the stakes and expectations may be high. The CBD itself, however, provides, some guidance on what benefits should consist of, and this is complemented by the concerns of the international community expressed at the WSSD and in the MDGs.

The regime should provide a list of potential benefits to stimulate the imagination, as proposed in Appendix II to the Bonn Guidelines. This list should be expanded and specified with regard to income opportunities and non-monetary benefits such as empowerment to negotiate, self-confidence, self-organization, etc., to place greater emphasis on the non-monetary aspects of an ABS regime.

4.4.6 Benefit-sharing – geographical indications

(j) Geographical indications for biological resources and associated knowledge

1. *Parties shall establish national laws on geographical indications for products based on genetic, biochemical and biological resources and associated knowledge if this provides a useful means of ensuring benefit-sharing with the country and area of origin.*
2. *Parties shall provide the legal means to prevent the use of any means in the designation or presentation of a good that indicates or suggests that the good in question originates*

in other than the true place of origin, thus misleading the public as to the geographical origin of the good.

3. *Parties should take the policy measures necessary to contribute to the creation of market opportunities for those products.*

For biological products from a distinct region geographical indications may prove to be a useful tool for ensuring benefit-sharing. Geographical indications protect products that are identified with a certain region and are not used as a generic term. As can be seen in the *Kava* case, a geographical indication could not prevent other countries from producing kava, but it would prevent them from marketing it under a typical name (e.g. True Kava or Kava Pacifica). Geographical indications lead to market segmentation and can be used as marketing instruments with the aim of generating higher profits than in a situation where the product cannot be distinguished from its competitors.

Like intellectual property rights in general, geographical indications are governed by national law. States need to agree in bilateral or multilateral agreements on the mutual recognition of their geographical indications if the latter are to enjoy international protection. Section 3 of the TRIPs Agreement codifies basic standards for the mutual recognition of geographical indications, with stronger protection for wines and spirits.

On 14 July 1992 the European Union adopted Council Regulation No 2081/92 on geographic indications enabling groups and natural or legal persons to register designations of origin and geographical indications for agricultural products and foodstuffs. Designation of origin refers to the quality or characteristics of an agricultural product or foodstuff which are essentially or exclusively due to a particular geographical environment with its inherent natural and human factors. Geographical indications refer to the specific quality, reputation or other characteristics of an agricultural product or foodstuff which are attributable to the defined geographical origin. Both terms also refer to quality and characteristics attributable to production, processing and preparation in the defined geographical area.⁵²

Geographical indications as a means of enhancing benefit-sharing have the advantage that they do not have to be related to an ABS agreement. They are stand-alone protection measures. One disadvantage is that they provide protection only in specific circumstances, i.e. if there is a product that meets the protection requirements. Another disadvantage is that they presuppose the existence of national legislation on geographical indications. However, CBD Parties that are members of the WTO will in any case have to develop a system for the protection of the geographical indications of other members of the WTO.

Where protection does not yet exist, the Parties should carefully analyze whether legislation on geographical indications relating to products from their regions will be a useful poverty

⁵² See EC (2002), p. 11.

alleviation tool. They might consider teaming up with one or more Parties who are potential user countries to explore and develop international markets for the products concerned.

4.4.7 Harmonizing transactions: ABS certification

(k) Standardized ABS transaction form/certification

An ABS certificate that is clear and easy to understand is being developed. It will contain information necessary to identify genetic resources covered by the ABS agreement, associated traditional knowledge, PIC and benefit-sharing mechanisms of relevance beyond national boundaries.

The Parties involved and the content of ABS agreements⁵³ can vary considerably. Some provisions are subject to confidentiality. Nevertheless, there are core requirements that need to be agreed on, as pointed out above and proposed in the Bonn Guidelines (Appendix I). This core information on ABS agreements should be formalized in a standard ABS certificate or transaction form. The certificate serves several purposes: it will be published by the competent national authority through the Clearing-House Mechanism (see (c) above); it will be clear evidence of international ABS guidelines having been followed in cases where disclosure of origin may be required (e.g. when a patent is applied for); it will help to monitor compliance; it will reduce transaction costs to users and providers of genetic resources and associated knowledge.

Many international conventions contain more or less detailed provisions on standardized information.⁵⁴ The form of the certification should be developed by the Secretariat of the CBD.

4.4.8 Mechanism to support verification, enforcement and compliance

An ABS regime is only as good as its provisions on verification, enforcement and compliance, since deliberate or accidental failure to comply with the requirements of national ABS is easy whereas bringing violators to justice in the provider country is difficult.

For provider countries it is extremely difficult to monitor the implementation of the agreements in other countries. Moreover, most of the provider countries are developing countries, if not least developed countries, and will lack both the capacity and the means to

⁵³ The term “ABS agreement” encompasses the term “material transfer agreement”. “ABS agreement” is understood as a broader type of agreement. It can also contain associated knowledge.

⁵⁴ For example, the Basle Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, 22 March 1989, Annex V; Convention on International Trade in Endangered Species of Wild Fauna and Flora, 3 March 1973.

check on contracts executed far away. In the spirit of exchanging information (Article 17 of the Convention) and of technical and scientific cooperation (Article 18), user countries need to support the monitoring of ABS agreements by taking adequate user measures. This in turn will require provider countries to inform the user countries' competent national authorities about ABS agreements and their main elements (with certain information treated as confidential).

