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Regulating Access and Benefit Sharing

Basic issues, legal instruments, policy proposals

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TABLE OF CONTENTS

Part 1: Basic Issues

PART I: Basic Issues

1. Introduction

In the context of developing biotechnological procedures and products, the protection and sustainable use of biological diversity is of paramount importance. However, in establishing the framework conditions for their application, not only complementary but also contradictory, sometimes even opposing objectives need to be as closely coordinated as possible. Approaches to handling genetic resources hesitate between efforts to **preserve** these resources in their **natural habitat** and endeavours to **conserve** them through use, to increase the incentive for their conservation by **economic embedding**. Three international forums address the institutional terms for using genetic resources. Although they overlap in scope and competence, they by no means coincide. They are the Convention on Biological Diversity (CBD), the FAO Commission on Genetic Resources for Food and Agriculture (CGRFA), and the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS).

1.1. The Convention on Biological Diversity (CBD)

The Convention aims to regulate both the conservation of biological diversity and the economic use of its components, thus reconciling the diverging interests of Southern countries with their wealth of biological diversity and the technologically advanced countries of the North. It can best be described as a multilateral framework providing criteria for the development of bilateral cooperation and the concerted settlement of key aspects of access to genetic resources and the technology based on them.

Under the Convention, member states are conceded sovereign rights over the biological diversity existing in their territory (under in situ conditions), but also made fully responsible for conserving it. The conservation of biological diversity and its economic utilization are thus placed on a new basis binding under international law. However, if the Convention is to have any practical impact, it needs to be implemented by the member states, i.e., translated into national law and then enforced.

Resources collected before the coming into force of the Convention and stored in so-called ex-situ collections are formally excluded from its purview. These are, in particular, the plant collections of the International Agricultural Research Centres (IARCs), the Microbial Resource Centres (MIRCENs) microbe collections, botanical gardens collections, and private collections of breeding companies and biotechnology firms, about which no precise data on scope and composition are available. However, given their crucial economic importance, especially for agriculture, the resources held in these ex-situ collections could be more relevant than biological diversity under in situ conditions.[1]

[1] SIEBECK, E.: Überblick über die Eigentumsrechte und Zugangsbedingungen zu genetischen Ressourcen auf internationaler Ebene – Probleme und Lösungsmöglichkeiten, in: F.Begemann (ed.): Zugang zu Pflanzengenetischen Ressourcen für die Ernährung und Landwirtschaft – der Diskussionsprozeß in Deutschland, Bonn (ZADI) 1996, pp.50-76

These gene banks can contain up to 95% of the known and agriculturally used cultivated varieties[2], which thus do not fall within the legal ambit of the Convention on Biological Diversity. The same is true for microbial collections. 86% of stocks are held in the industrial countries[3] and, where the material originates from Southern countries, there is no obligation to regulate access and terms for equitable benefit sharing. The Nairobi Declaration stated that the FAO Commission on (Plant) Genetic Resources was to be called upon to establish rules for handling plant-related ex-situ collections, and to address the problem of Farmers' Rights[4] not treated by the Convention. For many years, Farmers' Rights have been on the agenda in FAO discussions on handling (plant) genetic resources. Such rights are intended to ensure that farmers have access to good seeds, and that traditional agricultural practices like planting back seeds on the basis of harvested material from previous years are not prevented – for example by the preclusive effect of patent rights.

1.2. The FAO-International Undertaking

The FAO Commission on Genetic Resources for Food and Agriculture (CFRFA) was set up in the early 1980s to establish framework conditions for the conservation and sustainable use of the resources that are vital for feeding the world. The Commission aims to create a so-called "Global System" encompassing a whole range of measures, mechanisms and codes[5] intended to regulate the sustainable use of (plant) genetic resources. The institutional basis for the Global System is the International Undertaking, adopted in 1983, which pursues similar goals to the Convention on Biological Diversity, but which, unlike the Convention, is not yet binding under international law. The Undertaking, which is intended especially to clarify the handling of (agriculturally relevant) ex situ collections, is currently being revised, and will then, according to one option, be attached to the Convention on Biological Diversity as a protocol, implementing the objectives of the Convention relating to crops.

One problem is that the ex situ collections were made in accordance with the old "common heritage of humankind" principle to serve the common good of humankind and were not subject to national sovereignty as would now be the case since the coming into force of the Convention on Biological Diversity. Bilateral arrangements on dealing with these collections are therefore extraordinarily problematic from a legal point of view, not to mention the practical problem that the stocks of many collections are not registered, so that unambiguous identification of their origin cannot be ensured. Moreover, the germ-

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2 According to the World State Report issued on the occasion of the Fourth International Technical Conference of the FAO in 1996 (ITC-4). Collections are claimed to hold 95% of domesticated species and 60% of wild species of wheat, 95% and 15% resp. for maize, 95%/40% for potatoes, 70%/5% for sugar, etc.: World State Report, Rome 1996: 276 (following pages)

3 UNDP: Conserving Indigenous Knowledge, Integrating Two Systems of Innovation. An Independent Study by the Rural Advancement Foundation International, commissioned by the United Nations Development Programme, New York 1994, p.15

4 The Interrelationship Between the Convention on Biological Diversity and the Promotion of Sustainable Agriculture, Resolution No. 3, in: GLOWKA, L.; BURHENNE-GUILMIN, F.; SYNGE, H.; McNEELY, J.; GÜNDLING, L.: A Guide to the Convention on Biological Diversity, IUCN Gland and Cambridge 1994, pp.140-141

5 For example a "Code of Conduct for Plant Germplasm Collecting and Transfer,", a "Code of Conduct on Biotechnology," a "Basic Agreement on Genebanks," a "World Information and Early Warning System on Plant Genetic Resources" the World State Report, and the Global Plan of Action.

plasm of plant varieties contains genetic inputs from many different countries, so that, on this basis, bilateral approaches to benefit sharing would entail hundreds if not thousands of international agreements. The administrative effort involved would wipe out any benefits.

A solution must therefore be found in the context of the Undertaking to integrate bilateral and multilateral approaches in regulating the handling of (plant) genetic resources. This would make sure that multilateral arrangements on access to plant collections essential for food purposes – hitherto an informal concern – would remain open to the greatest possible number of interested parties. This access, which is imperative because of strong interdependence with regard to crop germplasm, would also be restricted neither by the strict bilateralism of the Convention on Biological Diversity nor by the exclusionary impact of intellectual property rights.

"In assessing the implications of national decision-making processes and policies on international negotiations, one must therefore focus on the multilateral approach. The bilateral approach being the 'default', a successful conclusion to the negotiations over PGRFA hinges on whether delegates at FAO can agree to the terms for a multilateral component".[6]

1.3. The TRIPS-Agreement

Intellectual property rights play an increasingly important role in the use of genetic resources. IPRs protect intangibles, that is to say developments or inventions expressed in the form of gene constructs, organic components, or entire organisms, subjecting them to more or less extensive exclusive rights. In a given national context, these materials may consequently no longer be used by third parties without the consent of the owner. This need not be granted or can be subject to payment of high license fees and the acceptance of far-reaching conditions, which can amount to a de facto denial of access. There is therefore a risk that a growing proportion of biological diversity will be withdrawn from unconditional use over time, and, furthermore, that it will no longer be available for commercial development purposes.

In this context the provisions of the TRIPS Agreement are particularly relevant. The Trade-Related Aspects of Intellectual Property Rights Agreement was a component in a package of agreements that finally led to the establishment of the World Trade Organization (WTO), and which could be accepted or rejected only in its entirety. All WTO member states are obliged to raise their national standards on the protection of intellectual property to a uniform minimum level, and to provide also protection for subject matter not hitherto covered at the national level in most developing countries.

These provisions of the TRIPS Agreement have caused great and widespread dismay in developing countries. It is claimed that they reflect the Western perception of innovation, thus entrenching an inequitable relationship between the protective treatment of so-called formal innovations that satisfy the established criteria of patenting prac-

[6] PETIT, M.; FOWLER, C.; COLLINS, W.; CORREA, C. and THORNSTRÖM, C.-G.: Why Governments Can´t Make Policy. The Case of Plant Genetic Resources in the International Arena, CGIAR (Draft) 2000, p.43

tice and informal innovations achieved by farmers and local communities in cumulative, incremental, and multigenerational form.[7]

Given their informal nature, these traditional achievements are not covered by the property rights provisions of the TRIPS Agreement – particularly with regard to patent protection. The demand is therefore to improve protection for these achievements in comparison with formal innovations, either by taking account of agriculture-related activities under a national sui generis system or by amending the TRIPS provisions and explicitly mentioning indigenous and local innovations with the proviso that TRIPS rules are not to prevent them nor to jeopardise their continuance.[8]

Both the national implementation of the necessary legislation and the pending reviews of the TRIPS Agreement offer considerable scope for interpreting, amending, or supplementing the Agreement to align intellectual property rights with the objectives of the Convention on Biological Diversity. In elaborating guidelines, these options should enter the appropriate negotiating processes and be clearly and unambiguously articulated in the chosen language of agreement.

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7 CRUCIBLE II GROUP: Seeding Solutions, IPGRI (International Plant Genetic Resources Institute), DHF (Dag Hammarskjöld Foundation), Rome, Uppsala 2000, p.10

8 CORREA, C.: Options for the Implementation of Farmers´ Rights at the National Level, in: PETIT, et al., pp.15-50 (28-29) gives an overview of the changes or amendments to TRIPS provisions demanded by developing countries.

2. Basic problems of access and benefit-sharing

2.1. Access to genetic resources

In recent years biodiversity has become an increasingly important issue in the sphere of international policy-making. The regulatory approaches to biodiversity under discussion in various fora are mainly concerned with safeguarding terrestrial and marine life-sustaining systems, yet with the enhanced interest in biotechnological methods, the debate is now focusing more strongly on aspects of economic exploitation, i.e. the organisation of industrial processes that add value on the basis of specific biological resources[9].

Since all the signs indicate that the new methods and products of biotechnology will occupy a crucial position over the coming years, access to or control over biological/genetic resources is increasingly becoming a strategic factor. In this context, genetic/organic material serves both as the starting point for the generation of biotechnological innovations and as a technological medium (microorganisms, plants, animals) through which innovations are actually realised and thus turned into economic values.

Those countries that provide the genetic/biological resources for further utilisation as part of biotechnological processes have a particularly strong interest in participating in technologies developed on this basis, since they want to ensure that their own economies can also profit from the value added potential offered by technological advances. For this reason the resource-supplying countries seek to place conditions on access to their resources, i.e. to make access dependent on compliance with certain terms. The aim of such conditions is to give the provider countries a share in the benefits resulting from the use of these resources, ensuring that such benefit-sharing takes place on mutually agreed terms and is subject to prior informed consent, i.e. clear information is given in advance on the intended purposes of resource utilisation. The countries of the South in particular have a major interest in ensuring that national sovereignty over their genetic/biological resources, now enshrined in international law under the CBD[10], is properly reflected in the framing of terms of access and that these resources are no longer freely available to anyone without any obligations to provide compensation.

The desired granting of access to technologies based on biological resources in return for access to these resources is also subject to far-reaching conditions and is by no means automatic. These restrictions primarily result from the prohibitive effects of intellectual property rights that generally accompany innovations, especially in the field of biotechnology. The exclusive effects associated with such proprietary rights enable the

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[9] Further reading: UMWELTBUNDESAMT (Ed.): Access and Benefit Sharing, Intellectual Property Rights, Ex-situ Collections: Proceedings and Materials. European workshop on genetic resources issues and related aspects, Erich Schmidt-Verlag, Berlin 2000; C. CARBUCCIA: National Access Legislation: An Updated Survey, in: Umweltbundesamt (Ed.), op.cit., pp.19-57; A. DREWS; A. GETTKANT: The Philippine Access Legislation: A View from Practice, in: Umweltbundesamt, op.cit., pp.60-78 (for more information: http://www.gtz.de/biodiv); GLOWKA, L.; Th. PLÄN; P.T. STOLL: Best Practices for Access to Genetic Resources. Information paper, cosponsored by the DG XI, European Commission and the German Federal Ministry of the Environment, Nature Conservation and Nuclear Safety, 1998 (available via InstBN@t-online.de)

[10] In Art. 3 "Principles", and Art. 15 "Access to Genetic Resources", para 1 and 3

holders of these rights to set the terms of access to their innovations on an individual basis. Indeed, there is no compulsion whatsoever to even grant such access, which may have to be gained by taking legal action, such as via proceedings to attain compulsory licensing.

Specifically, the granting of proprietary rights over innovations generated on the basis of genetic material from the countries of the South can have far-reaching consequences for access arrangements as a whole because exclusive rights may be defined so broadly as to cover germplasm from developing countries, e.g. possibly even unmodified plants or plant components (cf. comments on this point in chapter 4). The prohibitive effect of such claims can in practice undermine the national sovereignty accorded to the CBD Member States over their in-situ genetic resources, as can inadequate scrutiny of patents that lead to unlawful appropriation of the South's germplasm and associated systems of knowledge[11]. Since claims to exploit such legally protected "innovations" may possibly be asserted in dozens of countries at once[12], it becomes apparent just how far-reaching the problems can be in relation to the undermining of a country's national control over its own biological resources as a result of claims to innovations linked to genetic resources.

2.2. Access to traditional knowledge

Moreover, in elaborating the terms of access for each case, it is necessary not only to establish the relevant competencies at national level, which can lead to rivalries over jurisdiction between local/regional and national decision-makers, but also to involve actors in civil society, especially the representatives of indigenous and traditional groups wherever access extends to their material or non-material achievements. Since the Convention on Biological Diversity explicitly commits the signatory States to preserve and maintain knowledge, innovation or practices of indigenous and local communities embodying traditional lifestyles and to promote their wider application with the approval and involvement of the holders of such knowledge[13], there are other tasks to be considered when formulating appropriate terms of access.

Here, too, the initial problem is to establish the competent bodies/negotiating partners - a question that is complicated because the political and social relationships shaping the lives of traditional communities may often have little in common with Western concepts of law and the administrative regulations derived from them. Yet it is essential to take account of the interests of the holders of this indigenous/traditional knowledge in having their material and intellectual achievements safeguarded, respected and valued.

In addition to ensuring adequate participation of these knowledge holders in the development of appropriate terms of access, there are other aspects to be considered, such as the provision by the applicant of adequate information needed for prior informed consent (PIC) to any agreement. This is not only a matter of overcoming linguistic barriers but also of respecting local attitudes to the natural environment, which often have a sacred and religious frame of reference that may run counter to the idea that isolated components of biodiversity are available for commodification and

[11] If they do not, for example, meet the patenting criterion of novelty
[12] Under the Patent Cooperation Treaty an international application can be made in 112 states
[13] In Art. 8(j)

commercialisation. Among other things, this implies that those who draw up the terms of access have a responsibility to ensure that traditional values are not destroyed by economic interests, and to guarantee that the indigenous knowledge holders have appropriate participation in any benefits resulting from the utilisation of their achievements.

In view of the unpredictability of commercial success, it is recommended that a mixed benefit package be adopted, certainly including a share in the profits that may one day be earned, but also comprising short and medium-term transfers in the form of up-front payments, seed sample fees or the transfer of other material (e.g. equipment) or non-material (know-how). Commercial actors, especially in the pharmaceutical sector, are often confronted with uncertainties as to the development of potentially marketable new products, yet it is only their marketing that can generate the real benefits to be transferred. So some individual companies have now adopted the practice of providing, up front, substantial financial and material compensation and then getting these benefits to the holders of indigenous/traditional knowledge by setting up transfer mechanisms designed for this purpose (e.g. Shaman/Healing Forest Conservancy).[14]

Shaman´s reciprocal benefits

From its beginnings in 1989, the US-company Shaman has been committed to the concept of reciprocal benefits: to developing new therapeutic agents by working with indigenous and local peoples of tropical forests and, in the process, contributing to the conservation of biological and cultural diversity. Terms of this reciprocity are driven by the expressed needs of the peoples themselves. Shaman´s approach to questions surrounding reciprocal benefits involves three timeframes – immediate, medium-term and long-term. This approach has been developed in part to address a potential conflict between the company´s recognized obligations to local communities and the nature of the pharmaceutical industry. Although the needs of indigenous peoples are often urgent, development of a therapeutic agent generally requires a long lead-time, which can easily be a lengthy timeframe of five to ten years. Shaman considers it unacceptable to delay compensation for indigenous peoples until a product to which they have contributed is ready for market. It is stated company policy that their collaborators are entitled to a percentage of the profits from sales after the product is on the market, and to some return even if the product never achieves commercial potential. For every product, Shaman has committed to return a portion of the profits to **all** of the communities and countries in which they have worked, **no matter where** in the world the plant or information used for product development, originated. Through this process, the risk of receiving no compensation for a commercial product is lessened for individual countries or communities that did not contribute to product discovery. In a financially unpredictable industry, spreading the benefits and risks among all contributors increases the opportunities for compensation and hastens compensation returns. This commitment includes profits derived from a product licensed from another company. When Shaman was formed, a nonprofit conservation organization has been founded, the Healing Forest Conservancy, to create and implement a compensation process to return benefits to indigenous colleagues after a product has reached the commercial stage[15].

Derived from: KING, S.; T. CARLSON: Biocultural Diversity, Biomedicine and Ethnobotany: The Experience of Shaman Pharmaceuticals, in: Interciencia No. 3/1995, pp.134-139; KING, S.; T.CARLSON, K. MORAN: Biological Diversity, Indigenous Knowledge, Drug Discovery, and Intellectual Property Rights, in: S. Brush; D. Stabinsky (Eds.): Valuing Local Knowledge: Indigenous People and Intellectual Property Rights, Island Press 1996, pp.167-185

[14] Shaman, has set up its own transfer mechanism, called the Healing Forest Conservancy, specifically for benefit-sharing purposes

[15] Further reading: MORAN, K.: Mechanisms for Benefit Sharing: Nigerian Case Study for the Convention on Biological Diversity, Case Study prepared and distributed to the Conference of the Parties to the Convention on Biological Diversity, Fourth Meeting, Bratislava, Slovakia, 4 to 15 May 1998; CARLSON, T.J.; M.M. IWU; S.R. KING; C. OBIALOR; A. OZIOKO: Medicinal Plant Research in Nigeria: An Approach for Compliance with the Convention on Biological Diversity, in: Diversity, No. 1/1997, pp.29-33; KING, S.R.; T.CARLSON; K. MORAN: Biological Diversity, Indigenous Knowledge, Drug Discovery and Intellectual Property Rights: Creating Reciprocity and Maintaining Relationships, in: Jounal of Ethnopharmacology No. 51/1996, pp.45-57;

Such an approach, which certainly goes beyond the letter of the CBD, is not only suited to compensating the providers of relevant knowledge in a fast and pragmatic manner for the knowledge they have provided and to improving their social and economic conditions without undue delay, but it also enables a whole number of different groups, possibly in several countries or even on different continents, to profit from possible future benefits by means of a lump-sum performance in anticipation of those benefits without having to incur high transaction costs and without having to pursue lengthy case-by-case solutions that may be disputed by all parties and only be of short duration.

Moreover, the pursuit of such an approach can improve the social and political standing of the holders of indigenous and traditional knowledge vis-à-vis their own governments and ensure that the benefits to be transferred are not intercepted and diverted for other purposes by the national authorities (designated as responsible in each CBD Member State for exercising sovereignty over its genetic resources) but actually reach the holders of the knowledge themselves. In this way, national sovereignty rights over a country's own resources are not undermined, but the role of the achievements of indigenous and traditional communities, which the Convention on Biological Diversity tends to treat as a secondary matter, is significantly strengthened along with their position in the context of drawing up appropriate ABS arrangements.

2.3. Protection of intellectual property rights

The provisions of the Convention on Biological Diversity to ensure sustainable use of genetic/biological resources also require that access to and transfer of technologies subject to patents or other intellectual property rights shall be provided on terms consistent with the adequate and effective protection of these rights. This passage, enshrined in Article 16.2 of the Convention, may be interpreted to mean that the proceedings initiated for compulsory licensing for technologies based on transferred germplasm must comply with the usual criteria for the application of the relevant legal instruments of protection (patents, copyrights etc.) or at least that such proceedings are not explicitly facilitated in the context of the technology policy objectives pursued by the Convention. However, the Convention does concede that the exclusive effects of the instruments to protect intellectual property can have an influence on the implementation of the Convention and establishes that the Contracting Parties should cooperate on this point to ensure that such rights are supportive of and do not run counter to the (technology) policy objectives of the Convention (Art. 16.5).

Thus, a basic characteristic of both aspects of the access issue (access to resources and to the technologies based on them) is that the development of solutions in the continuum of this complex is predicated on the provision of options for setting the conditions of access. Such options for defining access conditions will necessarily strengthen the negotiating positions of the relevant stakeholders in the process of arriving at appropriate access arrangements and are explicitly set out in writing in the provisions of the Convention on Biological Diversity. They follow from the national sovereignty accorded expressis verbis to the resource-supplying countries of origin, over the genetic/biological diversity that exists in in-situ conditions on their territory, and can be derived from the obligation to comply with all the rights to the (bio-)technological innovations based on these resources.

A problem that arises here is that the symmetry, which the Convention seeks to maintain as a principle uniting all its provisions, between the aspects of protection and use of biological diversity, as well as between the different interests of the industrialised and the developing countries, breaks down when it comes to setting conditions. The conditions for technology transfer, which under the provisions of the CBD should be set on the basis of "mutually agreed terms"[16] and within an "appropriate" framework[17], must (pursuant to Art. 16 of the Convention) be consistent with rights attached to the technologies to be transferred.[18] At this level at least, a clear logical connection is necessarily established between the objectives of the Convention on Biological Diversity and other binding agreements under international law which set out inter alia standards and details of intellectual property rights while, for their part, also carrying far stronger sanction mechanisms to ensure compliance.

"Despite their difference in coverage, it can not be denied that the interaction between the rights referred to in the TRIPs Agreement and the subject matter of the CBD is considerable. There is a range of issues upon which both agreements do have implications such as biotechnology, plant varieties, environmental technology relating to conservation and sustainable use, traditional knowledge and benefit sharing."[19]

The asymmetry between the observance of intellectual property rights, possibly backed up by strong sanction mechanisms and the provisions for resolving the access issue contained in the Convention on Biological Diversity, which for its part only constitutes a framework agreement, might contribute to a situation in which CBD objectives will not only be widely circumvented but also overridden by economic and trade policy goals contained in sanction-backed agreements such as the TRIPs Agreement. This is all the more relevant as the TRIPs Agreement forces the assignment of intellectual property rights to (innovations in the field of) living material and thus provides clear and unambiguous instruments for regulating certain aspects of the treatment of biodiversity while, for its part, failing completely to define interfaces with the provisions of the Convention on Biological Diversity, e.g. on the question of disclosing details of the origin of living material.

2.4. Benefit sharing: technology transfer

The compensation for the (economic) benefits arising from the use of germplasm made available through specific arrangements represents a cornerstone of the CBD philosophy of convergence between the interests of the South and the North. This endeavour to

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16 In Art. 16.2: "... including on concessional and preferential terms where mutually agreed"

17 In Art. 16.3: "Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties, in particular those that are developing countries, which provide genetic resources are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms ..."

18 In Art. 16.2 : "... In the case of technology subject to patents and other intellectual property rights, such access and technology transfer shall be provided on terms which recognise and are consistent with the adequate and effective protection of intellectual property rights."

19 Review of the Provisions of Article 27.3(b) of the TRIPs Agreement. Draft Communication by the European Communities and Their Member States on the Relationship Between the Convention on Biological Diversity and the TRIPs Agreement, transmitted by the Commission to the 133 Committee on 23.02.2001, para 12

achieve a convergence of (diverging) interests runs through the entire structure of the text and is expressed most succinctly in the statement of its objectives:
Art. 1 (Objectives): "The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources ..."

The problem of tensions between different objectives (access versus sharing of benefits) becomes apparent when the above sentence in Art. 1 goes on to qualify the objectives of the CBD. The substance (and ramifications) of this passage are often forgotten in the discussion when people refer to the central concerns of the Convention on Biological Diversity:

"... including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding."

The wording here already tells us that fair benefit-sharing does not have to take the form of technology transfer, although it can of course be expressed in this way and, where this is the case, is completely consistent with the objectives of the Convention, assuming the pertinent rights are observed. Access to the relevant technologies was the main concern of many developing countries in the negotiations leading up to the finalisation of the Convention. Indeed, many of these countries made access to technology just as much a condition for their participation in the negotiations as access to the other benefits arising from the use of genetic resources.[20]

What lies behind the strong focus on technology transfer, as expressed in the very objectives of the CBD, is the understanding on the part of the Southern country decision-makers that, as interest grows in the instrumental significance of biodiversity for the development of new biotechnological methods and products, they must avoid a situation whereby their environments merely (and only for a limited period) represent an extension of the international production lines of the industrialised countries. The scenario to be avoided is that their environments merely supply genetic resources as raw materials without their being able to profit significantly from the value added in industrial processes. Only access to the relevant expertise and knowledge systems of the North - which certainly cannot by reduced to know-how in biotechnology and genetic engineering – allows developing countries both to participate in the value added from utilising their own biological resources and to advance local scientific and technological capacities, and in these ways to improve their negotiating position when agreeing terms of access, and to promote, from their own perspective, the sustainable use of genetic resources in the national framework.

Indeed, scientific and technological capacity-building in one's country in return for access to genetic resources is certainly likely, in the medium and long term, to be the most effective approach to improving the basic economic position of the country concerned. Pursuant to the provisions of the Convention, this approach must also be followed when the industrialised countries undertake scientific research on the basis of genetic resources provided by the South, for the Contracting Parties are obliged under

[20] GLOWKA, L., et al., p.5

the rules on access arrangements to endeavour to plan and carry out R&D projects with the participation of and, where possible, within the territory of provider countries (Art. 15.6).

2.5. Benefit-sharing: other approaches

Other approaches by which the provider countries are able to share in the benefits arising from the use of genetic resources can be divided into a list of monetary and non-monetary measures, which include financial incentive mechanisms already referred to in the wording of Art. 1. The following table, which is by no means exhaustive, offers an overview of the relevant instruments that are available for ensuring fair and equitable benefit-sharing.

It is pointed out in the scientific literature that the provisions on the terms of access and on fair benefit-sharing require a case-by-case approach and that the application of standard solutions appears to be ruled out by the complex problems under consideration. The interrelated issues raised by ABS arrangements (property rights, nature conservation concerns, human rights, national versus regional jurisdiction, political versus botanical demarcation of conceivable target areas, private versus public interests, etc.) are extremely wide-ranging and demand the careful elaboration of a set of suitable instruments tailored to each prospecting project.

Non-monetary	Monetary
- acknowledgement in publication - joint research and increased scientific capacity - participation in planning and decision-making - control over samples and research results - voucher specimens deposited in a national institution - co-ownership or sole ownership of intellectual property rights - free access to technology and products resulting from the agreement - protection of local existing applications of intellectual property rights - technology transfer (equipment and material donation) - training in bioprospecting methods, collection and preparation of samples, biodiversity monitoring, socioeconomic monitoring, and/or nursery and agronomic techniques (increased conservation capacity)	- bioprospecting fees - per-sample fees - percentage or research budget - percentage of royalties - development of alternative income generating schemes - commitment to re-supply in source country, sample - (int. fund based on levies and sales) - specific funds (Trust Funds)

Source: Columbia University School of International and Public Affairs: Access to Genetic Resources: An Evaluation of the Development and Implementation of Recent regulation and Access Agreements. Environmental Policy Studies, Working Paper No. 4, New York 1999, p. 75

Moreover, the aims pursued by the various industrial actors with potential interests in access to biological/genetic resources are also extremely heterogeneous. In this respect, the availability of technological options for taking a synthetic path to producing the desired substances (leads) will certainly play a not inconsiderable role in the process of elaborating terms of access to particular resources. On the other hand, completely different interests are articulated by representatives of scientific institutions such as gene banks or botanical gardens responsible for carrying out basic taxonomic research and maintaining their specimen inventories. They also depend on opportunities for exchanging or accessing germplasm. If these institutions are limited to non-commercial

activities, they have very little scope for generating transferable benefits and will therefore tend to emphasise the importance of maintaining valuable germplasm stocks and obtaining results from basic research into botanical taxonomy, which is indeed ultimately indispensable to the implementation of the Convention on Biological Diversity.

2.6. Criteria for developing guidelines

A number of different political and legal instruments are available for implementing appropriate ABS arrangements. They help decision-makers to give adequate attention to the constellation of different actors involved in a particular case and their respective interests, so that the multi-facetted and complex cluster of problems relevant to the conservation and sustainable use of components of biodiversity can be adequately taken into account.

Such instruments, which - applied alone or in combination - are suited to addressing the core issues to be regulated when designing the terms of access and benefit-sharing, include codes of conduct, bilateral and multilateral agreements, voluntary commitments, material transfer agreements or know-how licenses. However, in order to match the many different interests and sets of issues requiring consideration in each case, more encompassing guidelines capable of providing a coherent approach must also be developed. These guidelines will help to use the available legal and political instruments in such a way that the objectives of the Convention can be realised as far as possible.

Furthermore, the development and application of such guidelines is also needed to ensure that the available political and legal instruments can be applied in conformity with the CBD provisions to genetic material which had been collected before the Convention came into force on 29 December 1993. Where this material is contained in ex-situ germplasm collections located beyond the territorial or legal sovereignty of the respective country of origin, access to the material is not formally subject to the CBD provisions on negotiating mutually agreed terms, on obtaining advance informed consent, or on fair sharing of the economic benefits arising from the use of these stocks.

Nevertheless, both the countries of origin and the ex-situ collections themselves[21], have the option of choosing, in conformity with their other obligations, to apply the provisions of the Convention to these specimen inventories - a policy which, to some extent, makes the objectives of the Convention apply retroactively. This is the case, for instance, with germplasm collected and stored prior to the Convention's entry into force and kept in a collection which remains under the relevant jurisdiction of the country of origin. Here, the Member State concerned has discretion over whether to apply the provisions of the Convention retroactively.[22] Indeed, even in the case of ex-situ collections located outside the legal jurisdiction of the respective country of origin it is possible, in the absence of statutory provisions to the contrary, to arrange access to the germplasm samples kept in those collections in compliance with CBD provisions. However, this voluntary policy may, in certain cases, involve higher transaction costs due to the increased administrative

[21] Or rather the institutions responsible for managing them

[22] PETIT, M., et al.: Why Governments Can't Make Policy, op.cit., pp. 64-65

workload.

In cases to which the provisions of the Convention do not formally apply, but which nevertheless demand the maximum possible realisation of its objectives on conservation and sustainable use, it appears particularly useful for those attempting to define the best solution to be able to draw upon a certain instrument for orientation purposes. It is therefore important to carefully develop such guidelines so that they offer sufficient scope not only for taking account of the manifold interests of stakeholders seeking access and benefit-sharing, but also for addressing all the different legal questions of ownership and control associated with access to collections that do not formally come under the scope of the CBD. However, it must be clearly stated that no state party to the CBD is formally required to apply its stipulations retroactively, nor is such a voluntary retroactive application entirely clear or precisely delineated in legal terms. Therefore, the main focus of any guidelines designed to regulate access and benefit sharing issues should be those specimens which clearly fall within the CBD´s purview, i.e.: samples placed in ex-situ-collections and resources accessed from their in-situ conditions after its entry into force on December 29, 1993.

Guidelines should be flexible enough in their application to take account of the different characteristics of the germplasm that is to be made available, and they should in particular allow for bilateral, plurilateral or multilateral approaches to be combined in cases where this appears sensible - for instance where there is heavy international dependency on access to the germplasm in question and where unnecessarily high transaction costs should be avoided. This applies above all to access to germplasm collections of the most important crop species. Since many international actors depend on the maintenance of multilateral access for the continuation of their plant breeding activities, relevant stipulations are currently being developed as part of the overhaul of the International Undertaking of the FAO. The purpose of these stipulations is to ensure that access to the germplasm stocks essential to world food supplies are not endangered either by the exclusive effects of intellectual property rights or by restrictions resulting from bilateral access arrangements.

It is important when elaborating guidelines to make sure that their application, in combination with the other instruments for resolving ABS issues, is consistent as far as possible with CBD objectives. At the same time, however, it must be ensured that the outcomes of multilateral agreements which, for certain segments of biodiversity (e.g. staple crops), provide for specific regulatory instruments appropriate to their objects, are not impaired or that the guidelines can at least be corrected easily where necessary. Moreover, it should be taken into account that guidelines on ABS arrangements will, in many respects, interface - possibly revealing inconsistencies - with other legal instruments that are also critical in this context: for instance, property questions, land ownership systems, and above all the various instruments available for protecting intellectual property.

In other words, guidelines have to be implemented in and form part of a larger web of legal relationships. The task is equally then, to ensure that the provisions of the Convention on Biological Diversity are neither undermined nor overridden by the stipulations of other international agreements which may not be very suitable to promoting the Convention's objectives and which could, in their implementation, pose a threat to the CBD.

Irrespective of the question of the initial status of such guidelines, it is clear that - with the necessary insight and with due regard to the interests of the stakeholders involved - they should ultimately become a basic instrument for regulating ABS issues. In so doing, they should both operationalise the objectives of the CBD and create the legal certainty needed by industry and other access-seeking actors as a reliable basis for planning ABS-related activities as part of their strategic considerations. At the same time, it must be ensured that the holders of indigenous practices and traditions are sufficiently involved whenever their material and non-material contributions and achievements become the object of access negotiations.

3. Stipulations of the CBD pertaining to access and benefit sharing

The CBD places great emphasis on access and benefit-sharing. Indeed, it forms one of the three overriding objectives of the Convention (i.e. "the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding").