The international regime should establish minimum requirements regarding mutual information and measures that the user country should take where ABS agreements have been completely ignored or seriously violated. It should be requested to adopt penalties and other forms of sanctions against the illegal acquisition of genetic resources.

(l) Disclosure of origin in applications for intellectual property rights

*Parties who grant intellectual property rights in respect of inventions that use or are based on genetic resources and associated traditional knowledge shall require that the origin of the genetic resource and the traditional knowledge or, if the origin is unknown, the source of the genetic resource be disclosed in patent applications. The authority responsible for the application process shall inform its competent national authority of the application.*⁵⁵

In decision VI/24, the COP calls on the Parties and governments to help monitor compliance with ABS agreements. As one option, it encourages the Parties and governments "to disclose the origin of genetic resources in applications for intellectual property rights, where the subject matter of the application concerns or makes use of genetic resources in its development" (decision VI/24 C, paragraph 1).

There has been much debate about this tool for verifying compliance, with regard to what the disclosure should encompass, what consequences it should have and what the implications for TRIPs might be.⁵⁶ As CEAS points out in a comprehensive analysis of currently held views on the relationship between the CBD and TRIPs, "many different actors have a wide variety of views about IPRs and biodiversity. They disagree about the philosophical basis, the relative costs and benefits of the new (legal) framework developing in this area, and the long-term effects."⁵⁷

Some argue that such a requirement would raise insurmountable legal and administrative difficulties for patent offices. Considering the quantity and quality of information a patent office has to process in the countries where most of the users of ABS agreements will be

⁵⁵ The proposed provision is not meant to pre-empt the political debate on the legitimacy of IPRs for inventions related to biotechnology, particularly genetic engineering. Instead, it regards the current legal situation in many countries as a *de facto* situation which any ABS regime has to deal with.

⁵⁶ For a comprehensive analysis, see CEAS (2000).

⁵⁷ CEAS (2000), p. 53.

located, namely industrialized countries, and given what is at stake – the implementation of the ABS regime – this argument would seem to be trying to conceal another intention.

Transparency and disclosure form the very essence of the patent system. A patent right is granted for disclosure of the invention. In the EU, for example, a number of provisions require disclosure beyond the disclosure of the invention: (1) an enabling disclosure (Article 13(1)(b) of Directive 98/44/EC on the legal protection of biotechnological innovations⁵⁸) is required where an invention involves the use of “biological material which is not available to the public and which cannot be described in a patent application in such a manner as to enable the invention to be reproduced by a person skilled in the art”. The description “shall be considered inadequate for the purpose of patent law unless the application as filed contains such relevant information as is available to the applicant on the characteristics of the biological material deposited”. (2) Rule 27(1)(b) of the European Patent Convention⁵⁹ requires that the content of the description of the patent should indicate the background art which can be regarded as useful for understanding the invention; (3) Article 81 of the European Patent Convention requires that “The European patent application shall designate the inventor” where the applicant is not the inventor or not the sole inventor.

These provisions at European level are not enough to satisfy a comprehensive requirement for disclosure; nor, obviously, do they apply at world level. There is a need for a separate disclosure requirement that allows Parties to keep track, at global level, of all patent applications concerning genetic resources.

The patent office will inform the competent national authority in its own country of the application. It will be for the national authority to inform the country of origin, the source or, if the applicant fails to provide the appropriate information, the CHM (see provision (c) above).

(m) International ABS certificate

After the adoption of an international ABS certificate under the international regime, IPRs relating to inventions that use or are based on genetic resources and associated traditional knowledge shall be granted only if an international ABS certificate is submitted with the patent application.

A standardized international ABS certificate will make it much easier for patent offices to process patent applications. A question currently under discussion is whether the legal consequence of such a requirement should be an additional formal or substantial patentability

⁵⁸ Official Journal of the European Community, L 213, 30 July 1998 pp. 13–21, at http://europa.eu.int/documents/index_en.htm.

⁵⁹ Convention on the Grant of European Patents (EUROPEAN PATENT CONVENTION) of 5 October 1973, text as amended by the act revising Article 63 EPC of 17 December 1991 and by decisions of the Administrative Council of the European Patent Organisation of 21 December 1978, 13 December 1994, 20 October 1995, 5 December 1996 and 10 December 1998, <http://www.european-patent-office.org/legal/epc/>.

criterion or whether it should lie outside the ambit of patent law.⁶⁰ Making the requirement a condition for the granting of the patent would greatly increase the incentive to the user to negotiate an ABS agreement.

Whether the TRIPs Agreement would allow for such provisions under the CBD has been a focus of discussions for quite a while.⁶¹ Intellectual property rights are granted by national legal systems. The international regime governing the protection of intellectual property rights, with its different agreements within the WIPO framework, provides mainly for minimum standards to guarantee a certain degree of protection and, for example, the coordination of patent application processes relating to national patents. The TRIPs Agreement is a further step towards an internationally harmonized system of intellectual property protection. Article 29 of the TRIPs Agreement sets out minimum requirements for the patent application. While there may be many policy reasons for wanting to alter the provisions of TRIPs, there is no need to do so from a legal point of view with regard to the disclosure of origin or an ABS certificate as conditions for the granting of a patent. The TRIPs Agreement does not prohibit any standardized specification on patents. Thus, as a general example, it does not prohibit regulations under the European Patent Convention, nor does it interfere with specific rules concerning the application procedure.