However, developing ABS regulations at the national level is a complex task and only a few countries so far have enacted and implemented such rules.

Recognising this, governmental representatives participating at the 5th meeting of the Conference of the Parties to the CBD in May 2000 decided that "in the absence of comprehensive legislation and national strategies for access and benefit-sharing, voluntary measures, including guidelines, may help ensure realization of the objectives of the Convention" (Decision V/26).

In order to develop such guidelines, the Parties agreed to establish an Ad hoc Open-ended Working Group on Access and Benefit-sharing. In addition to this task, the Working Group was also required to "assist Parties and stakeholders in addressing the following elements", all of which relate to access and benefit-sharing:

- terms for prior informed consent and mutually agreed terms;
- roles, responsibilities and participation of stakeholders;
- relevant aspects relating to in situ and ex situ conservation and sustainable use;
- mechanisms for benefit-sharing, for example through technology transfer and joint research and development; and
- means to ensure the respect, preservation and maintenance of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity.

This section of the study explains how the CBD and certain COP decisions deal with these elements, and identifies issues to be addressed when integrating these elements into ABS guidelines.

3.1. Prior informed consent (PIC)

According to the CBD, the authority to determine access to genetic resources rests with national governments, with such access being "subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party" (Article 15.5). The phrase "unless otherwise determined" indicates that it is left to governments whether or not to make access subject to PIC.

In 2000, the Conference of the Parties extended the application of prior informed consent to access to traditional knowledge when it decided (by virtue of decision V/16) that:

> Access to traditional knowledge, innovations and practices of indigenous and local communities should be subject to prior informed consent or prior informed approval from the holders of such knowledge, innovations and practices.

Thus users of traditional knowledge will need to seek PIC not from the government (as represented by a designated authority), but from an indigenous or local community, or an authority nominated or established by the community to represent it.

The PIC concept has its origins in medical treatment with patients providing consent to treatment based on information provided by a doctor or surgeon. In international law, PIC has been adopted mainly in the context of transboundary movements of hazardous wastes. So ABS provides a new context for PIC. So far there have been few experiences in applying PIC this way and it is hoped that guidelines will provide some assistance for state parties so they can develop appropriate and effective procedures.

PIC and other access procedures should not be so onerous as "to impose restrictions that run counter to the objectives of this Convention" (Article 15.2), but should still require enough information from prospective users so providers can make an informed decision on whether it is in their interests to grant access to this particular Party, collector or company, and on what terms such access should be granted.

A number of issues arise in implementing PIC such as:

- The extent of the information that should be required of prospective users.
- Whether all genetic resources should be subject to PIC requirements, or only some categories, such as in situ resources, or those found in certain locations, such as public lands or protected areas.
- Whether different PIC procedures should apply to collections for commercial or non-commercial purposes.
- Whether different PIC procedures should apply according to the type of genetic resource and use e.g. genetic resources for health and for food and agriculture.

Many if not most countries are likely to be users of genetic resources originating in other countries as well as providers. Given this reality and the fact that controlling access to genetic resources can be very difficult in practice, all governments have an interest in helping PIC procedures to be effective through supportive user measures. They might for example consider requiring importers of genetic resources to provide customs authorities with PIC certificates issued by foreign governments and – where appropriate – traditional knowledge holders.

3.2. Mutually agreed terms

In the specific context of ABS, the CBD applies the principle of mutually agreed terms (MAT) to the following:

- Access to genetic resources (Article 15.4);
- Fair and equitable sharing of the results of research and development, and the benefits arising from commercial and other use of genetic resources (Article 15.7);

- Access to and transfer of technology (Article 16.3); and
- Access to the results and benefits arising from biotechnology (Article 19.2).

Of these, only access to genetic resources is a binding obligation. The other provisions are not legal obligations *in the direct sense*. Rather, governments must take appropriate legislative, administrative, policy or practical (15.7 and 16.3) measures in order that such provisions might more easily be implemented through negotiations to be concluded on terms that are mutually agreed. There is a clear presumption that holders and owners of relevant technologies and research and development institutions are likely to be private sector institutions rather than governmental agencies.

MAT is closely related to PIC. In fact, PIC should be seen as a pre-condition for ABS terms to be mutually agreed upon.

3.3. Roles, responsibilities, participation of stakeholders

The CBD does not specify who the stakeholders might be. Nor does the CBD place binding legal obligations on any stakeholder except for national governments, which of course are the parties to the Convention. But these governments have the authority to place legal obligations on other stakeholders and to determine what their roles and responsibilities should be.

The Panel of Experts on Access and Benefit-sharing identified the following stakeholders in its report (UNEP/CBD/WG-ABS/1/2):

(a) Ministries, and government agencies concerned with natural resources, environment, agriculture, rural development, social welfare, culture, economic issues including fisheries and forestry, customs, protected areas, health, research, justice, finance;
(b) Regional and provincial level government agencies;
(c) National and international organizations involved in genetic-resources conservation;
(d) The industrial sector, in particular seed, pharmaceutical, plant-health horticultural, personal care and cosmetics, flavouring and fragrance, food and beverage, and other biotechnological companies;
(e) The scientific and academic communities or their representative organizations;
(f) People's organizations;
(g) Farmers, foresters and their organizations;
(h) Traditional healers or their associations and communities;
(i) Local and indigenous communities and their organizations;
(j) Non-governmental organizations working in the field of genetic resources;
(k) Elements of civil society that are not organized; and
(l) Media.

Broadly stakeholders can be divided into those who are – or are representatives of – users and those who are -- or represent -- providers. Users include the private sector, universities, scientific research organisations, and *ex situ* collections such as botanic gardens and culture collections. Providers are national and local governments, public and private sector in-country suppliers of genetic resources, landowners, and indigenous and local communities. Users and providers are not mutually exclusive groups. For example, botanic gardens may provide genetic resources to industry. Thus, both roles and responsi-

bilities of different stakeholders can vary. But however governments choose to define the roles and responsibilities, guidelines need to provide clarity and realism.

3.4. In-situ and ex-situ conservation and sustainable use

Although ABS should support the objectives of conserving biological diversity and sustainably using its components (the other two objectives of the Convention), the CBD provides little in the way of specific measures to reinforce such complementarities. Article 9(d) requires that collection of genetic resources for ex situ conservation purposes be regulated and managed so as not to threaten ecosystems and populations of species. However, users of genetic resources could be required to provide scientific information and technologies that are relevant to conservation and sustainable use such as biological inventories, taxonomic studies, and some of the technologies that can be applied to conservation and sustainable use referred to below.

3.5. Mechanisms for benefit sharing, including technology transfer and joint research and development

The CBD provides for the following benefits to be shared with countries providing access to genetic resources:

- the results of research and development;
- benefits arising from the commercial and other utilization of genetic resources (Article 15.7);
- access to and transfer of technology (including biotechnology) *including technology protected by patents and other intellectual property rights* (Article 16); and
- the results and benefits arising from biotechnologies (Article 19.2).

In paragraphs 16.1 and 16.2, state parties undertake to provide and/ or facilitate access and transfer of technologies to other parties under fair and most favourable terms. The only technology referred to is biotechnology, but Article 16 is concerned with any technologies "that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment" (Article 16.1).

What technologies are relevant to the CBD? A Note by the Secretariat of the CBD to the 2nd meeting of the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) refers to in situ and ex situ conservation technologies and sustainable use technologies (CBD Secretariat 1996). Thus, in situ conservation and sustainable use technologies include aerial survey equipment, geographical information systems, fencing equipment, and "technologies associated with low-external input agriculture, integrated pest management, re-vegetation and other on-farm management techniques". Soft technologies may take the form of "know-how, management routines, and behavioural patterns and attitudes". Ex situ conservation and sustainable use technologies include "tissue culture, field-based propagation, protoplast fusion, and cryopreservation". Common mechanisms for transferring such technologies include: "joint R&D, the training of na-

tionals in foreign universities and other institutions, [and] technology partnerships undertaken under biodiversity-prospecting arrangements".

It is likely that many of these technologies are in the public domain. But recognising that technologies are sometimes subject to patents and other IPRs, provision of such technologies must be provided and/or facilitated under terms that are consistent with the *adequate and effective* protection of intellectual property rights. Adoption here of the clause beginning "adequate and effective protection" was specifically to establish a link with the TRIPS Agreement, which also uses this language.

The private sector plays a key role in technology transfer, yet it is governments that are required to implement the CBD. Therefore, while governments can act as facilitators[23] by, for example, helping to build capacity and providing financing so that developing countries are in a position to make best use of technologies transferred to them, the providers of technologies will mostly be companies.

3.6. Means to ensure the maintenance of traditional knowledge and innovations

The CBD is the only international treaty that specifically acknowledges the vital role of traditional knowledge, innovations and practices in biodiversity conservation and sustainable development, as well as the need to guarantee their protection. Article 8 (j) requires the State Parties of the CBD to "respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote the wider application 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 utilisation of such knowledge, innovations and practices."

The implication of this is that where users seek access not only to genetic resources but also to associated traditional knowledge, innovations and practices they will be encouraged to share benefits arising from use of such knowledge with the holders. But before doing so they must secure their approval (i.e. prior informed consent or prior informed approval according to Decision V/16) and involvement.

With respect to implementation, the Conference of the Parties to the CBD agreed at its 3rd meeting (COP 3) in November 1996 on the need to "develop national legislation and corresponding strategies for the implementation of Article 8 (j) in consultation with representatives of their indigenous and local communities" (Decision III/14). Pursuant to this, the CBD Secretariat arranged a Workshop on Traditional Knowledge and Biodiversity. The Workshop took place in Madrid, Spain in November 1997, and was attended by representatives of governments and 148 indigenous and local community organisations.

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[23] And are required by TRIPS to do so in the case of least developed countries: "[d]eveloped country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base" (Article 66.2).

At COP 4 in May 1998, Decision IV/9 on Implementation of Article 8 (j) and Related Provisions recognized "the importance of making intellectual property-related provisions of Article 8 (j) and related provisions of the Convention on Biological Diversity and provisions of international agreements relating to intellectual property mutually supportive, and the desirability of undertaking further cooperation and consultation with the World Intellectual Property Organization (WIPO)." The Parties agreed to establish an "ad hoc open-ended inter-sessional working group" to address the implementation of Article 8 (j) and related provisions to be composed of Parties and observers including, in particular, representatives of indigenous peoples and local communities. The mandate of the working group includes the following items: "to provide advice on the application and development of legal and other appropriate forms of protection for the knowledge, innovations and practices of indigenous and local communities"; and "to develop a programme of work, based on the structure of the elements in the Madrid report".

The working group had its first meeting in Seville, Spain, in March 2000. Based upon its recommendations, COP 5, which took place two months later, extended the mandate of the working group and adopted a programme of work on implementation of Article 8 (j) and related provisions including the following tasks relating to legal elements:

> Task 11: The Working Group to assess existing sub-national, as appropriate, national and international instruments, particularly intellectual property rights instruments, that may have implications on the protection of the knowledge, innovations and practices of indigenous and local communities with a view to identifying synergies between these instruments and the objectives of Article 8(j).
>
> Task 12: The Working Group to develop guidelines that will assist Parties and Governments in the development of legislation or other mechanisms, as appropriate, to implement Article 8(j) and its related provisions (which could include *sui generis* systems), and definitions of relevant key terms and concepts in Article 8(j) and related provisions at international, regional and national levels, that recognize, safeguard and fully guarantee the rights of indigenous and local communities over their traditional knowledge, innovations and practices, within the context of the Convention.

4. The Role of Intellectual Property Rights in Implementing the Access and Benefit-Sharing Provisions (ABS) of the CBD

The Convention on Biological Diversity seeks to couple the conservation and the use of biological/genetic resources. In addressing the use aspect, it seeks to strengthen incentives to conserve biological diversity and in this way to place nature conservation concerns in an economic context. Achieving this necessarily involves a range of activities outside the regulatory ambit of the CBD in which nature conservation interests or equitable benefit sharing tend to play an instrumental or at best secondary role.

There are thus divergent interests with regard to the ABS issue, which are only partly consistent with the CBD's overriding objective of achieving a balance between the countries of the South with their wealth of resources and the technologically more advanced countries of the North. Nevertheless, regulatory instruments (guidelines, etc.) need to take these interests into account. Furthermore, the economic aspects of handling biological diversity are essentially governed by other internationally binding rules, especially the patent right provisions of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. Since access to knowledge and technology is a key objective of the Convention on Biological Diversity, there have been fears that the granting and recognition of intellectual property rights in activities relating to biological diversity could run counter to the (technology) policy goals of the CBD. Moreover, it is predicted that the nature conservation idea pursued by the Convention will suffer. The IPR rules embodied in the TRIPS Agreement must therefore also be implemented at the national level in a fashion that permits the regulation of economic action patterns in handling biological diversity in broad harmony with the Convention.

4.1. IPR Provisions of the CBD

Recognising that intellectual property rights, especially patents, do not entitle the owner to engage in production but are exclusive rights reliably preventing third parties from the unrestricted use of the subject matter, negotiators drafting the Convention on Biological Diversity concluded that intellectual property rights most strongly affect the **technology policy** objectives of the Convention.[24] Efforts to **conserve** biological diversity, however, could be only **indirectly** undermined by the granting of intellectual property rights.

For this reason, the passage stating that intellectual property rights should support rather than frustrate the objectives of the Convention was finally inserted in Article

[24] UNEP/CBD/COP/3/22: para 4: "Article 16.5 provides that the Parties, "recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.". The use of the term "may" implies that the negotiators could not agree on whether IPR have a positive effect, a negative effect, or a negligible effect on technology transfer or on the achievement of the Convention's objectives generally. …

16[25] (Access to and Transfer of Technology), this placement stressing the link with the CBD's technology policy objectives: "The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives." (Art. 16.5)

This clearly indicates that intellectual property rights can be a suitable instrument for implementing the Convention. However, as the ambivalent wording suggests, there is no conclusive answer to the question of whether they promote or prevent technology transfer – a key aspect of equitable benefit sharing.

Art. 16 contains further clarificatory provisions on the role of intellectual property rights in implementing the Convention's technology policy objectives. Access to and transfer of technology are stated to be essential elements in attaining the objectives of the Convention, and the contracting parties undertake to provide and facilitate access to technology relevant to the conservation and sustainable use of biological diversity. They are also required to provide access to such technology for developing countries on concessional or preferential terms. These terms must be mutually agreed, and, where necessary, the provision of financial resources must be considered to facilitate access to and the transfer of technology.

Contracting parties are in particular required to make technology using germplasm available to the provider countries on mutually agreed terms. This applies explicitly to technology protected by patents and other intellectual property rights. With regard to the transfer of technology subject to patents or other intellectual property rights, the Convention requires access and transfer under terms that recognise and are consistent with adequate and effective protection of intellectual property rights.[26] In addition, contracting parties are required to take legislative, administrative or policy measures to ensure that access to such technology is also facilitated for the private. That is to say, transfer and joint technology development should benefit not only governmental institutions but also companies in the developing countries.[27]

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[25] UNEP/CBD/COP/3/22, para 5: "The placement of paragraph 5 in Article 16 implies that IPR have an impact on the Convention's objectives, this is most likely to occur in the context of technology transfer, rather than in the context of conservation and sustainable use. The paragraph's language is, however, quite broad, implying the potential for influence on any of the Convention's objectives or provisions. It also implies the possibility that Parties will need to take steps cooperatively to manage the influence of IPR to ensure that it is positive rather than negative."

[26] CBD, Art. 16.2: "Access to and transfer of technology ... to developing countries shall be provided and/or facilitated under fair and most favourable terms, including on concessional and preferential terms where mutually agreed, and, where necessary, in accordance with the financial mechanism established by Articles 20 and 21. In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights. …"

[27] CBD, Art. 16.3: "Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties, in particular those that are developing countries, which provide genetic resources are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights, where necessary, through the provisions of Articles 20 and 21 and in accordance with international law ..."

Given the importance assigned to technology transfer in attaining the objectives of the Convention on Biological Diversity, the provisions requiring respect for intellectual property rights relating to this technology are central. The Convention does not address the material standards for the protection of intellectual property rights nor does it make any statement on the administrative measures needed at the national level to enforce these rights. Nevertheless, under the provisions on fair benefit sharing, the Convention imposes compliance with the rights attached to the technology, thus steering member states regardless of their socio-economic and technological level of development towards the standards of protection deemed necessary by industrial players in developing marketable products based on the germplasm provided. In regulating technology transfer, the Convention thus requires member states to comply with material protection standards that can go beyond those laid down by the TRIPS Agreement.

In determining the conditions for technology transfer the CBD requires member states to ensure that the transfer of and access to technology is provided under terms that recognise and are consistent with the effective protection of intellectual property rights (Art.16.2). Thus, it employs the same wording as is used in the TRIPS Agreement with regard to the sui generis regime for the protection of living material. Academic observers therefore point out that not only the TRIPS Agreement but also the Convention on Biological Diversity will in time raise its member states to the level of protection rights established in the Western industrial countries:[28]

"In the case of technology subject to patents and other intellectual property rights such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights." (Art.16.2).