(n) Disclosure of origin in food and drug administration

The international ABS Advisory Body examines how applications for permits for food and drugs based on genetic, biochemical and biological material and associated knowledge might require the disclosure of the origin or source of such material or associated knowledge and the submission of an international ABS certificate in an effective and efficient manner

The disclosure of origin in IPR applications is only one way of ensuring compliance with the ABS regime. If the user does not seek patent protection or if a country has no relevant IPR, this instrument is not applicable. Another option for revealing the use of genetic resources and associated knowledge without an ABS agreement is a disclosure requirement when food and drug applications are submitted to the relevant agencies. However, in the case of food and drug applications, the concern that the competent authority will be overburdened with checking on the origin of the material and the associated knowledge must be taken seriously. Before international provisions on this are drafted, an analysis of the feasibility of such a disclosure requirement in the various countries with user situations should be undertaken. One easy option might be to require an assertion in the food and drug application that the resource used has been acquired in accordance with international and national rules and regulations on ABS and associated knowledge.

⁶⁰ See EC (2002), p. 13.

⁶¹ See, for example, EC (2002a); von Hahn (2001), p. 11; CEAS (2000); Wolfrum/Stoll (1998).

(o) Reporting mechanism

National competent authorities shall report on ABS agreements and submit the international ABS certificate to the Clearing-House Mechanism.

4.4.9 International institutions of the ABS regime

(p) ABS Advisory Body to facilitate legislation and negotiation

1. *The ABS regime establishes an independent international ABS Advisory Body.*
2. *The Advisory Body advises on how to improve and advance the ABS regime. If requested, it should facilitate the negotiation of ABS and advise on the national implementation of the regime.*
3. *Special emphasis is placed on the equity and fairness of the benefit-sharing mechanism. The ABS Advisory Body draws on all expertise, experience and best practice available.*

A regime is only as good as its implementation. Implementation often fails due to a lack of capacity and knowledge and to impracticability. New norms need to be tested against reality and improvements proposed. The ABS Advisory Body should be an independent body and consist of only a limited number of experts and practitioners. Its terms of reference need to be developed; the body might consist of 12 experts from relevant disciplines (biology, biotechnology, law, sociology, rural development, economics, etc.) and include two representatives of traditional knowledge holders. Members would be linked to a wide network of scientists and development agencies and a roster of experts to whom they could turn if specialized knowledge was needed.⁶² The ABS Advisory Body should not replace bilateral or multilateral development cooperation but rather act as a point of reference. Independence is crucial. Ideally, the body would not have governmental officials as members, only scientists, practising lawyers, etc. and representatives of local and indigenous communities.

(q) ABS Compliance Body

1. *The ABS regime establishes an independent international Body on ABS Compliance.*
2. *The Body on ABS Compliance settles disputes concerning the implementation of an ABS agreement. The Body on ABS Compliance can be approached by Parties and, if referred to in the ABS agreement, by any Party to the ABS agreement. Governments shall include the Body on ABS Compliance as one option for the settlement of disputes in their national implementation of the ABS regime and encourage the Parties to an ABS agreement to designate the Body on ABS Compliance as the dispute settlement body.*

⁶² For example, the UNCTAD Biotrade Initiative could be one partner of the experts.

3. *An appeal can be made to the Body on ABS Compliance where genetic resources and related traditional knowledge have been used without an ABS agreement. Parties should include in their national legislation the option of an appeal to the body as an additional course of action.*
4. *Details on composition, competencies etc. are set out in separate provisions on the ABS Compliance Body.*

From a political point of view, this proposal may meet with some initial resistance. From a legal perspective, however, dispute settlement should be part and parcel of an efficient regime. Without a means of settling disputes, the ABS regime will be less effective because it cannot be enforced. It will make the ABS regime and thus access to and the sharing of benefits arising from genetic resources more secure and predictable. The aim is not to pass judgment but rather to settle disputes, through consultation if possible. The procedure for the selection of members of the ABS Compliance Body could be either that used for the selection of the judges of the International Court of Justice or the members of the WTO's Dispute Settlement Body.

If there is no special body under the ABS regime, a dispute between Parties will be settled in accordance with the provisions of the CBD, i.e. through arbitration and conciliation (see Annex II to the CBD) or ultimately through the International Court of Justice as the legal body that rules on disputes in public international law. None of the three options is very realistic. It is hard to see a Party taking such a route in its CBD relations with other Parties. Furthermore, there is no dispute settlement for parties to an ABS agreement. They are subject to national law and in general to the national legal system under which the ABS agreement has been concluded. This, however, does not take into account the specific features of the ABS regime. National litigation can be very time-consuming and not very satisfactory. The ABS Body on Compliance would be there specifically for issues relating to the ABS regime. It should be less time-consuming and costly and more efficient than a civil law body. It would meet only if called upon.

4.5 ABS provisions at the national level

A number of the norms proposed for the international regime are framework provisions that need implementation at national level for both provider and user countries. Not only do national law and policy need to be consistent with the international regime, but many national provisions are specifications of the international regime, tailored to a country's individual situation and needs. Some national provisions may derive "naturally" from the international regime, i.e. they will be easy to translate to the national situation. Others will have to be adapted by the legislative process. As situations in countries vary widely, specific national provisions cannot be proposed in an international study. Instead, this section highlights norms that need some general consideration before the legislative and policy-making process begins.