While protagonists of the highest possible protection standards point out that these rights are of enormous instrumental value for the potential generation of benefits because of the temporary, exclusive monopoly on exploitation they provide, critics object that the owners can prevent or impose far-reaching conditions on access to innovations. These conditions may be so sweeping that they are tantamount to a denial of access, and may thus evade the technology transfer provided for by the CBD.

The frequent difficulty in harmonising interests in the handling of genetic resources becomes especially evident with the granting and recognition of intellectual property rights. Implementation of the balance-oriented CBD objectives therefore demands that account be taken of the different expectations players have of intellectual property rights, and that implementation of the Convention's ABS provisions ensures that IPRs do not run counter to Convention objectives.

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[28] BELL, J.; M. PIMBERT: Introduction, in: BAUMANN, M.; J.BELL; F. KÖCHLIN; M. PIMBERT: The Life Industry, London 1996, p.19; NOIVILLE, Chr.: Patenting Life – Trends in the US and Europe, in: BAUMANN, M., et al., op. cit., p.92; CRUCIBLE GROUP: People, Plants and Patents, Ottawa 1994, p.34; WALDEN, I.: Intellectual Property Rights and Biodiversity, in: BOWMAN, M.; C. REDGEWELL (Eds.): International Law and the Conservation of Biological Diversity, London 1996, p.179

4.2. IPR can further ABS objectives

It must be recognised that there are areas between access to genetic resources and traditional knowledge (access) and participation in their use (benefit sharing) that lie outside the strict regulatory ambit of the CBD. They are primarily economic in nature, and characterized by investment in material assets, the need to amortize R&D spending, and the growing importance of intellectual property rights. In exploiting genetic resources and traditional knowledge, it is also indispensable to use specific technologies, which generate (marketable) results in the form of a product, a process, or a service, and which can in turn constitute a new and innovative technology.

If demand is sufficient, the marketing of products, processes, and services may bring substantial benefits (profits, income from licences, etc.), which in accordance with the ABS regime can be shared with the providers of the original materials. Given the many imponderables and the long lead time in developing a new product – especially in pharmaceuticals, industrial players have an interest in protecting their innovative activities against rapid product imitation by means of intellectual property rights to at least amortize their R&D expenditures. Over and above this, IPRs can be used to establish monopolies in as many countries as possible for the sale of protected products and processes, which during the term of the rights can bring high returns.

The providers of genetic resources also have an interest in maximizing profits and licence income from the sale of marketable results, since the economic gains from equitable benefit sharing will be more substantial, provided that turnover or profit-sharing has been agreed under the ABS arrangements negotiated. In this sense, there could be congruence between the interests of industrial players seeking access and of providers wanting a fair share of the benefit that covers not only the aspects governed by the CBD but also areas of action which, although apt to facilitate the equitable sharing of benefits, are not within the direct ambit of the CBD, namely intellectual property rights.

Apart from bringing a share in any profits resulting from commercialisation, it should be pointed out that intellectual property rights can indeed involve a transfer of knowledge and technology. This can occur, for example, through licensing, joint ventures, or common R&D projects, but especially through disclosure of the protected invention in public patent specifications. **Thus, intellectual property rights can indeed contribute to attaining the objectives set forth in Art. 1 of the Convention, namely the participation of providers in the benefits accruing from the use of their resources in the form of financial resources or access to the relevant technology**. Furthermore, intellectual property rights can help improve providers' positions in negotiating access, provided that their own activities or (intermediate) products already contain processing phases that justify the granting of property rights. They can also help create incentives for conserving the knowledge of indigenous communities and at least markedly impede misappropriation and the subsequent improper grant of IPRs abroad.

4.3. IPR can hinder ABS objectives

Since, as a rule, the information on the protected invention disclosed upon publication does not suffice to carry out innovations independently, which generally necessitates additional know-how agreements, there are widespread reservations that the patent in particular is a form of intellectual property right that can, in effect, hamper rather than promote technology transfer. Empirical studies also reveal a contradictory picture.[29] This is all the more reason for concern, because the TRIPS Agreement, which most CBD member states are committed to implementing, explicitly provides that patent protection must be given regardless of whether the products are produced locally or imported.[30]

Since technology transfer can be involved especially in local production, but TRIPS forbids use of 'local working' as both a condition for the maintenance of patent rights in force and a justification for compulsory licensing, there is understandable concern that life patenting might well protect innovations but not make them accessible in a way developing countries can follow up on.

The objection that intellectual property rights could run counter to the technology policy goals of the CBD is cogent for patenting, since it grants the strongest conceivable exclusive rights. The patent owner has the exclusive and sole right to use the protected subject matter for industrial purposes[31] and can effectively prevent third parties from exploiting the invention for the entire term of the patent (at least 20 years). Countermeasures like compulsory licensing have to be examined in each specific case and presuppose compliance with relevant conditions and possibly costly and time-consuming litigation. Since a patent confers exclusive exploitation rights (albeit subject to regulatory approval for certain kinds of product), but a patent owner cannot be obliged to transfer technology, patents on living organisms may conceivably run counter to the (technology) policy objectives of the CBD.

Products may perhaps not be made available, or access made subject to radical conditions that amount to a denial of access. One example is a patent on all genetically modified cotton plants that display built-in resistance to certain pesticide chemicals. The firm owning the patent charged so much for a license to use the technology that prospective licensees from Southern countries were unable to pay and had to renounce access to the technology.[32] Other common licensing terms include export bans or grantback clauses in the event of own technological advances, and can thus also have far-reaching implications which a technology-importing country may be unwilling to accept for overall economic reasons.

Insofar as exclusive rights apply only to innovations generated by using germplasm in downstream scientific-technical development, the negative impact of denying access

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[29] UNCTAD: The TRIPS Agreement and Developing Countries, New York and Geneva 1996, p.2

[30] TRIPS Art. 27.1: "... patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. … patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."

[31] Subject to a production permit.

[32] RAFI: Enclosures of the Mind: Intellectual Monopolies, A Resource Kit on Community Knowledge, Biodiversity and Intellectual Property, p.36 (http://www.rafi.org/web/docus/pdfs/iprkit.pdf)

is first and foremost in stopping technology transfer, thus preventing one of the most important forms of fair benefit sharing. However, patent practice shows that claims can also concern germplasm on which no innovation in the real sense of the word has been effected (isolation of genes), or to improperly acquired germplasm from Southern countries. Or claims may be so extensive and imprecise that they may cover unmodified material as well.

In some industrial countries it is possible to patent gene sequences that have merely been isolated from the genome of a natural organism provided that the function of the gene can be identified, thus meeting the criterion of industrial applicability/utility for the purposes of the patent authority.[33] Such patents apply to gene sequences that have been isolated but occur in nature (full-length DNA) and which have not been further technically modified, as occurs, for instance, in producing synthetic copies (c-DNA) on the basis of expressed mRNA. For example, a patent on unmodified full-length DNA has been granted for a bacillus thuringiensis sequence (b.t.), an isolated but unmodified gene of a bacterium that plays an important role in the production of certain genetically modified crops.[34]

If a gene encoding for a specific amino acid is patented in completely unmodified form (as full-length DNA) and a patent applied for in a few dozen countries pursuant to the Patent Cooperation Treaty, foreign patent owners can theoretically acquire exclusive rights in all these countries for this unmodified, i.e., naturally occurring DNA sequence.[35] The protected sequence can then no longer be the subject matter of access agreements on a national sovereignty basis, or at least not in unrestricted form. At the very least, this could effectively exclude the granting of a patent to a domestic company on the same sequence, which would strengthen the firm's position in negotiating benefit sharing or joint R&D projects on the use of amino acid sequence (protein) encoded by the protected gene.

Even if patent law practice seeks a pragmatic solution, restricting preclusive effect in the case of isolated and patented full-length DNA to use in **biotechnological** processes, so that **conventional** activities (e.g., breeding strategies) using these gene sequences are not affected,[36] the problem remains that at least activities **involving** biotechnology require the consent of the (foreign) patent owner. Since commercial actors, where they operate biotechnologically, do not really want access to germplasm but to the genes encoding for specific metabolic processes, it is conceivable that the sovereignty over their genetic resources conceded to provider countries is impaired at least insofar as these countries, for patent law reasons, may no longer be able to offer already screened and isolated genetic material if the protected gene sequences are included.

This can also undermine efforts to increase a country's net domestic product by the use of national genetic resources and frustrate the objective of promoting development in sections of the economy coupled with the protection of biological diversity. It is unimportant whether the isolated gene sequences are patented in the **provider countries themselves**, entailing a conflict of norms within the national territory. Where the import

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[33] CORREA, C.: Intellectual Property Rights, the WTO and Developing Countries. The TRIPS Agreement and Policy Options, London 2000, pp.172, 179

[34] CORREA, C., op.cit., p.180

[35] On the basis of the rights necessarily granted in the given national context

[36] CORREA, C., op.cit., p.181

of protected gene sequences infringes patents in the **target countries** (countries from which access-seeking players originate or in which they want to engage in biotech R&D), the prospects for provider countries to supply the genes encoding for the desired metabolic processes themselves – thus improving their negotiating position on ABS – are called into question by the increasing patenting of isolated genetic material.

It is important to remember that, in the case of product patents, the TRIPS Agreement requires a broad range of activities with respect to the protected subject matter to be covered. Not only making, using and selling but also importing the protected product is precluded[37] (for the necessity to establish broad research exemptions, please see chapter 5). Access agreements on an isolated gene in the provider country could thus be defeated alone by the preclusive effect of product patent protection, which also covers the import of the product. **Thus, through product patents on living matter that has been merely isolated but is otherwise technically unmodified, the patenting of living matter demanded by the TRIPS Agreement can run counter to the access and benefit-sharing mechanisms of the Convention on Biological Diversity.**

The sovereignty over their genetic resources conceded to provider countries under the Convention on Biological Diversity may, however, be even more directly jeopardized by the TRIPS Agreement. The Agreement obliges all member states to grant product patents on micro-organisms. This can be interpreted to mean that protection is to be given only to micro-organisms that meet patenting requirements, i.e., that are new, industrially applicable, and constitute an inventive step, and not to those which have been found in nature. However, an obligation can also be derived from this provision to extend product patent protection to parts of micro-organisms (cell components, proteins, genes, etc.), provided that national patenting criteria are met.

If a developing country is willing to grant product patent protection, without the preclusion of discoveries, also for parts and components of micro-organisms that have merely been isolated but otherwise completely unmodified, it must be taken into account that the TRIPS provision on national treatment obliges the authorities to extend this protection to foreign applicants. However, the facilities of the latter place them in a much better position to profit from rights in parts and components of germplasm, and to exploit the option on the basis of their superior technical and scientific backgrounds.

Therefore, if, in implementing TRIPS at the national level, a developing country should decide **not to exclude** discoveries, i.e., naturally occurring, isolated, but otherwise completely unmodified organisms, their parts or gene sequences, a growing proportion of domestic biological diversity or individual components relating to specific metabolic processes can for a limited period come under the control of foreign patent owners. **At the national level, too, individual exclusive rights would thus undermine the sovereign power to negotiate access to germplasm located in the national territory where the protected components are to be found precisely in this germplasm and are subject to the preclusive effect of the rights conferred.**

To the extent that isolated components of (micro-) biological diversity are subject to exclusive rights in foreign ownership, such claims and the genetic material underlying

[37] TRIPS, Art. 28.1 "A patent shall confer on its owner the following exclusive right: (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;"

them can no longer be used to improve a country's position in negotiating ABS arrangements. **Furthermore, they can be neither the basis for nor the outcome of the joint R&D the CBD encourages among member states**. This objective of the CBD, too, can be hampered by the granting of such patents. If a WTO Dispute Settlement Panel were to accept as definitive the definition of 'micro-organisms' adopted in the EPO granting practice, which encompasses all living entities below the visibility level including plant cells, animal and human cells,[38] the restrictions on national sovereignty to which patenting could give rise would also apply to plant and animal germplasm falling within the scope of the CBD.

This problem is further exacerbated by the fact that the TRIPS Agreement, while imposing the patenting of innovations in the field of living organisms, has nothing to say on the form in which the material underlying these innovations is acquired. Member states are thus obliged to offer patent protection for such innovations, e.g., in handling micro-organisms or their components, but TRIPS offers no foothold towards denying a patent in the case of misappropriated germplasm. Since patent protection cannot be denied if patentability requirements are met, and, in keeping with the national treatment principle, must be extended equally to foreign applicants, there might be a conflict of norms in this case, too, which can jeopardize the sovereignty of provider countries over their genetic resources.

The patent-law provisions of the TRIPS Agreement – provided they are correctly applied and implemented at the national level – are concerned only with innovations, so that a patent owner's exclusive rights cover only steps taken on the basis of foreign germplasm after its (possibly unlawful) acquisition. Nevertheless, the CBD principles can be undermined not only by patents on unmodified gene sequences but also by unreasonably extensive claims that go far beyond the actual innovation. This makes it possible for unmodified germplasm native to developing countries to be claimed provided that certain activities in respect of this germplasm are subject to the preclusive effect of the rights granted.

For example, the European Patent Office granted a firm patent protection in connection with conventionally developed maize plants,[39] characterised by both high oil content and a high level of specific oleic acids. The plants were the outcome of a conventional and known breeding and selection method using breeding lines already characterised by a high oil content and a high level of a specific oleic acid. The patent specification covered not only the new hybrid plants and seeds and the oil they contain but also the method of crossing plants with the given parent characteristics, i.e., high oil content and a high level of oleic acids.

The patent[40] filed through the WIPO for 74 countries under the Patent Cooperation Treaty thus forbids the conventional production of maize plants whose seeds have a total

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38 In terms of European Patent Office practice: "The term 'microorganism" includes not only bacteria and yeasts, but also fungi, algae, protozoa and human, animal and plant cells, i.e. all generally unicellular organisms with dimensions beneath the limits of vision which can be propagated and manipulated in a laboratory. Plasmids and viruses are also considered to fall under this definition.", in: GOLDBACH, K.; H. VOGELSANG-WENKE; F. ZIMMER: Protection of Biotechnological Matter under European and German Law, Weinheim 1997, p.223

39 EP 0 744 888 B1

40 WO 95/22598

oil content of at least 6% of the total seed weight **and** an oleic acid content of not less than 55% of total oil content. Since the patent specification defines "normal" (i.e.: non-"innovative") maize plants as those with an oil content of 5.1%, it is apparent that at least one of the characteristics named might be easily achieved by another technique. An oleic acid content of 30% also seems to lie within the normal range and can possibly be easily increased. The patent specification itself points to fatty acid levels of up to 64% in investigated maize plants (para 0010, page 03). The combination of the two characteristics by third parties in the form described would now, however, constitute an infringement of patent.

Since the patent specification also contains product claims concerning the seeds of the plants in question, and product claims cover **all** technical processes for the production of the protected subject matter, there is a problem in that the preclusion extends to processes other than the method of hybridising parent lines explicitly mentioned in the specification. This means that all other approaches, i.e., including potential methods, of producing corn grains characterised by a combination of "high oil content" and "high oleic acid level" are prohibited, although the specification itself points out that both characteristics are to be found in maize plants that occur in nature ("normal maize plants").

Even without negotiating access conditions on the basis of the core elements provided for by the Convention (mutually agreed terms, prior informed consent, etc.), specific activities in handling naturally occurring germplasm are thus affected, undermining the sovereignty of countries to which the parent plants are native with regard to engagement in such activities. This is also the case if more precise screening of agrobiological diversity brings new crop varieties to light that, in their present form, already combine the characteristics stated in the patent specification. At least the use of harvested crops would in this case be subject to preclusion under the exclusive rights conferred unless it can be proved that the plants with the characteristics in question had been developed **before** the patent application was filed.

In the case of unreasonably extensive patent claims, too, it is thus apparent that the sovereignty over national genetic resources accorded signatories to the CBD can be undermined by the patenting practices of national authorities in these very countries, even if the preclusive impact is perhaps less drastic in practice than might be feared. However, to the extent that such claims can also prohibit **potential** uses of local, naturally occurring germplasm aimed at increasing the country's domestic product, **such a conflict of patent and environmental law can also call in question the link between the conservation of biological diversity and sustainable development set forth in Art. 1 of the CBD.**

National patent offices can, however, better harmonise the norms for using biological diversity contained in various regimes in order to ensure that the objectives of the Convention are not placed in jeopardy by unreasonably extensive or even unjustified patent claims, especially as regards access to genetic resources and equitable benefit sharing.

4.4. Formulating national IPR practices to promote the ABS objectives of the CBD

This section outlines a number of approaches to formulating national legislation on intellectual property rights to avoid running counter to the provisions of the Convention on Biological Diversity pertaining to sovereignty over national genetic resources. The ABS provisions seek to create incentives for conserving genetic resources by realising their potential and to promote economic development at the local/national level by transferring monetary or non-monetary benefits.