As the focus of this study is on poverty and biodiversity, the emphasis is on regulations that are particularly relevant to poverty alleviation. General provisions for a national ABS regime concerning such aspects as scope, a national focal point, competent authorities, the involvement of national research institutions, penalties for illegal access, etc. derive directly from the provisions proposed above for the international regime or have been widely discussed.⁶³ It is understood that they will be taken up by national policy-makers and legislators as obvious elements of an ABS regime.

For the focus on poverty and genetic resources two types of actor are of particular relevance: communities living in areas where genetic/biological resources could be cultivated or harvested, and holders of traditional knowledge associated with genetic or biological resources. These actors may be identical, but do not need to be (e.g. in *INBio* parataxonomists do not have traditional knowledge, in *Hoodia* they do; in *Kava* some do, others do not). If both actors are to be strengthened, the national benefit-sharing regime needs to ensure that their knowledge is valued and legally safeguarded and their appropriate participation in ABS is secured. As we can see from *Kava*, both provider and user countries need to play equal parts in ensuring benefit-sharing for local actors. Two main issues have to be taken into account if benefit-sharing as a means for poverty alleviation is to be achieved: the involvement (and rights) of the holders of traditional knowledge must be ensured, and provision must be made in the benefit-sharing regime for the alleviation of the poverty of the local population to be one of the criteria for the benefits to be agreed.

4.5.1 Provider situation

There are several ways an ABS regime can be established at national level. For provider situations, Glowka⁶⁴ identifies five types of legislation: (1) provisions contained in general environmental framework laws, but they are only enabling in nature and thus not entirely appropriate for provisions on substance as proposed above; (2) framework laws on sustainable development, nature conservation or biodiversity which are more detailed than framework enabling environmental legislation; (3) dedicated or stand-alone national laws or decrees on ABS. These are the most comprehensive types of legislation for ABS; (4) modification of existing laws/regulations; (5) action taken at regional level. An analysis of how best to translate the international regime into national law should obviously precede national legislation. This should include the consideration of benefit-sharing needs with a view to alleviating poverty.

National ABS policy and law cannot prescribe benefit-sharing since the latter is the outcome of negotiations between the parties to the ABS. However, they might suggest certain benefits and call on the competent authority to inform local and indigenous communities

⁶³ See, for example, the Bonn Guidelines; Glowka (1998); ten Kate/Laird (1999), p. 17; Henne (1998).

⁶⁴ See Glowka (1998), p.23.

comprehensively of the pros and cons of certain types of benefit. National policy and law can do a great deal to help ensure that benefits contribute to poverty alleviation. Such benefits are, for example:

- (1) Monetary benefits for local and indigenous communities:
 - a. advance payments allocated to local and indigenous communities (e.g. via a trust fund)
 - b. contributions to the local economy – creation of income opportunities through the cultivation or processing of the resource
 - c. protection of local applications of IPR
 - d. payments accompanying valorization (“milestone fees”), deposited in a fund
 - e. free access of population in the case of product development (e.g. medicines)
 - f. providing markets in user country
- (2) Non-monetary benefits
 - a. research directed at local priority needs
 - b. participation in decision-making (political empowerment) and negotiation
 - c. self-administration of the fund
 - d. recognition of value of traditional knowledge – marketing with approval of knowledge holder on an international scale

4.5.2 User situation

The task of user countries/countries with users under their jurisdiction is twofold: firstly, to encourage genetic resource users under their jurisdiction to focus benefit-sharing on poverty alleviation and the creation of sustainable income opportunities in the provider country in a way that targets poverty alleviation. This cannot be achieved through legislative measures but should be done by offering the users incentives, e.g. through support for public-private partnerships; secondly, to ensure that benefit-sharing regimes in provider countries are respected by entities under their jurisdiction and that ABS agreements are negotiated and complied with. The international regime proposed above requires the introduction of a number of measures. They will need to be complemented by awareness raising and the education of potential users under the country’s jurisdiction.

5 Recommendations for policy-makers

ABS agreements and trade in biological resources can contribute to poverty alleviation if local and indigenous communities are partners in the ABS or trade activities. To ensure an optimum contribution to poverty alleviation, ABS agreements need to be form part of an international and national legal and policy regime that encourages poverty alleviation while contributing to biodiversity conservation and sustainability. It is not enough for development assistance to focus on supporting individual projects and capacity-building for ABS agreements at community and local level, although this is one important building-block in the ABS architecture. Action is needed at levels: international collaboration on ABS in the context of the CBD with a view to building an international regime of access and benefit-sharing based on fairness and equality (5.1), support for regional and national regime-building in both provider and user situations (5.2), and the provision of development cooperation (5.3).

This multi-layer approach can help to establish economic structures which foster pro-poor growth, create scope for poverty reduction and increase employment and so help to generate permanent improvements in welfare for poor sections of society. The following proposals are consistent with the priorities defined in the Program of Action 2015 of the Federal Ministry for Economic Cooperation and Development and will contribute to the achievement of the MDGs. They have the potential to create a win-win situation for both the alleviation of poverty and the implementation of the Convention on Biological Diversity.

5.1 International collaboration

5.1.1 Building the international ABS regime

Policy-makers should:

- adopt the provisions proposed in Chapter 4 concerning the building of an international ABS regime; the provisions should be clear, short and concise;
- encourage other international biodiversity regimes (e.g. the International Treaty on Plant Genetic Resources) to consider how poverty alleviation objectives might be integrated into their agenda and scope;
- use the CBD Clearing-House Mechanism effectively to exchange experience and to analyse the viability and effectiveness of market creation as a tool for the achievement of CBD's objectives; this includes the establishment of best practice, support for infrastructure development and the international dissemination of the findings.

5.1.2 Institutional framework

Policy-makers should create the following institutions:

- “Poverty coordinator”: policy-makers should ensure that the international ABS regime provides a norm setting for benefit-sharing that contributes to poverty alleviation. Special emphasis should be placed on the sharing of benefits with local and indigenous communities that provide genetic or biological resources and associated knowledge. To prevent the focus from shifting from poverty, a special independent rapporteur or coordinator could be instructed to ensure that poverty alleviation measures were taken at all levels.
- An ABS Advisory Body and an ABS Compliance Body should be created to facilitate the implementation of ABS agreements and the resolution of any conflicts arising from them.

5.1.3 Policies in related fields

Policy-makers should:

- ensure that the relationship between biodiversity and poverty remains a strategic issue for the CBD by building on the links between livelihood development and the conservation and sustainable use of biodiversity; it should be included as a key element of the mandate contained in the Multi-Year Programme of Work of the Conference of the Parties up to 2010;
- ensure that ABS poverty alleviation approaches are liaised with other policies and incentives that may be important to prevent and counteract marginalization within countries. Policies which are important in this respect include: agrarian reform and rural development policies (land tenure, agricultural productivity growth, rural industries and rural labour markets); micro-credit; support for small and medium-sized enterprises; promotion of backward linkages from export activity; broad-based human resource development through investment in education and health; establishment of profit-related pay systems; and decentralization;
- ensure that international and national regulatory frameworks, including the regulation of trade and investment and intellectual property rights regimes, enable the development of technological capabilities and skills in developing countries at national and local level.

5.2 Policy advice and support at national and regional level

5.2.1 User countries

User countries should:

- create incentives for companies using genetic resources and traditional knowledge to enter into ABS agreements with communities holding traditional knowledge, e.g. offer public-private partnerships on trade in biological resources related to traditional knowledge and on the development of products based on genetic resources and associated traditional knowledge.
- create fair trade opportunities by facilitating market access for the community-based cultivation of biological resources or the production of goods from the country of origin.
- establish a national Action Team on Benefit-Sharing to ensure the sharing of benefits arising from biological and genetic resources and related knowledge, consisting of relevant companies, NGOs and governmental institutions with the aim of negotiating ABS agreements with “traditional knowledge communities” and providers of biological material and goods.
- create awareness in user countries’ governments with a view to changing national laws and regulations on intellectual property rights, particularly patents, to facilitate the implementation of the international ABS regime. Specifically, when a patent is sought for an invention incorporating genetic resources or associated traditional knowledge, the international ABS certificate should be used as evidence that the resources have been acquired in accordance with the provisions and in the spirit of the CBD.
- ensure that support is provided for technological R&D that is relevant to people living in poverty. User countries should help to build up R&D capacity in developing countries.
- ensure that financial and technical support is provided for the development of dynamic national innovation systems in developing countries.
- recognize the existence of local natural resources from other countries through awareness-raising campaigns. International recognition of a local natural resource can lead to local recognition of that resource, thus resulting in increased local demand and ensuring additional employment and income possibilities for local people.
- analyse the way in which national application systems for food and drugs might be used to ensure that ABS regulation is respected.
- adopt policies to prevent the illegal acquisition of traditional knowledge while the ABS regime is in the process of being established. Where traditional knowledge is used without the approval of its holders, the country having jurisdiction over the user of such knowledge should negotiate with the user benefit-sharing mechanisms, with the holders

of the knowledge involved, and contribute to the benefit-sharing mechanism in an appropriate manner.

- analyse whether legislation on geographical indications for biological products in the regions of developing countries may be a useful poverty alleviation tool. Developing countries might consider forging partnerships with one or more Parties that are potential user countries with a view to exploring and developing international markets for the product.

5.2.2 Provider countries

Legislation

- Create a legal basis for benefit-sharing with the poor. Countries should establish the legal basis for genetic resource ownership and related access to land and land ownership.
- Countries should establish ABS laws and regulations with the focus on community-based benefit-sharing mechanisms that ensure poverty alleviation.
- Ensure the participation of communities with traditional knowledge, NGOs and civil society in the elaboration of national policies, laws and regulations on access and benefit-sharing.
- Create a legal basis for the protection of traditional knowledge: countries should determine which type of legal protection of traditional knowledge best suits its specific national requirements and the needs of its traditional knowledge holders. For example: analyse whether the use of trademarks and geographical indications is a legal option for the country or whether other forms of protection are more appropriate and efficient.
- Evaluate tenure structures and strengthen the rights of indigenous people and traditional communities to their cultural identity and the collective intellectual property of their traditional knowledge. The analysis should in particular evaluate how to support sustainable management practices and how to establish rights to biological resources.

Policies on benefit-sharing and poverty alleviation

- Country strategies for poverty reduction and food security should take account of the complex link between poverty and biodiversity and its consequences for biological diversity. At the same time, strategies and action plans in the area of biodiversity should no longer neglect the poverty dimension.
- In ABS agreements, benefits should promote conservation, the sustainable use of biological diversity and poverty alleviation.