It must therefore be taken into account that the intermediate field between access and benefit sharing is characterised by goals and interests whose regulation does not fall within the ambit of the Convention on Biological Diversity. Other regimes take effect that are indispensable in formulating regulatory framework conditions, and which were especially developed to control economic activities: antitrust and competition law, innovation policy, technology assessment, intellectual property rights, etc. The last, in particular, play an increasingly important role in handling biological diversity, and can affect Convention objectives both constructively and adversely.

The actors concerned with exploiting genetic resources, too, are involved in a network of diverse action patterns and economic rationalities, which can plausibly not be expected to prioritise the Convention's purposes in protecting and conserving biological diversity. Nonetheless, efforts should be made to ensure that the conservation notion embodied in the Convention can in time find a place high on the agenda of economic players. To encourage the inclusion of conservation and benefit sharing as goals of economic activity, the various instruments for the protection of intellectual property offer a range of possibilities. They go beyond patent protection, including, for example, geographic indications of source, trade secrets, breeders´ rights, and utility models.

With regard to all intellectual property rights affecting biological material, care must be taken that their implementation furthers the objectives of the CBD rather than frustrating them in the interests of stronger economic rationalities. Naturally, this applies above all to patent protection because of its strong preclusive and exclusionary impact, and the associated broad opportunities for abuse. It is particularly important to investigate the scope remaining after the coming into force of the TRIPS Agreement for differentiation at the national level in granting such protection for activities involving living matter. Other protective instruments also need to be examined as to whether they offer suitable alternatives to patenting that promote the coupling of incentives for conserving biological diversity and measures for its use provided for by the Convention.

Since the sovereignty over national genetic resources accorded member states by the CBD can also be impaired by protective rights granted abroad, it must also be ensured that such rights, too, further the objectives of the Convention rather than running counter to them. Since intellectual property rights are granted at the national level, this can be achieved formally only by amending international intellectual property rights regimes to oblige non-signatories to the CBD to improve coherence between national practices and the environmental and development policy goals of the CBD. With regard to the TRIPS Agreement, which regulates material standards and granting procedure for seven intel-

lectual property instruments,[41] this can be done, for example, in the pending review processes. Since the TRIPS Agreement also obliges non-signatories to the CBD to comply with the relevant provisions, it is advisable to define the unclarified interface between the two regimes in such a way as to prevent the objectives of the CBD being either frustrated or interfered with.

In implementing the provisions of the TRIPS Agreement, it seems advisable to differentiate clearly between patentable inventions and mere discoveries[42] for which no intellectual property rights have to be granted. This could ensure that, at least in the national context, the misappropriation of tangible or intangible assets associated with genetic resources[43] and their subsequent patenting is prevented. In a number of developing countries, legislation has therefore stipulated that substances occurring in nature as well as natural organisms, including their parts and components, cannot be patented. This prohibition applies in individual countries even where the substances taken from nature are available in isolated form. This goes much further than the preclusion of discoveries under the European Patent Convention, which, although it also rules out the patenting of discoveries,[44] permits genes or DNA sequences[45] to be patented[46] if they are in an isolated or processed form.[47]

In Mexico and Costa Rica, for example, the patenting of genetic material is absolutely forbidden. Legislation in Argentina, and the countries of the Andean Community also forbid the patenting of natural substances.[48] The Brazilian Patent Act prohibits patents

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[41] Copyrights and Related Rights, Trademarks, Geographical Indications, Industrial Designs, Patents, Layout-Designs of Integrated Circuits, Protection of Undisclosed Information

[42] CORREA, C., op.cit., pp.51,52

[43] e.g., breeding activities condensed in molecular form.

[44] European Patent Convention (EPC), Art. 52.2 : "The following in particular shall not be regarded as inventions ... a) discoveries, scientific theories and mathematical methods; b) aesthetic creations; c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers; d) presentations of information.

[45] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions: No. 22: "Whereas the discussion on the patentability of sequences or partial sequences of genes is controversial; whereas, according to this Directive, the granting of a patent for inventions which concern such sequences or partial sequences should be subject to the same criteria of patentability as in all other areas of technology: novelty, inventive step and industrial application; whereas the industrial application of a sequence or partial sequence must be disclosed in the patent application as filed;"
No. 23: "Whereas a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention;"
No. 24: "Whereas, in order to comply with the industrial application criterion it is necessary in cases where a sequence or partial sequence of a gene is used to produce a protein or part of a protein, to specify which protein or part of a protein is produced or what function it performs;"
No. 25: "Whereas, for the purposes of interpreting rights conferred by a patent, when sequences overlap only in parts which are not essential to the invention, each sequence will be considered as an independent sequence in patent law terms;"

[46] See also: MEYER-DULHEUER, K.H.: Der Schutzbereich von auf Nucleotid- oder Aminosäuresequenzen gerichteten biotechnologischen Patenten, in: GRUR No. 3/2000, pp.179-182

[47] Directive 98/44/EC, Art. 3: (1): "For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used."
(2): "Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature."

[48] C.CORREA: Intellectual Property Rights, the WTO and Developing Countries, op.cit., pp.101-122 provides an overview of the patenting situation in Latin America.

on living beings, materials occurring in nature, and germplasm, as well as on the genome of any living being, even if available in isolated form.[49] Patents can, however, be granted for transgenic materials in Brazil provided that the patenting requirements of novelty, inventive step, and industrial application are met.[50]

Another aspect to be considered in formulating national legislation is preventing the misappropriation of the traditional assets of local and indigenous communities. Their knowledge can be important for access to genetic resources, but is often available only in oral form. It concerns not only the location of genetic resources but also (plant) physiological properties, active agents and their processing, and can therefore not be separated from the resources themselves. Since traditional knowledge is generated and passed on cumulatively and across generations, and it is often impossible to attribute an element to a given individual, safeguarding it by means of any of the established intellectual property rights instruments can be difficult.

On the other hand, traditional knowledge is acquired by foreign players and patented abroad without agreement on equitable benefit sharing. This practice can be hindered by developing countries if they collect and, where necessary, publish the knowledge and achievements of local and indigenous communities in concentrated form at a national focal point, thus destroying novelty worldwide, one of the central patenting criteria. In addition, the provisions of the TRIPS Agreement could be amended to the effect that the oral transfer of such information be recognised by all member states of the WTO as destroying novelty.

Precisely this is currently not the case in the United States. The oral transfer of such information is recognised as destroying novelty only if the transfer has taken place within the territory of the United States.[51] Only on the basis of this legal peculiarity has it so far been possible in the United States to obtain a patent for natural substances/processes already known abroad, e.g., for the use of the active substances of turmeric. If the United States is therefore to be forced to amend its national legislation to prevent such appropriation of traditional knowledge, thus committing the United States, too – as a non-signatory of the Convention on Biological Diversity – to one of its core components, the relevant provision must become binding under international law, i.e., be embodied in the TRIPS Agreement itself.

Further options are available at the national level to improve protection of the knowledge of indigenous and traditional communities against formal innovators. For example, (longer) grace periods can be allowed in granting patent protection, i.e., periods within

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[49] CORREA, C.: Integrating Public Health into Patent Legislation in Developing Countries, South Centre, Geneva, June 2000, p.18, Footnote "c"

[50] "According to the new law, 'all or part of natural living beings and biological materials found in nature or isolated therefrom, including the genome or the germplasm of any natural living being, and any natural biological processes' are not considered inventions. Similarly, 'living beings, in whole or in part, except for transgenic microorganisms meeting the three requirements of patentability - novelty, inventive step and industrial application' are not patentable. Patents may be granted, however, in the case of transgenic materials," in: PETIT, M.; C. FOWLER; W. COLLINS; C. CORREA and C.-G. THORNSTRÖM: Why Governments Can't Make Policy. The Case of Plant Genetic Resources in the International Arena, CGIAR (Draft) 2000, p.23, Footnote No. 5

[51] PETIT, M., et al., op.cit., Footnote No. 21, p.74: „According to the U.S. Patent Law, the disclosure outside the United States of information in a nonwritten form (e.g., by use) does not destroy novelty, and therefore a patent can be granted if the other patentability requirements are met."

which a potentially patentable innovation may already be published or made known in some other fashion without such activities being regarded as destroying novelty. A country's own nationals would primarily benefit from this, been conceded longer periods to prepare the formal, often unaccustomed patent application procedures, and in so doing to include a certain measure of already existing knowledge. The playing field could also be similarly levelled for the local population by linking patents to the first-to-invent principle and not to the first-to-file principle. Since in this case patenting is contingent on proof of the applicants' inventive activity, application of the first-to-invent principle would help make it more difficult to misappropriate germplasm/indigenous knowledge.[52]

In patenting biological innovations, it is also possible to demand that applicants disclose the origin of the materials used. This could ensure that where material from Southern countries is used, it can be ensured within the patenting process itself that the prospective patent owner has come by the materials in accordance with the rules of the Convention on Biological Diversity. Disclosure of origin is meanwhile a binding criterion in the legal arrangements of some developing countries[53] and is also recommended to applicants in the EU Directive on the legal protection of biotechnological inventions.[54] Under certain circumstances, the EU Commission, too, seems willing to support origin disclosure in the context of a multilateral approach.[55]

"In this respect, the European Commission/Member States are prepared to engage in a positive manner in an attempt to agree, within the appropriate fora, on a multilateral system for disclosing and sharing information about the origin of biological material relied on in patent applications. Such discussions could also address the issue of a self-standing obligation for patent applicants to disclose the origin of biological material relied on in patent applications. If such a system could be agreed, it would be a logical step to include it as a mandatory minimum standard in a future TRIPS agreement."[56]

There is disagreement on whether an obligatory link between the granting of patent protection and origin disclosure is consistent with the current provisions of the TRIPS

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52 One reasonable objection to this proposal is based on experiences in the United States, which follows the first-to-invent principle. In that country, inventions must keep thorough records to prove the invention was made on a given date. Otherwise, it becomes difficult to defend a patent in the courts from others claiming an earlier date for the same invention and who can back up their claim with written records.

53 PETIT, M., et al., op.cit., p.68

54 Directive 98/44/EC, No.27: "Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications of the validity of rights arising from granted patents."

55 Review of the Provisions of Article 27.3(b) of the TRIPS Agreement. Draft Communication by the European Communities and Their Member States on the Relationship Between the Convention on Biological Diversity and the TRIPS Agreement, transmitted by the Commission to the 133 Committee on 23.02.2001, para 29: "The European Commission's /Member States' willingness to address the issue of origin disclosure is subject to the existence of sound access legislation. The European Commission/Member States are aware that many developing country members do not necessarily have the capacity to implement such laws in a proper way. Therefore, technical assistance from other WTO Members or by relevant international organisations may be an appropriate solution, especially in view of drafting effective and realistic laws. The European Commission/Member States are, if requested, prepared to provide such assistance."

56 Review of the Provisions of Article 27.3(b) of the TRIPS Agreement. Draft Communication by the European Communities and Their Member States, op.cit., para 22

Agreement.[57] While such a binding obligation aims to prevent patenting in cases where the material in question is not acquired in accordance with the rules of the Convention on Biological Diversity, there is the problem of how to proceed when no such proof can be furnished. Moreover, it should be remembered that, even if the granting of patent protection were made subject to this condition, it would not prevent the misappropriation of (physical access to) Southern germplasm.

Misappropriation remains possible even in the event of an obligatory link between patenting and proof of compliance with CBD access rules. The innovations made on this basis could then, if necessary, be protected by other instruments, especially trade secrets. It has been recommended, therefore, that the **enforcement measures** TRIPS requires countries to introduce not be extended to patents for inventions relating to material acquired without the required proofs or that are clearly based on misappropriated material.[58] This recommendation also implies that any link between patenting and the Convention provisions regulating ABS issues should at present be only recommendatory, not binding, at least while such a link has not been embodied as a binding provision in the TRIPS Agreement in the course of renegotiation. Origin disclosure and proof of fulfilment of the other ABS provisions in connection with patenting should therefore already be included in guidelines on the ABS issue.

What activities are regarded as destroying novelty and what grace periods are provided for at the national level also play a central role in the protection of traditional knowledge. The documentation or scientific investigation of the tangible/intangible assets of traditional communities, must make sure that the rights of approval and involvement granted indigenous communities by Art 8 (j) of the Convention are not violated in exploiting their knowledge systems. This can, for example, be ensured by reference in scientific publications to parties from Southern countries associated with research projects. The CBD provisions on the equitable sharing of benefits can also be taken into account through co-authorship and copyright sharing. Apart from the correctness of the procedure, this may even generate financial benefits.

At the same time, however, everyone concerned should be aware that the scientific investigation and, especially, the written publication of such traditional knowledge irretrievably destroys novelty – one of the key criteria for (individual or collective) intellectual property protection. Written publication thus makes it impossible to derive commercial benefit from the knowledge at a later date – for example when domestic scientific and technical capacities permit – or, for example, to secure exclusive exploitation rights under patents to maximise this utility. It should be noted that the destruction of novelty is crucial not only with regard to patenting but also because it bars other options for securing exclusive rights in the exploitation of local knowledge, innovations and practices – for instance, through trade secrets protection. Trade secrecy protection and legal action in the event of infringement presuppose that plausible steps have been taken to safeguard the knowledge at issue. Publication – possibly even under co-authorship – is definitively no longer a basis.

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[57] N. P. de CARVALHO: Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications without Infringing the TRIPS Agreement: the Problem and the Solution, in: Washington University Journal of Law & Policy No. 2/2000, pp. 371-400

[58] N.P. de CARVALHO, op.cit., pp.398,399

The same is true of another protection instrument conceivable with regard to generating benefits, and on whose configuration and material standards the TRIPS Agreement remains silent: the utility model. This IP instrument can be very important for developing countries, in particular. Utility models ("petty patents") are interesting primarily because requirements are less stringent than for industrial patents. For example, a more incremental achievement might be deemed sufficient, no costly patent examination is imposed, and the term is limited to a few years. The use of this instrument, which seems particularly suitable for protecting local innovations generated in developing countries, is also prevented by the destruction of novelty.

The possibility that the granting of protective rights consistent with the given technological capacity to safeguard indigenous assets and improve the local negotiating position may be prevented must be a major concern in drawing up guidelines to regulate the ABS issue. Given the situation described, the implications of publication for scientific activities directed merely towards generating and collecting data and with no direct commercial intent also need to be addressed.

5. Options for Implementing the TRIPS-Agreement[59]

5.1. Article 27.3 (b)

The binding stipulations of the TRIPS Agreement oblige its member states to offer patent protection for technical inventions provided they are new, constitute an inventive step and are capable of industrial application. Patent protection shall be available for innovative products and processes irrespective of place of invention, the field of technology, and whether the products are imported or locally produced. On grounds of this stipulation, member states are principally obliged to provide patent protection for inventions related to animate matter, although there are some notable exemptions to this provision.

Article 27.3 "Patentable Subject Matter":

Members may also exclude from patentability:

a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Based upon this wording WTO member states are unequivocally obliged to offer patent protection for micro-organisms as well as microbiological and non-biological processes (for the production of plants and animals). They are not obliged to grant patents for higher taxonomic levels of plants and animals (e.g. species or genera), but have to provide for patent protection, or an effective sui generis system, or a combination thereof in the case of plant varieties. Actually, according to the present stipulations as laid down in the TRIPS Agreement, no member state is formally obliged to provide patent protection for either plants (i.e. taxonomic ranks higher than plant varieties) or plant varieties. Plants above plant varieties (i.e. plant "majorities" like species or genera) and plant varieties can be entirely exempted from patent protection if member states provide a sui generis system to protect innovations at the level of plant varieties (option 1). If member states´ national legislation ensures that the exemption from patentability of plants and plant varieties for which they have opted, extends to both product as well as process claims, then they are neither obliged to protect plants nor plant varieties as products directly obtained by means of non-essentially[60] biological processes for their production.

When it comes to the interpretation of the term, "micro-organism", member states are not obliged to follow the juridical approach of the European Patent Office, according to

[59] For the same reason, material and data documenting traditional and indigenous knowledge which have been recorded and stored in libraries has come under "public domain" and can therefore no longer be treated as matter potentially subject to individual or collective intellectual property rights.

[60] I.e.: non-biological or microbiological **processes** for which patent protection must be made available

which all living units below the limits of visibility - including plant, animal, and human cells - are to be classified as "micro-organisms", thus rendering them, in principle, patentable subject matter. This approach, which holds for the European granting practice, may be highly instrumental in undermining the options for exemption from patentability of plants and animals, as provided for in the TRIPS Agreement; it need not be followed by WTO member states.

If they choose to decide not to provide patent protection for plant varieties at national level, member states are obliged to safeguard the protection of plant varieties by a legal system of their own, that is, sui generis. The TRIPS Agreement contains no stipulations as to how such a sui generis protection system must be shaped; it does state, however, that the protection for plant varieties conferred by such a specialized system must be "effective". Scientific observers interpret this qualifier as an obligation on the part of legislators to enable the holder of such a sui generis right to prevent third parties from carrying out certain acts in relation to the protected subject matter, or to provide for a system of remuneration if this right is infringed upon.

Furthermore, it will be necessary at national level to provide for legal and institutional implementation procedures in order to create an effective deterrent to infringement. Concerning the establishment of such protection systems sui generis for plant varieties, no special transition periods apply. Since sui generis systems are explicitly admitted in the TRIPS Agreement as an alternative to patents for the protection of inventions at the economically crucial level of plant varieties, their effectiveness and compliance with the TRIPS stipulations will be, in particular, under scrutiny within the context of the ongoing review process of Article 27.3 (b).

Although it has not been stated explicitly in the TRIPS Agreement, it does seem to be clear to many member states that, in terms of the substance of their legislation, they are to orientate their sui generis system - at least to a certain extent - towards the stipulations laid down under the International Convention for the Protection of Plant Varieties (UPOV). The stipulations of this convention are currently applied on the basis of two separate acts – namely, UPOV 78 and UPOV 91. These acts differ significantly in several respects. Nevertheless, both provide for the possibility of breeders to freely use propagating material of protected varieties for the purpose of breeding new varieties. The option for farmers to use harvested material obtained from protected varieties for propagating purposes on their own holdings[61], a practice which is not mentioned at all but is silently tolerated under UPOV 78, can be equally allowed under the new act, but must be made subject to certain conditions.

Since the entry into force of the UPOV 1991 revisions, in April 1998, at least formally, an accession to the earlier act is no longer possible. Accordingly, based upon the present wording of the TRIPS Agreement in Article 27.3 (b), member states so far had four strategic options from which they could choose:

[61] Since, under the UPOV 91 Act, farmers may only be allowed to propagate on their own holdings the product of the harvest obtained by planting the protected variety, this act clearly prohibits the practice of farmer-to-farmer exchange. For further information see: IPGRI: Key Questions for Decision-Makers. Protection of Plant Varieties under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights, International Plant Genetic Resources Institute, Rome 1999, p.18, (available at: http://www.ipgri.cgiar.org)

- to make provisions for the patent protection of plant varieties
- to join the International Union for the Protection of new Varieties of Plants (UPOV) in either of both variants (UPOV 78 or 91)
- to provide for comparable plant variety protection (PVP) without formally joining the UPOV Convention
- to devise a sui generis system which is better designed to suit national interests and to take into account the protection demands of informal and local communities.

Concerning the more technical issue of which protection system can be implemented for the protection of plants/plant varieties, there are at least four different options:

1. Neither plants nor plant varieties are patentable. Following this approach member states are obliged to provide a sui generis system for the protection of plant varieties.
2. Plants and plant varieties are patentable. In this case, a sui generis system would merely be in addition to the coverage of patent protection for plant varieties.
3. Plants are not patentable, but plant varieties are. This scenario provides an option for a sui generis system in addition to the patent protection for plant varieties.
4. Plants are patentable, but plant varieties are not. In this case, member states are again obliged to provide a sui generis system for the protection of plant varieties.

Option 1:

	Utility Patent Protection	Sui Generis/ (UPOV)
Plants (Plant "Majorities")	no	
Plant Varieties	no	yes

Option 2:

	Utility Patent Protection	Sui Generis/ (UPOV)
Plants (Plant "Majorities")	yes	
Plant Varieties	yes	optional

Option 3:

	Utility Patent Protection	Sui Generis/ (UPOV)
Plants (Plant "Majorities")	no	
Plant Varieties	yes	optional

Option 4:

	Utility Patent Protection	Sui Generis/ (UPOV)
Plants (Plant "Majorities")	yes	
Plant Varieties	no	yes

Source: SEILER

Comparison of main provisions of PBR under the UPOV Convention and Patent Law

Provisions	UPOV 1978 Act	UPOV 1991 Act	Patent Law
Protection Coverage	Plant Varieties of nationally defined species	Plant varieties of all genera and species	Inventions
Requirements	- Novelty - Distinctness - Uniformity - Stability	- Novelty - Distinctness - Uniformity - Stability	- Novelty - Inventiveness - Non-obviousness - Industrial application and usefulness
Protection term	Min. 15 years	Min. 20 years	Min. 20 years
Protection scope	Commercial use of reproductive material of the variety	Commercial use of all material of the variety	Commercial use of protected matter
Breeders exemption	Yes	Not for essentially derived varieties	No
Farmers Privilege	In practice: yes	Up to national laws	No
Prohibition of double protection	Any species eligible for PBR protection can not be patented-	---------	---------

Source: van Wijk,J.; Joel Cohen; John Komen: Intellectual Property Rights for Agricultural Biotechnology, ISNAR-Research Report No.3, Den Haag 1993, p.8 (slightly modified), for a more detailed overview see DUTFIELD, G.: Intellectual Property Rights, Trade and Biodiversity, Earthscan Publications, London 2000, p.30

International Union for the Protection of New Varieties of Plants (UPOV)

Member states of UPOV as of July 20, 2001 (47)[62][63]

Argentina, Australia, Austria, Belgium, Bolivia, Brazil, Bulgaria, Canada, Chile, China, Colombia, Czech Republic, Denmark, Ecuador, Estonia, Finland, France, Germany, Hungary, Ireland, Israel, Italy, Japan, Kenya, Kyrgyzstan, Mexico, Netherlands, New Zealand, Norway, Panama, Paraguay, Poland, Portugal, Republic of Moldova, Romania, Russian Federation, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, Trinidad and Tobago, Ukraine, United Kingdom, United States of America, Uruguay

States or organizations which have initiated with the Council of UPOV the procedure for becoming Members of the Union (22)

Azerbaijan, Belarus, Costa Rica, Croatia, Egypt, Georgia, Honduras, India, Kazakhstan, Latvia, Lithuania, Morocco, Nicaragua, Republic of Korea, Tajikistan, The former Yugoslav Republic of Macedonia, Tunisia, Venezuela, Yugoslavia and Zimbabwe, as well as the European Community and the African Intellectual Property Organization

[62] 28 states are bound by the 1978 Act, 17 states by the 1991 Act

[63] Belgium and Spain are still parties to the pre-1978 version of the UPOV Convention, but the latter has already amended its law to conform to the 1991 Act

(Republic of Benin, Burkina Faso, Republic of Cameroon, Central African Republic, Republic of Chad, Republic of Congo, Republic of Cote d´Ivoire, Equatorial Guinea, Gabonese Republic, Republic of Guinea, Republic of Guinea-Bissau, Republic of Mali, Islamic Republic of Mauritania, Republic of Niger, Republic of Senegal, Togolese Republic (16)

Another 39 states have been in contact with the office of the Union with a view to developing legislation in line with the UPOV Convention

Albania, Algeria, Armenia, Barbados, Burundi, Commonwealth of Dominica, Cuba, Cyprus, Djibouti, Dominican Republic, El Salvador, Fiji, Ghana, Greece, Guatemala, Iceland, Indonesia, Jamaica, Madagascar, Malawi, Malaysia, Mauritius, Oman, Pakistan, Peru, the Philippines, Saudi Arabia, Seychelles, Sri Lanka, Suriname, Tanzania, Thailand, Tonga, Turkey, Turkenistan, Uzbekistan, Vietnam, Yugoslavia, Zambia (39)

Source: International Union for the Protection of new Varieties of Plants (UPOV), at http://www.upov.int

5.2. Sui Generis

The obligation to provide a sui generis system as laid down in the TRIPS Agreement refers to plant varieties. If member states decide to establish a sui generis system as an alternative (options 1 and 4), respectively in addition to the provision of patent protection for plant varieties (options 2 and 3), then the regulatory framework to be implemented must be subject to the principles of national treatment and most-favoured nation treatment. Consequently, any bias in favour of one´s own **population** is prohibited. Irrespective of that, the option to positively discriminate as to the **place** of invention **does** exist. That is, contrary to patent protection, sui generis protection (which, in accordance with the national treatment principle must be provided equally to foreign nationals) might be granted only with the proviso that the creation or invention in question was achieved on the home territory. In this way, incentives could be created to increase the transfer of technology and know-how, both of which are desirable from a developmental perspective.

"According to the TRIPS Agreement only **patents** have to be available and enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced. This principle is therefore not binding for **sui generis** systems for the protection of plant varieties. It should be noted however that under the UPOV Acts discrimination as to the **place of breeding** is not allowable."[64][65]

Informal innovations generated by indigenous or traditional communities - paramount for the sustaining of agricultural and biological diversity, but not related to **plant varieties** in the sense that they might be covered by patent or plant breeders rights - might be protected as well at the national level by an appropriately devised legal system. Yet, such a system is not necessarily appropriate for meeting the obligations to protect plant varie-

[64] LESKIEN, D., M. FLITNER: Developing a Decision Tree as a Tool for Shaping Sui Generis Systems for the Protection of Plant Varieties under the TRIPS Agreement, German Agency for Technical Cooperation, mimeo, Eschborn 2000, p.9, (for further information view: http://www.gtz.de/biotech)

[65] TRIPS Art. 27.1: "(…) patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."

ties as laid down in Article 27.3 (b) of TRIPS. Rather, **supplementary** protection mechanisms will be created at national level, intended to ensure that informal achievements, the intellectual content of which cannot be covered by any of the instruments provided for under TRIPS, can be protected by an additional legal framework; this would diminish the asymmetry in the legal treatment of formal versus informal innovations.
The TRIPS Agreement does not prohibit the establishment of such **additional** sui generis systems for the protection of traditional achievements. Since those additional protection systems/instruments are not covered by the TRIPS Agreement itself, they are not subject to the principles of national and most-favoured nation treatment. Consequently, such an instrument can be used to discriminate in favour of one´s own population. However, other states are not obliged to acknowledge the legal protection of informal creations established by such an instrument, nor are they obliged to prevent infringements. Therefore, in order to prevent the misappropriation and misuse of genetic resources/informal achievements and the subsequent granting of patent protection in the industrialized countries, the present stipulations of the TRIPS Agreement must be amended in such a way as to require all member states to protect these informal achievements through their national laws, devising the necessary rules for implementation. The wide range of sui generis approaches pursued by different categories of actors can be roughly classified according to the following scheme[66]:

Intellectual Property Rights for Communities

This approach could be used to provide communities with IPRs for their informal innovations and biodiversity-related skills that cannot be protected by conventional IPR systems. Many Southern non-governmental organizations (NGOs) and indigenous peoples' organizations criticize the fact that, by vesting those rights in communities, the commodification and monopolization of life forms will be even more strongly established worldwide.

Community Intellectual Rights and Collective Rights

This strategy could be pursued to protect the rights of indigenous communities from being usurped by foreign interests. All biodiversity-related rights of local communities (farmers as well as indigenous peoples) are to be protected by adequate legislation that the state must abide by. The primary objective is to prevent biopiracy. It is not intended to be in full compliance with the TRIPS stipulations.

Modified Plant Variety Protection

This approach is grounded on the stipulations of the PVP system as laid down in the UPOV conventions. Slight modifications to improve the situation of farmers are included. Instruments under development are Community or Farmers Rights Funds based upon royalties on protected seeds. Other measures include grace periods for filing appli-

[66] GRAIN: Strategy Ideas for the 1999 TRIPS Review and Beyond, in: GRAIN (Eds.): Signposts to Sui Generis Rights, Bangkok 1997, pp. 36-37, (http://www.grain.org/publications/signposts.htm)

cations on farmers varieties and the exclusion of certain categories of farmer-controlled plant materials.

Comprehensive Biodiversity Legislation

In this case, an encompassing legislation deals with the protection and sustainable use of biodiversity. It aims at the definition of coherent policy measures in the national context. Aspects covered range from the question of access to genetic resources, to issues of biosafety, IPRs, and communal rights.

Sectoral Community Rights Regime

Following this approach, a regulation system is designed especially to deal with the interests of local communities concerning specific categories of biodiversity. National legislation does not encompass all the biodiversity-related problems coherently but concentrates only on specific areas that must be protected, for instance medicinal plants and the related indigenous knowledge systems. Such a pragmatic approach does not exclude attempts to implement broader legislation.

Main dates in the application of the TRIPS Agreement

Final Act of the results of the Uruguay Round	14.04.1994
Entry into force of the WTO Agreement	01.01.1995
Special arrangements for pharmaceuticals and agricultural chemical products not protected in a member country as of the date of entry into force of the Agreement (Art.70.8-9)	
a) Means for filing applications	01.01.1995
b) Criteria for patentability (to be applied as of the time that the patent protection has become available in the country in question)	01.01.1995
c) Exclusive marketing rights for five years (to be applied once all conditions of Article 70.9 are met.	01.01.1995
Entry into force of TRIPS Agreement (Art.65.1)	01.01.1996
National treatment principles applicable to all countries	01.01.1996
Most-favoured-nation treatment applicable to all countries (Art.4)	01.01.1996
Review of issue of patentability of plants and animals other than micro-organisms (Art.27.3(b))	01.01.1999
Transitional arrangement for developing countries (Art. 65.2)	01.01.2000

Transitional arrangement for economies in transition, but only if conditions of article 65.3 are met	01.01.2000
Review and amendment by Council of TRIPS Agreement (Art.71.1)	2000 ⇒ ⇒
Transitional arrangement for developing countries concerning product patent protection – to technologies not previously protected by product patents (Art. 65.4)	01.01.2005
Transitional arrangements for least developed countries (Art. 66.1)	01.01.2006

Source: UNCTAD: The TRIPS Agreement and Developing Countries, New York, Geneva 1996, p.35

5.3. Strategic Focal Points for the Shaping of Creative Legislation

The TRIPS Agreement aims at the worldwide harmonization of IP instruments, obliging its member states to fulfill its provisions, even in those sectors where no such regulations have thus far existed, in order not to endanger the people´s supply of affordable drugs or food. The TRIPS Agreement is open for more extensive protection schemes but, at the same time, the stipulations in Article 65.5 prevent a rolling back of protection standards once implemented (during the transitional periods); thus, the present obligations are minimum requirements which must be met by all WTO member states in the WTO context. For many countries, those minimum requirements are at once the maximum that they are prepared to implement because of the enormous difficulties they face in adhering to the new protection standards that have been imposed on them.

Apart from the fact that the international standards for the protection of intangible assets are actually going to be enhanced due to the increase in the share of knowledge and know-how embedded in new products and processes (inevitably strengthening the tendencies towards a further dematerialization of the production system), many countries attempt to take into account all legal possibilities at their disposal, to enhance the space for maneuver which has been left to them in order to meet the demands of their respective populations and to make allowances for development-oriented goals. To this end there are multiple starting points within the framework of the present TRIPS stipulations; either they result from the maneuvering space provided for by the Agreement, or they are based on the fact that essential key notions have not been defined in the text of the Agreement. Given this background, there are at least three strategic approaches that enable member states to downgrade the imposed IP protection levels in a manner consistent with the TRIPS stipulations, in order to maximize the remaining space for maneuver and to mitigate possible negative effects arising from implementation of the TRIPS Agreement.

5.3.1. Parallel Imports

The protection of intellectual property rights guarantees the innovator a time-limited, monopolistic right to the exclusive utilization of the protected invention. This thus enables innovators to accrue profits in a one-sided manner from innovations. In ac-

cordance with disclosure of the principle behind/underlying an invention, which must be provided in return for the patent, the economy of the granting state should benefit, although, for the term of protection, utilization of the disclosed principle or the disclosed invention is subject to the patentee's consent.

Apart from the utilization of the invention consented to by the patentee, it is of utmost importance for the dissemination of the protected innovation and accrual of economic benefits that the protected invention can be freely used as early as possible with as few accompanying conditions and costs as possible. This might be achieved if the member states opt for a system of international exhaustion when implementing new protection standards on a national scale. Contrary to a system of national exhaustion, international exhaustion allows for the import of patent protected goods - once they have been legitimately released on the market by the patentee or with his/her consent - from country A to country B, without allowing the patentee the possibility to prevent further actions from being carried out on a once protected good, even if the production of this specific type of good were to be forbidden in both states A and B, or subject to the patentee's consent. The protection of the good in question has exhausted (ceased to exist) and will not be re-established, according to the system of international exhaustion, should the good be exported to state B. Although production of the good in question is prohibited, even in state B, or is subject to the patentee's consent, concrete products that had been put on the market abroad with the patentee's consent can nevertheless be freely imported. This thus provides a possibility to undermine the monopolistic character of exclusive rights and accrual of cost advantages through the parallel import of (pre-)products which are decisive for the competitiveness of economies in times of global economic interactions.

The TRIPS Agreement stipulates that the exhaustion of intellectual property rights is not subject to the dispute settlement mechanism provided for by the WTO treaty:

> Article 6 "Exhaustion"
>
> For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 (national treatment) and 4 (most-favoured-nation treatment), nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

While developing countries derive from this stipulation the political option to decide for a system of international exhaustion that would seem to be more appropriate for them,[67] the juridical literature in industrialized countries delineates from the same wording the political option to exercise unilateral trade sanctions against those states whose protection system does not meet their expectations - that is, whenever the industrialized countries feel economically disadvantaged.[68] The juridical literature in these countries emphasizes that the TRIPS stipulation in question does not cover/apply to the non-governance of exhaustion of rights - which would mean that a decision for either a system of national or international exhaustion would be subject to

[67] CORREA, C.: Intellectual Property Rights, the WTO and Developing Countries, London 2000, pp. 81-88.