- While different forms of benefits may contribute to poverty alleviation, it should be ensured that a share of the benefits goes directly and in the short term to local and indigenous communities. In general, ABS agreements should recognize the right of the poor to define and negotiate the benefits best suited to their needs.
- Help indigenous and local communities appropriately to address resource access and land ownership issues and facilitate processes that seek to bring marginalized people into decision-making processes concerning land use (through capacity-building, provision of information, applied “socially” oriented research activities, etc.).
- Support national and regional authorities to help integrate biodiversity conservation strategies and poverty alleviation strategies into the planning of land use and to support cooperation among the organizations involved (government authorities, local authorities, environmental and development organizations, social movements, development cooperation institutions). A possible form of support is to ensure that yields from the use of genetic resources are proportionately supplied to protected areas.
- Support empowerment as a crucial poverty alleviation strategy when ABS policy and law are established, including the possibility of the poor organizing themselves, especially at local community level, project their views and interests and gain a bigger say in decision-making on local resource allocation.
- Support indigenous and other local people to address resource access and land ownership issues and facilitate processes that bring them into decision-making processes concerning land use.

Capacity-building

- Stimulate the flow of information on innovative and successful community practices that include biodiversity and poverty alleviation.
- Build up the country’s own biotechnology capacities that might help to increase the gross national product and so to reduce poverty. Like international users, national users of genetic resources and traditional knowledge must obey the country’s ABS legislation.
- Enhance market opportunities: support private-sector development (including public-private partnerships) and the productive potential of economically poor but knowledge- and biodiversity-rich communities by supporting entrepreneurial capacity with respect to biological resources and associated knowledge. Microfinance programmes might be used to this end. This should be complemented by easier market access and IPR protection in the user country (as a means of benefit-sharing).

Technology transfer

- To ensure sustainable, long-term development, policy-makers and development agencies should focus their attention on the development of local ability to develop, adapt and use technologies. To permit the development of technological capabilities that will meet the needs and priorities of the poor, public support for pro-poor R&D and the regulation of investment and trade will be essential.
- Owing to the rising demand for genetic resources national biological diversity inventory programmes and ecosystem research need to be supported so that sustainable utilization strategies with a clear poverty alleviation target may be established.

5.3 Development cooperation

Many provider countries will need assistance when implementing the proposals mentioned in this study and in the Bonn Guidelines. Industrialized countries have a responsibility to support developing countries with development cooperation. The following recommends further ways of encouraging the implementation of an international ABS regime.

- Create awareness among indigenous peoples and local communities of their right to approve (or deny) the wider application of traditional knowledge and of benefit-sharing through various information channels, e.g. radio, press, television and extension services.
- Support efforts to document/take stock of biodiversity-related traditional knowledge where this is requested by the community having that knowledge.
- Support the creation of local production and cultivation opportunities, expand and support national and international market opportunities. This could be done through institutions that distribute information on ABS locally and provide assistance with the marketing of biodiversity goods and services, technology transfer and legal advice. Centres similar to the local and regional “Technology Transfer Centers” in Germany could be adapted to developing-country conditions.
- Use ‘biodiversity-friendly’ forms of development: develop alternative ways of achieving viable and sustainable poverty reduction by building on the conservation of existing valuable biodiversity assets. Those actions should be seen as complementary ways forward, with the potential to manage the trade-offs and to maximize the win-win opportunities between biodiversity conservation and poverty reduction more effectively.
- Create more effective conditions in production and trade for small producers so that poor groups may contribute significantly to the achievement of a higher and more sustainable pace of development, promoting not only economic growth but social cohesion.
- Create both nationally and internationally secure markets by ensuring, *inter alia*, long-term sales and distribution partnerships.

- Establish certification systems for sustainably produced community goods and services.
- Trademarks for environmental products can be crucial to their success and help facilitate widespread acceptance of a product. So-called “green labelling” programmes apply trademark or related principles (e.g. a not-for-profit organization allows a vendor to use an environmental seal of approval if certain requirements are satisfied).
- Consider innovative financing mechanisms to ensure that there is sufficient capital for the establishment of industries and for the build-up of the capacity to absorb technology transfer. This could include venture capital funds to support investments in the commercialization of biodiversity products and services. These funds could be established at national, regional or international level, depending on the size of the fund and who should be the trustee – e.g. a number of development agencies or just one - and who the administrator of the fund – e.g. an international organization such as UNDP or a national or regional NGO. The fund would support investment and enterprises with potential for growth and promote labor-intensive cultivation of biological resources or the production of bioproducts that are both competitive and sustainable in the long term. An alternative is microfinance programmes to encourage the entrepreneurial activities of poor people and so foster the productive potential of the poor and their share in the benefits of increased economic activity based on the sustainable use of biological resources.