[68] STRAUS, J.: Bedeutung des TRIPS für das Patentrecht, GRUR International, No.3, 1996, pp.179-205 (193-4); see also footnote No.131, p.193.

the member states' own legislation - but states only that disputes arising therefrom are not subject to established dispute resolution mechanisms.[69]

Beginning with the ambiguity of this stipulation, the question of national or international exhaustion and the intrinsic option to neutralize the monopolistic character of private exclusive rights through parallel imports will be one of the most contentious issues in IPR, in terms of the implementation or legal interpretation of the TRIPS Agreement. Without international exhaustion of rights, the overall economic costs for imported goods will become increasingly more expensive due to the constantly rising share of immaterial assets embedded in new products, thus leading to a situation where, on a static point of view, the competitive position of economic subjects in world trade might become significantly disadvantaged.

On the other hand, proponents of national exhaustion stress that the decision for a system of international exhaustion would actually not lie in the real economic interests of developing countries. They emphasize that, on the basis of a title holder's rational behavior, the principle of international exhaustion will end in a stalemate where patentees will decide neither to file their innovations in the country in question (country B), nor to produce locally or to authorize local production, nor to export patent protected goods to any other country from which markets in country B could be served in accordance with international exhaustion. Consequently, national exhaustion proponents conclude that the risk of deteriorating opportunities for technology transfer that are linked to such a decision can hardly be in the economic self-interest of developing countries.[70]

5.3.2. Compulsory Licenses

A part of the TRIPS Agreement which is of crucial importance to developing countries concerns the option to receive, under certain conditions, licenses for the government-authorized use of protected goods and processes without the patentee's consent. The conditions for those compulsory licenses are precisely set out in Article 31, although the TRIPS Agreement abstains from mentioning exclusively the grounds on which such a compulsory license can be based, thus leaving considerable space for maneuver.

While the TRIPS Agreement refers to five permissible grounds for the granting of compulsory licenses, the circumstances allowing for any such granting must be examined on a case-by-case basis. The corresponding use of the protected goods or processes without the authorization of the patent holder must be time-limited; it is subject to adequate remuneration, and it must undergo judicial review or any other independent review by a distinct higher authority. Further, decisions related to remuneration for such use are also subject to judicial review or review by any other distinct higher authority. Compulsory licenses granted to remedy anticompetitive practices, after determination of such anti-competitive practices through a judicial or an administrative process, may be handled differently, when deciding on the amount of remuneration. The scientific literature emphasizes that this part of the TRIPS Agreement may be in-

[69] STRAUS, J.: op cit., p.194.
[70] STRAUS, J.: op cit., p.195.

terpreted in a way that allows the granting of compulsory licenses in those specific cases at a reduced rate of remuneration or even without any compensation at all.[71]

The TRIPS Agreement refers explicitly to five reasons for the conditional granting of compulsory licenses, but it does not exclude any other possible grounds. Thus, it is possible on a national level to provide additional reasons such as "to safeguard the supply of the people with affordable drugs". Those reasons must be formulated in a "positive way", for instance, "(to) safeguard . . . the people . . ." and they must not discriminate against any specific field of technology. The five explicitly stated reasons for the conditional granting of compulsory licenses are:

- efforts to obtain the authorization from the right holder on reasonable commercial terms have been unsuccessful (refusal to deal);
- situations of national emergency or other circumstances of extreme urgency;
- public, non-commercial use;
- to correct anti-competitive practices after determination in judicial or administrative processes;
- exploitation of a patent which cannot be exploited without infringing another patent.

An essential part of Article 31 refers to compulsory licenses in the case of dependent patents, that is, patents, which cannot be used, without infringing on another patent. In those cases, the following additional conditions must be met:

1. the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent,
2. the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent, and
3. the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

Irrespective of whether the granting of compulsory licenses actually plays a significant role in practice, the existence of such an instrument alone would lead to more reasonable behavior on the side of titleholders, for example, during licensing negotiations. Thus, the position of economic actors interested in licenses or technology transfer would be generally strengthened, even if the granting of compulsory licenses continues to be of subordinate value. Regarding science-intensive, high-technology products and processes, it must be emphasized that disclosure in the context of the patent application procedure will reveal only a fraction of the skills actually necessary to exploit the protected invention. The larger and continuously increasing share of know-how essential for exploitation is usually transferred on the basis of additional transfer (know-how) contracts, without which, especially in the high-technology sector, protected inventions could not be used at all for commercial purposes. This highlights the necessity to use great caution in applying the compulsory license instrument, because the titleholder's cooperation is still necessary even when he/she is antagonistic to the idea; moreover, for macroeconomic reasons, a compulsory approach to (northern) technologies can be a reasonable strategy only to a limited extent.

[71] CORREA, C.: op cit., p. 90.

5.3.3. The Research Exception

A patent has the effect that the patent holder is entitled to prevent third parties who do not have his/her consent from making, using, offering for sale, selling, or importing for these purposes the protected invention.[72] The rights conferred are exclusive; in the case of exemption for some narrowly defined purposes, rights may be slightly restricted. One such restriction refers to activities which serve scientific research purposes with the aim to scrutinize in-depth the protected invention. Legal practice in the industrialized countries provides such an exemption for research, but corresponding activities must refrain from orientation with commercial intent. Based on appropriate case law, this provision - practically in force in the U.S. at present - at least permits research to develop other products[73] outside the protection scope of the patent. However, on a narrower interpretation of the research exemption (not found in written form even in U.S. patent statutes), a titleholder can successfully prevent any third party from using patent protected starting material, for instance, for individual breeding efforts, even when such efforts are restricted solely to conventional means of cross- and selective breeding. Contrary to the U.S. situation, the European legal system provides in written form for a research exemption, at least under the (non-binding) Common Patent Convention,[74] CPC (not to be confused with the binding European Patent Convention,[75] EPC) in Article 27.b: ". . . no infringement in the case of acts done for experimental purposes relating to the subject matter of the patented invention".[76]

The German Patent Law allows "acts done for testing purposes relating to the object of a patented invention" (§11.2). There is also a provision to cover instances of single preparation of a drug in a pharmacy to fill a physician's prescription, and acts relating to drugs prepared in this way (§11.3). According to German scientific literature, an exemption for research designed to scrutinize the research object itself (i.e., in order to check investment decisions relating to licensed technologies) permits, at the same time, acts for the purpose of follow-up development of the protected invention. The aim here is to obtain new patents; in this case, problems arising from dependency would not have to be tackled as long as the original patents do not cover new (clearly independent) products or processes.[77] According to the EU Directive on the Legal Protection of Biotechnological Inventions, further utilization of protected germplasm, for instance, in the context of commercial follow-up breeding programs, will be regulated by a system of cross-licensing.

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[72] Concerning importing, this stipulation is inconsistent with the principle of international exhaustion and will be one of the most contentious issues among the member states, in particular, when implementing the TRIPS Agreement in the coming years.

[73] CORREA, C.: op cit., p.192.

[74] Under the CPC, a system of uniform law(s) should be established in the EC member states for the granting of patents. The aim would be to confer patent holders a single, EC-wide, homogenous exclusive right, equally valid in all parts of the territory of the Common Market. Because not every EC member country has ratified this convention, the CPC has not yet come into force.

[75] The EPC is the basis for the European Patent Application and Granting Procedure before the European Patent Office in Munich. It is not subject to the legal authority of the EC. Its geographical scope of validity is not confined to the EC member states, within whose national territory such a patent confers its holders rights according to (somewhat different) national patent laws; it extends beyond the EC, encompassing further countries such as Switzerland, Liechtenstein, Monaco, Cyprus, etc.

[76] CORREA, C.: op cit., p.76.

[77] BAUER, C.: Patente für Pflanzen—Motor des Fortschritts? Werner-Verlag, Düsseldorf, 1993, p.237.

An effective way to implement TRIPS stipulations at national level would be to combine a broad research exception with a narrow claim interpretation, with the option to discern the innovative principle underlying the invention in question and to use it both for (dependent) improvements (follow-up inventions) and for development of original innovations in order to circumvent the claimed scope of protection. Both aspects promote an economy's innovation capacity and allow the accrual of maximum benefits from the exclusive rights granted to the patentee. Since, in Third World countries especially, the bulk of innovative effort is incremental rather than outstanding, singular steps constituting a quantum jump in technological capacity, exemption for research and narrow claim interpretation are key elements: They allow a conceivable blocking of innovative capabilities in the southern economies to be prevented, and, at the same time, they safeguard an early, affordable and, in principle, unconditional utilization of protected results, with the goal to disseminate these results on a national scale.

5.4. Options regarding claims and terms

There are further possibilities to downgrade the imposed protection standards, especially in the patent field, and to maximize options to address development objectives, when fixing the scope for the granting of claims to exclusive rights on a national level and when legally interpreting basic key terms not defined under the TRIPS Agreement. Care should be taken to balance the legitimate interests of (formal or informal) innovators in protecting their efforts - thereby promoting overall economic innovation incentives - with the necessity to ensure that the specific shaping of the protection systems devised meets corresponding technology and innovation policy objectives[78], and to prevent the abuse of such rights, especially the granting of unduly broad exclusive rights. This balance will vary between countries as well as among industrial branches[79]. Furthermore, it will be necessary to adjust this balance regularly and appropriately[80].

5.4.1. Claims

The scope and extension of exclusive rights for an innovation ultimately result from the (legal interpretation) of the claims published in the issued patent.[81] Such claims can belong to different claim categories which, in turn, may be separated essentially into product and process claims.[82] Product claims comprise devices and tools, but also chemical substances (e.g., DNA), mixtures of substances or means (e.g., pesticides) as well as arrangements, formations or circuit diagrams. In the case that an innovation is being protected by a product claim the exclusive right relates to the item as such; this means that it is protected irrespective of how it has been produced or how it will be

[78] UNCTAD: The TRIPS Agreement and Developing Countries, New York, op. cit., pp.1-4
[79] CORREA, C.: op. cit., pp.26-29
[80] THIRD WORLD NETWORK: Options for Implementing the TRIPS Agreement in Developing Countries, Penang, 1998, p.5
[81] The application of the theory of equivalents is not scrutinized in this paper.
[82] DÄBRITZ, E.: Patente. Praxis des Gewerblichen Rechtsschutzes und Urheberrechts. C. H. Beck-Verlag, München, 1994, p.13.

produced in the future.[83] A product claim cannot be circumvented; therefore, it confers upon the titleholder the strongest conceivable protection[84].

Process claims comprise either production processes (e.g., the production of a chemical substance), or working processes (e.g., the use of a herbicide), that is, the utilization of a process without thereby producing a concrete product (e.g., measuring, mining, freeze-drying, diagnostic methods, etc.). Both classifications, product and process claims, are main categories that are supplemented or extended, in western patent law or patent practice, by additional subcategories. Product-by-process claims are claims wherein a product, which cannot be sufficiently described by either its structure, or its physical or chemical properties (e.g., the melting point), can be characterized by a specific production process - product X obtain***able*** by process Y. Even though product X cannot be directly described in this case, such a claim nevertheless counts as a **product** claim,[85] with the effect that its production is prohibited to third parties, irrespective of how it has been produced or shall be produced in the future.[86] For the granting of such a claim, however, the **product** itself must be new.[87]

On the other hand, claims relating to a new **use** of an item currently protected or that has already become part of the public domain (after the term of protection has expired), are classified as process claims - use of product X for (technical) purpose Y. On this basis, a newly discovered effect of, for instance, a well-known medical substance can be protected "a second time". The subcategory of use claims is especially important in the field of medicine where only a small fraction of patents actually relate to new substances. Most claims in this area relate to new uses (or dosages), through which, according to practice in the industrialized countries, patent protection can be re-established even if original claims have already expired. Protection in such a case, however, is confined to a specific use of a substance whose general utilization remains unprotected (i.e., in the public domain).

Under the TRIPS Agreement (Article 28), developing countries are not obliged to grant product-by-process claims that could be used to obtain product patent protection indirectly; nor are they obliged to grant "second use" claims that would facilitate significant extension of the terms of protection, especially in the field of medicine. The TRIPS Agreement only establishes an obligation to grant product and process claims - in the latter case, this also includes products obtain**ed** directly from such processes[88] (product X obtain**ed** by process Y[89]). Moreover, developing countries could set out as a precondition for the granting of product patent protection that the claimed item must be described in structural terms—that is, it must be described in terms of its chemical composition and not just relevant physical or chemical characteristics (such as melting point or molecular weight), or solely according to its functionally.[90] Further, developing countries also have the option to make it a precondition that, in accordance with

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83 VENROOY, G.v.: Patentrecht. Eine Einführung für Patentingenieure mit Musterformulierungen. Verlag Stahleisen, Düsseldorf, 1996, p.89.

84 Apart from trade secrets, of course

85 GOLDBACH, K.; H. VOGELSANG-WENKE; F. ZIMMER: Protection of Biotechnological Matter under European and German Law. VCH-Verlag, Weinheim, 1997, p.57.

86 VENROOY, G.v.: op cit., p. 89.

87 GOLDBACH, K.; H. VOGELSANG-WENKE; F. ZIMMER: op cit., p.57.

88 For the purpose of preventing re-imports of products directly obtained through a process which may be unprotected abroad but protected domestically.

89 Nota bene the difference between "obtain**able**" and "obtain**ed**".

90 For instance, an increase in the tryptophan content of plants in the case of plant DNA.

Article 29, an applicant's obligation to disclose the best mode for carrying out an invention (best mode requirement) be fulfilled in such a way that would actually guarantee that the best mode is indeed disclosed for all of the claims filed, and that such a description or disclosure be made so that a skilled local person would be able to carry out said invention domestically - for example, in Burkina Faso and not Harvard.
In particular, concerning the protection of indigenous knowledge or local innovation, it should be taken into consideration that use claims in the medical field[91], if they are allowed at national level, are to be accorded equally to the nationals of other member states, in accordance with the principles of national treatment and most-favored-nation treatment, as established in Articles 3 and 4 of the TRIPS Agreement. Because of their access to better equipment, this could result in an actual advantage for nationals of other member states, for instance, in terms of extraction methods or the use of known properties for new purposes. However, as already mentioned, under the TRIPS Agreement member states are not obliged to grant product-by-process claims[92], nor are they obliged to allow/accept "second use" claims[93].

5.4.2. Terms

Because some essential key words have not been defined in the TRIPS stipulations, there is additional space for maneuver when implementing this Agreement on a national scale. Apart from the strategic approaches delineated above, in terms of the definition or legal interpretation of those key words that are the de-facto-basis of domestic patent protection practice, there are many options available for addressing structural needs and socioeconomic demands, thus taking into proper account development policy objectives that are only mentioned superficially in the TRIPS. The following will demonstrate how this can be achieved, taking as a case in point one of the most important concepts, namely, "plant varieties".

Plant Varieties

Under the TRIPS Agreement, member states are obliged to provide patent protection for inventions in all fields of technology including living material. There is the possibility to exempt from this provision plants and plant varieties, the latter of which must be protected, in such a case, by a special system designed to do so - sui generis - in accordance with the principles of national treatment and most-favored-nation treatment. The term "sui generis" is not defined in the TRIPS Agreement; the Agreement only the obliges member states to ensure that such protection is "effective" and, in so doing, indicates that the character of such an instrument is that of an intellectual property right. Although notion of a "plant variety" is ambiguous, it has been anchored via definition in patent law as well as in the Plant Breeders' Rights (PBR) Convention under the Union for the Protection of New Varieties of Plants (UPOV) Act of 1991. Nevertheless, nothing in the TRIPS Agreement obliges member states to stick to the

[91] CORREA, C.: Integrating Public Health Concerns Into Patent Legislation in Developing Countries, South-Centre, Geneva 2000, pp.22-26
[92] CORREA, C.: Intellectual Property Rights, …, op. cit., pp.70,72
[93] CORREA, C.: op.cit., pp.228-229

criteria established in the western PBR systems for the granting of plant variety protection - i.e., that the variety be distinct, uniform, and stable (DUS) - when devising a sui generis system.