References

- Anuradha, R.V.** (2000): Sharing the benefits of biodiversity: The Kani-TBGRI deal in Kerala, India. In: A. Kothari, N. Pathak, and F. Vania (eds.). *Where Communities Care: Community Based Wildlife and Ecosystem Management in South Asia. Evaluating Eden 3*. International Institute for Environment and Livelihoods (IIED), London.
- Bernhardt, R** (1995): Interpretation in International Law, in: *Encyclopedia of Public International Law*, Vol. 2, Amsterdam, Lausanne, New York, pp. 1416-1426.
- Caillaux, J.; M. Ruiz** (2002): Legislative Experiences on Access to Genetic Resources and Options for Megadiverse Countries. Prepared for the First Meeting of Like-Minded Megadiverse Countries, Cancún, Mexico, 18 February 2002; www.megadiverse.org/armado_ingles/five/five5.pdf.
- CBD/COP/6/20/PART2**: UNEP/CBD/COP/6/20/PART2, Report of the sixth meeting of the Conference of the Parties to the Convention on Biological Diversity Part 2 (Annex I), www.biodiv.org/doc/meetings/cop/cop-06/official/cop-06-20-part2-en.pdf.
- Centre for European Agricultural Studies (CEAS)** (2000): Study on the Relationship between the Agreement on TRIPs and Biodiversity related issues. Final Report. Consultants (Wye) Ltd., in association with Geoff Tansey and Queen Mary Intellectual Property Research Institute.
- Columbia University** (1999). Access to genetic resources: An evaluation of the development and implementation of recent regulation and access agreements. Columbia University, School of International and Public Affairs, Environmental Policy Studies Working Paper No. 4, Biodiversity Action Network, Washington D.C.
- Concepción, G.** (2003), Personal Communication, University of the Philippines, Marine Science Institute.
- Downes, D.R. / S. Laird** (2000): Innovative mechanisms for sharing benefits of biodiversity and related knowledge: Case studies on geographical indications and trademarks. In: M. P. Quiceno Mesa (ed.). *Biocomercio: Estrategias para el Desarrollo Sostenible en Colombia*. Instituto Alexander von Humboldt, Bogota.
- European Community (EC)** (2001): Second National Report to the Convention on Biological Diversity, <http://www.biodiv.org/doc/world/eur/eur-nr-02-en.pdf>.
- (2002): Second Report of the European Community to the Convention on Biological Diversity. Thematic Report on Access and Benefit-sharing. <http://www.biodiv.org/world/eur-nr-abs-en.pdf>.
- (2002a): Communication by the European Communities and their Member States to the TRIPs Council on the Review of Article 27.3 (B) of the TRIPs Agreement, and the Relationship between the TRIPs Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge and Folklore. "A Concept Paper", Brussels, 12 September 2002, Directorate-General for Trade.
- Federal Ministry for Economic Cooperation and Development (BMZ)** (2001): Poverty Reduction – a Global Responsibility. Program of Action 2015 The German Government's Contribution Towards Halving Extreme Poverty Worldwide, Bonn.
- Glowka, L.** (1998): A guide to Designing Legal Frameworks to Determine Access to Genetic Resources, IUCN Environmental Law Centre, Bonn.
- Government of Costa Rica** (1999): Benefit-sharing: Experience of Costa Rica. Paper prepared for the Second Regional Workshop of the UNCTAD "Project on Strengthening Research and Policy Making Capacity on Trade and Environment in the Developing countries", 31.05.-03.06.99, Havana.
- Grimble, R. / M. Laidlaw** (2002) : Biological resource management. Integrating biodiversity concerns in rural development projects and programs. The World Bank Environment Department, Discussion Paper No. 85, Washington, D.C.

- GRAIN / The Gaia Foundation** (2000): Biodiversity for sale: Dismantling the hype about benefit-sharing. Global Trade and Biodiversity in Conflict, No. 4.
- Gupta, A.K.** (2002). Value addition to local Kani tribal knowledge: patenting, licensing and benefit-sharing. Indian Institute of Management Ahmedabad (IIMA) Working Paper 2002-08-02.
- Hahn, A. von** (2001): Implementing the Convention on Biological Diversity: Analysis of the Links to Intellectual Property and the International System for the Protection of Intellectual Property, Submission by the Federal Republic of Germany at the Ad hoc open-ended Working Group on Access and Benefit-sharing, 4 October 2001, UNEP/CBD/WG-ABS/1/Inf/3.
- Henne, G.** (1997): ‚Mutually agreed terms’ in the Convention on Biological Diversity: Requirements under public international law, in: J. Mugabe et al. (eds.): Access to Genetic Resources. Emerging Regimes to Facilitate Regulation and Benefit-Sharing, ACTS, WRI, Washington D.C., Nairobi, pp. 71 – 91.
- (1998): Genetische Vielfalt als Ressource. Die Regelung ihrer Nutzung, Baden Baden.
- / S. Fakir (1999): The Regime Building of the Convention on Biological Diversity on the Road to Nairobi, Max Planck Yearbook of United Nations Law, Vol. 3, pp. 315-361.
- INBio** (2003): Personal communication.
- Krasner, S. D.** (ed.) (1983): International Regimes, London.
- Liebig, K. et al.** (2002). Governing Biodiversity. Access to genetic resources and approaches to obtaining benefits from their use: the case of the Philippines. German Development Institute, Reports and Working Papers 5/2002, Bonn.
- List, Martin / V. Rittberger** (1992): Regime Theory and International Environmental Management”, in: Hurrell, Andrew, Kingsbury, Benedict (eds). The International Politics of the Environment, Oxford.
- Like-Minded Megadiverse Countries (LMMC)** (2002): Cancún Declaration of Like-Minded Megadiverse Countries, Cancún, Mexico, 18 February 2002, www.megadiverse.org/armado_ingles/PDF/three/three1.pdf.
- Moran, K.** (2002): Bioprospecting: lessons from benefit-sharing experiences, in: *Int. J. Biotechnology*, Vol. 2, Nos. 1/2/3, pp. 132–144.
- Müller, K.** (2002): Armut und Sozialpolitik in den zentralasiatischen Transformationsländern. Deutsches Institut für Entwicklungspolitik, Bonn.
- Perrings, C. / M. Gadgil** (2003): Conserving biodiversity: Reconciling local and global public benefits. In: I. Kaul (et al.) (eds.): Providing global public goods. Managing Globalization. UNDP, Oxford University Press, New York, Oxford, pp. 532-555.
- Sen, A.** (1999): Development as freedom, Oxford.
- Stoll, P.-T.** (1999): Possible Elements of Guidance – Elements suggested, in: Stoll / Wolfrum (1999).
- / **Wolfrum (eds.)** (1999): Documents of the European Workshop on Genetic resources issues and related aspects. Workshop 6-7 May 1999, Heidelberg.
- ten Kate, K. / S. Laird** (2000): The commercial use of biodiversity. Access to genetic resources and benefit sharing, London.
- United Nations Development Programme (UNDP)** (2000): The Millennium Development Goals, www.undp.org/mdg.
- World Intellectual Property Organization (WIPO)** (2002): Practical Mechanisms for the Defensive Protection of Traditional Knowledge and Genetic Resources within the Patent System, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, fifth Session, 7 – 15 July 2003, WIPO/GRTKF/IC/5/6.
- (2003a): Composite study on the protection of traditional knowledge, July 2003, WIPO/GRTKF/IC/5/8.

- (2003b): Draft Technical Study on Disclosure Requirements to Genetic Resources and Traditional Knowledge, May 2003, WIPO/GRTKF/IC/5/10.
- (2003c): Overview on Activities and Outcomes of the International Committee, April 2003, WIPO/GRTKF/IC/5/12.

World Bank (2001): World Development Report 2000/2001: Attacking Poverty. New York.

World Summit for Sustainable Development (WSSD) (2002): Plan of Implementation of the World Summit on Sustainable Development. In: Report of the World Summit on Sustainable Development, Johannesburg, South Africa, 26 August - 4 September 2002, A/CONF. 100/20.

World Wide Fund for Nature (WWF) (2000): Living Planet Report. Gland, World Wide Fund for Nature Year 2000. List of Threatened Species. Available online at www.redlist.org.

Wynberg, R. (2003): A review of benefit-sharing arrangements for biodiversity prospecting in South Africa. In: IUCN (ed.). Developing Access and Benefit-Sharing Legislation in South Africa: A Review of International and National Experiences. IUCN South Africa, Pretoria.

Annex I

Millennium Development Goals (MDGs) and Targets	
Goal	Target
1. Eradicate extreme poverty and hunger	Halve, between 1990 and 2015, the proportion of people whose income is less than US \$ 1 a day and those who suffer from hunger.
2. Achieve universal primary education	Target for 2015: Ensure that all boys and girls complete primary school.
3. Promote gender equality and empower women	Targets for 2005 and 2015: Eliminate gender disparities in primary and secondary education preferably by 2005, and at all levels by 2015.
4. Reduce child mortality	Target for 2015: Reduce by two thirds the mortality rate among children under five
5. Improve maternal health	Target for 2015: Reduce by three-quarters the ratio of women dying in childbirth.
6. Combat HIV/AIDS, malaria, and other diseases	Target for 2015: Halt and begin to reverse the spread of HIV/AIDS and the incidence of malaria and other major diseases.
7. Ensure environmental sustainability	<ul style="list-style-type: none"> • Integrate the principles of sustainable development into country policies and programs and reverse the loss of environmental resources. • By 2015, reduce by half the proportion of people without access to safe drinking water. • By 2020 achieve significant improvement in the lives of at least 100 million slum dwellers.
8. Develop a global partnership for development	<ul style="list-style-type: none"> • Develop further an open trading and financial system that includes a commitment to good governance, development and poverty reduction – nationally and internationally • Address the least developed countries' special needs, and the special needs of landlocked and small island developing States • Deal comprehensively with developing countries' debt problems • Develop decent and productive work for youth • In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries • In cooperation with the private sector, make available the benefits of new technologies – especially information and communications technologies.

Annex II**MONETARY AND NON-MONETARY BENEFITS****COP-Dec. VI/24, Bonn Guidelines****1. Monetary benefits may include, but not be limited to:**

- a. Access fees/fee per sample collected or otherwise acquired;
- b. Up-front payments;
- c. Milestone payments;
- d. Payment of royalties;
- e. Licence fees in case of commercialisation;
- f. Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;
- g. Salaries and preferential terms where mutually agreed;
- h. Research funding;
- i. Joint ventures;
- j. Joint ownership of relevant intellectual property rights.

2. Non-monetary benefits may include, but not be limited to:

- a. Sharing of research and development results;
- b. Collaboration, cooperation and contribution in scientific research and development programs, particularly biotechnological research activities, where possible in the provider country;
- c. Participation in product development;
- d. Collaboration, cooperation and contribution in education and training;
- e. Admittance to *ex situ* facilities of genetic resources and to databases;
- f. Transfer to the provider of the genetic resources of knowledge and technology under fair and most favorable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity;

- g. Strengthening capacities for technology transfer to user developing country Parties and to Parties that are countries with economies in transition and technology development in the country of origin that provides genetic resources. Also to facilitate abilities of indigenous and local communities to conserve and sustainably use their genetic resources;
- h. Institutional capacity-building;
- i. Human and material resources to strengthen the capacities for the administration and enforcement of access regulations;
- j. Training related to genetic resources with the full participation of providing Parties, and where possible, in such Parties;
- k. Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;
- l. Contributions to the local economy;
- m. Research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in provider countries;
- n. Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities;
- o. Food and livelihood security benefits;
- p. Social recognition;
- q. Joint ownership of relevant intellectual property rights.