> "Variety" means a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a breeder's right are fully met, can be
> - defined by the expression of the characteristics resulting from a given genotype or combination of genotypes,
> - distinguished from any other plant grouping by the expression of at least one of the said characteristics and
> - considered as a unit with regard to its suitability for being propagated unchanged;. . .[94]

The qualification - explicitly laid down in patent law - that varieties defined in such a way must not necessarily fulfill all the conditions in order to be granted breeders' rights exemplifies the problem that arises even in industrialized countries when trying to match artificially botanic-taxonomic facts with juridical demands according to economic interests. It must be stressed that, in the industrialized countries, hybrid plants can also be granted patent protection, regardless of the patent exemption for plant varieties, since hybrids are usually unstable in terms of their progenies and therefore do not fulfill the criteria of plant varieties from the point of view of patent law.[95]

The DUS criteria for the granting of plant variety protection (PVP), as established under the PBR systems in industrialized countries and both variations of the UPOV Conventions, are being blamed by some observers for loss of (agri)cultural diversity, since those criteria orient plant breeding towards the production of uniform, high-yielding seeds[96]. The TRIPS Agreement, however, does not oblige its member states in any way to formally stick to the DUS criteria when shaping national sui generis legislation for the protection of plant varieties (as an alternative to patent protection). Therefore, scientific observers stress that the TRIPS Agreement allows for the possibility when shaping the national plant variety protection system, to stick to the DUS criteria if deemed appropriate but to interpret those criteria more generously in order to provide for the coverage of less-homogenous plant material, to modify them, or to establish additional requirements like the Declaration of Origin (DO)[97] or the Value for Cultivation and Use (VCU).

Whether an extension of the range of protectable subject matter, intrinsically linked with the broadening of the PVP criteria, is desirable from a socioeconomic point of view is debatable, since this means that the IP obligations which have been imposed on developing countries could well infringe upon traditional agricultural practices in a way deeper than that even intended by the TRIPS proponents themselves. Furthermore, it should be borne in mind that the shaping of an entirely new PVP system which is meant to specifically match the respective member states' agricultural needs

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94 UPOV 1991, Article 1 (vi), and EPC Implementing Regulations (as of 16 June 1999), Rule 23b (4).

95 GOLDBACH, K.; H. VOGELSANG-WENKE; F. ZIMMER: op cit., p.229

96 IPGRI: Key Questions for Decision-Makers, op.cit., p.5: "The present requirements for homogeneity/uniformity in PVP legislation is highly controversial and has been criticized for reinforcing trends towards genetic uniformity, thus leading to a higher degree of genetic vulnerability in farmers fields."

97 Ibid.; LESKIEN, D., M. FLITNER: Developing a Decision Tree as a Tool for Shaping Sui Generis Systems for the Protection of Plant Varieties under the TRIPS Agreement, op.cit.

and demands, requires a significant investment of human labour and legal expertise in order to ensure that the system is inherently consistent and does not entail unnecessarily high transaction costs. Finally, especially with a view to agriculture, it should be stressed that the provision of IPRs can play a significant role in creating incentives for the development of new plant varieties[98] and can make sure that access to improved plant material can be guaranteed.

"…various IPRs affect different aspects of agricultural activities. (…) IPRs systems may be designed or amended with a view to making the need for conservation of plant biodiversity (via some kind of compensation for traditional farmers) compatible with the convenience of introducing varieties which enhance productivity and increase farmers´ income. IPRs should, in sum, appropriately balance the different interests at stake and contribute to a sustainable development of agriculture."[99]

To that end, the option to expand the room for maneuver by broader (or narrower) interpretation of the relevant terms of the TRIPS-Agreement in accordance with the interests of the developing countries should be thoroughly scrutinized and not be rashly thrown away by referring to the legal **interpretation practices** prevalent in the industrialized countries where strong economic interests are matched by jurisprudential services.

[98] However, the empirical data on this point is inconclusive, see: Van WIJK, J.; W. JAFFÉ (Eds.): Intellectual Property Rights and Agriculture in Developing Countries. Proceedings of a seminar on the impact of plant breeders' rights, held March 7-8, 1995, Santa Fé de Bogotá, Columbia, University of Amsterdam (mimeo) 1996; JAFFÉ, W.; J. Van WIJK: The Impact of Plant Breeders' Rights in Developing Countries. Debate and experience in Argentina, Chile, Colombia, Mexico and Uruguay, Inter-American Institute for Cooperation on Agriculture, University of Amsterdam (mimeo) 1995

[99] CORREA, C.: Intellectual Property Rights and Agriculture: Strategies and policies for developing countries, in: Van WIJK, J.; W. JAFFÉ, (Eds.): Intellectual Property Rights and Agriculture in Developing Countries. Op.cit., pp.100-113(112)

Part II: Regulating Access and Benefit Sharing: Overview, Inventory and Analysis

There are three general approaches to regulating access and benefit-sharing. These are as follows:

1. Legal, policy and administrative rules and frameworks.

2. Private arrangements between providers and users of genetic resources and associated traditional knowledge. These include material transfer and licensing agreements.

3. Codes of conduct and voluntary guidelines.

Table II.1 provides a summary of these with some examples.

These approaches differ from each other and are applicable in different situations. But they may exist within the same regulatory framework. For example, ABS regulations may require that users negotiate a contract with a provider institution.

This section provides an overview of these three approaches, emphasising the ways that each deals with the following elements: prior informed consent; mutually agreed terms; roles and responsibilities of each stakeholder group; in situ and ex situ conservation and sustainable use; benefit sharing mechanisms, including technology transfer and joint R&D; and appropriate use of traditional knowledge, innovations and practices. Other important elements dealt with in Part II are intangible (including intellectual) property rights and tangible property rights.

Table II.1
Measures for regulating access and benefit-sharing

GENERAL MEASURES (WITH EXAMPLES AND MODELS
Legislative – ABS regulations including: • Supranational approaches (e.g. Andean Community Decision 391; OAU Model Legislation) • National approaches (e.g. Costa Rica Biodiversity Law; Philippines EO 247) • Local/indigenous people's access regulations • Model Laws (e.g. Third World Network Community Intellectual Rights and Collectors of Biological Resources Acts)
Existing private legal arrangements/contracts including: • Contracts • MTAs (Material Transfer Agreements) • Licensing agreements (e.g. Aguaruna-Searle know-how license) • Letters of intent/ memoranda of understanding • Model agreements

Non legally-binding instruments including:

- Scientific/academic codes of practice (e.g. International Society of Ethnobiology)
- Industry codes of practice
- Indigenous people/CSO statements and declarations
- Voluntary guidelines

6. Guiding the regulation of access and benefit-sharing: an overview

6.1. Access and benefit-sharing laws, policy measures, and legislative frameworks

Governments have exercised their authority to regulate access to genetic resources in various ways such as the following:

1. Environmental framework laws.
2. Framework sustainable development, nature conservation or biodiversity laws.
3. National laws or decrees on ABS.
4. Modified existing laws/regulations.
5. Regional (supranational) level regimes.[100]

In some cases, then, access and benefit-sharing are regulated through specific laws. In others, ABS rules constitute a component of more general regulatory frameworks dealing with nature conservation and/or sustainable development. And while the most common situation is for countries to develop their own laws and frameworks, regional/supranational approaches are also possible.

6.1.1. National and supranational approaches

While some countries have developed independent national-level (and sometimes also sub-national) regulations, others consider it advantageous to develop regional or supranational legislative frameworks rather than for each of them to develop separate and independent rules. For example, the member states of the Andean Community (Bolivia, Colombia, Ecuador, Peru and Venezuela) have common rules governing access and benefit-sharing. What are the advantages of a supranational approach?

The main advantage derives from the fact that many biological resources (usually more than 50 percent of them) in any given country are not endemic but shared with other countries. This makes it difficult for individual countries to negotiate with users from a position of strength. If the cost of access is considered too high, users can go to neighbouring countries sharing many of the same resources and negotiate access with the one that offers it most inexpensively. Therefore, a supranational ABS system should improve the bargaining position of participating countries.

Another reason why many developing countries are in a weak bargaining position vis-à-vis the users is that they lack the scientific and technological capacities to add value to their own resources. Indeed, they are essentially positioned at the low-value end of the biotechnological innovation chain. Supranational approaches can facilitate capacity building through greater cooperation between the member countries.

[100] See Glowka, L. (1998) A Guide to Designing Legal Frameworks to Determine Access to Genetic Resources. IUCN, Gland and Cambridge.

On the other side, supranational frameworks can be complicated to negotiate. One possible complexity is that national constitutions may define sovereignty over natural resources in very different ways.

6.1.2. Local/indigenous people's access regulations

Some indigenous and local communities with relatively secure land rights have developed regulations governing access to their genetic resources and associated traditional knowledge and/or scientific research more generally. Examples include the Kuna of Panama, the Awa of Ecuador, and the Inuit of Nunavik, Canada.[101]

6.1.3. Model Laws

Since access and benefit-sharing is a new regulatory domain, there is a shortage of existing national or supranational frameworks upon which new regimes can be modelled. Consequently, some organisations have provided model laws to serve as templates or as sources of useful rules and principles to guide the development of ABS regimes or components of such regimes. These include the Organization of African Unity's "Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources", and the Third World Network's "Community Intellectual Rights Act".

6.2. Contracts and other legal agreements

6.2.1. Contracts and material transfer agreements

A contract is essentially a legally-enforceable agreement between two or more parties consisting of an exchange of negotiated promises or actions.[102] In the case of exchanges of biological samples, such contracts are often of a type known as material transfer agreements (MTAs). Such MTAs establish standards for the transfer of biological or other resources for research and possible commercialisation in exchange for benefits to the party recognised as the supplier. Such a supplier might be a government, a collecting organisation (such as a botanic garden), or a local community.

A well-known MTA is the one drawn up between the National Biodiversity Institute of Costa Rica (INBio) and the drug company Merck.

In the case of bioprospecting, companies or other prospective users might undertake in a contract to provide countries, institutions or communities with some or all of the following:

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[101] Laird, S.A. (1995) *Fair Deals in the Search for New Natural Products*. World Wide Fund for Nature International, Gland; IUCN Inter-Commission Task Force on Indigenous Peoples (1997) *Indigenous Peoples and Sustainability: Cases and Actions*, International Books and IUCN, Utrecht.

[102] Posey, D.A. and Dutfield, G. (1996) *Beyond Intellectual Property: Toward Traditional Resource Rights for Indigenous Peoples and Local Communities*. International Development Research Centre, Ottawa. (including the unattributed input of Sarah Laird).

- fees per sample;
- advance payments;
- trust fund;
- joint research and/or reports on the results of their research;
- training for collaborating institutions and indigenous communities;
- royalties on any compounds;
- the option of filing a jointly-owned patent with collaborators.

Some MTAs grant the recipient of the material the right to apply for patents or other IPR protection if any of the material has commercial potential, while other MTAs deny such a right.

MTAs are not dependent on the existence of access and benefit sharing regulations, although such regulations sometimes require transfers of genetic resources and associated traditional knowledge to be formalised through contracts.

6.2.2. Licensing agreements

Many IPR holding institutions prefer not to commercialise a protected product or process but to license the right to use the IPR to another institution that is better equipped to commercialise that particular product or process either for a fee or a share of future sales. The greater the commercial potential of the invention, trade secret or know-how, the more expensive the licence will be.

There have been few cases of traditional communities licensing their technical knowledge to a company. One example is the agreement between some Aguaruna communities of the Peruvian Amazon and a United States pharmaceutical company, Searle (Case Study).

It is worth making the point that the *transfer* of knowledge and resources from a community to a corporation does not require all the *rights* over such knowledge and resources to be transferred as well. In fact, just as corporations may argue that it is perfectly legitimate when licensing their intellectual property to demand a share of the profits of all further commercial use for a certain period *even when the licensee adds value to the property with his or her own intellectual input*, it is no less reasonable for a community to expect the same conditions.

Case Study: The Aguarunas and their know-how license

In Peru, the Aguaruna people have negotiated a know-how licence with Searle (the pharmaceutical division of Monsanto). The Aguaruna pass on medicinal plants and knowledge (i.e. 'know-how') to the company and in exchange receive an annual know-how licence fee. This fee will increase to reflect success in research and development even before a product ever reaches the market. Such payments are often referred to as milestone payments. The licence is non-exclusive in that it does not affect the right of any Aguaruna communities to use, share or sell or otherwise transfer plants or knowledge whether or not they are parties to the agreement. According to Brendan Tobin, legal counsel for the Aguarunas, a trust fund will be established to distribute the

benefits, and a board appointed to administer the fund from within the Aguaruna people including representatives of both participating and non-participating communities.[103]

One of the main advantages of such an arrangement is that legal ownership of biological resources is not a pre-condition for the communities to benefit. The agreement implicitly accepts their intellectual property rights over knowledge about the resources irrespective of whether they legally own them.

6.2.3. Letters of intent and memoranda of understanding

Letters of intent and memoranda of understanding are non legally-binding agreements. Public institutions involved in bioprospecting such as botanic gardens and research institutions sometimes use such agreements when negotiating with overseas suppliers. For example, the United States National Cancer Institute (NCI) uses a letter of intent (which it calls a letter of collection) to obtain samples for its own research. Letters of intent usually outline the preliminary understanding between parties who intend to enter into a contract later on.

Some institutions employ a memorandum of understanding that, like a letter of intent, is not a binding contract but is similarly used as a statement of intentions and can serve as a starting point for subsequent negotiations.

These types of agreements can address issues of confidentiality, the sharing of research results, and the provision of benefits to suppliers, but they are not legally enforceable.

6.2.4. Model Agreements

Most suppliers of genetic resources lack experience in drawing up such agreements. For this reason a number of model contracts and MTAs have been developed to provide useful information to assist in the drawing up of fair agreements that serve the interests of suppliers. One notable example is the Third World Network's "Draft Model Contract between the Collector and the Government", the "Model Material Transfer Agreements for Equitable Biodiversity Prospecting"[104], and the "Biodiversity Prospecting Contract".[105]

[103] Tobin, B. (1997) 'Know-how licenses: recognising indigenous rights over collective knowledge'. *Bulletin of the Working Group on Traditional Resource Rights*, 4: 17-18.

[104] See Putterman, D. (1996) 'Model material transfer agreements for equitable biodiversity prospecting'. Colorado Journal of International Environmental Law and Policy 7(1):145-173.

[105] See Downes, D., Laird, S.A., Klein, C. and Carney, B.K. (1993) 'Biodiversity prospecting contract'. In: Reid, W.V. *et al* (eds.) Biodiversity Prospecting: Using Genetic Resources for Sustainable Development. WRI, INBio, Rainforest Alliance, ACTS, Washington DC: 255-287.

6.3. Codes of Conduct and voluntary guidelines

6.3.1. Scientific/academic codes of practice

Professional societies have begun to draft codes of practice to guide researchers, clarifying what is ethically acceptable behaviour for fieldworkers including bioprospectors, and in some cases providing a set of specific obligations to be observed. Although they are not legally binding, they are the result of consensus among concerned scientists, and they are expected to be complied with.

Examples of such codes and ethical guidelines produced by (among others) scientific and professional organisations include the following:

- The Code of Ethics of the International Society of Ethnobiology, 1998
- The Pew Conservation Fellows' Proposed Guidelines for Researchers and Local Communities Interested in Accessing, Exploring and Studying Biodiversity, 1996.
- Guidelines for Equitable Partnerships in New Natural Products Development of the People and Plants Initiative of WWF, Unesco, and RBG, 1993
- The FAO International Code of Conduct for Plant Germplasm Collecting and Transfer, 1993.
- Professional Ethics in Economic Botany: A Preliminary Draft of Guidelines of the Society of Economic Botany, 1991
- Code of Ethics for Foreign Collectors of Biological Samples developed at the Botany 2000 Herbarium Curation Workshop, 1990

6.3.2. Industry codes of practice

Business associations and individual corporations have produced statements expressing their commitment to the CBD and offering their suggestions on implementation of certain objectives, including ABS. Examples include the Japan Bioindustry Association and the Danish life-science corporation, Novo Nordisk.

6.3.3. Indigenous people/CSO statements and declarations

Indigenous peoples are of course key stakeholders and have become increasingly involved in proposing measures to implement ABS and other provisions of the CBD. For example, the International Indigenous Forum of indigenous peoples representatives meets before and during each COP meeting. The Forum was first to propose an Ad-Hoc Open-Ended Inter-Sessional Working Group on Article 8(j) And Related Provisions of the Convention on Biological Diversity, whose creation was approved at COP-4.

In additional, indigenous peoples hold conferences at which they issue declarations and statements which deal *inter alia* with the CBD and ABS. These include the following:

- Final statement from the conference on Protecting Knowledge: Traditional Resource Rights in the New Millennium hosted by the Union of British Columbia Indian Chiefs, 2000

- Final statement from the UNDP Consultation on the Protection and Conservation of Indigenous Knowledge, Sabah, Malaysia, 1995
- Final statement from the UNDP Consultation on Indigenous Peoples' Knowledge and Intellectual Property Rights, Suva, Fiji, 1995
- Statement/basic points of agreement from the COICA/UNDP meeting, Intellectual Property Rights and Biodiversity, 1994
- The Mataatua Declaration on Cultural and Intellectual Property Rights of Indigenous Peoples from the First International Conference on the Cultural and Intellectual Property Rights of Indigenous Peoples, 1993
- Statements from the Julayinabul Conference on Intellectual and Cultural Property, 1993

6.3.4. Voluntary guidelines

In the absence of ABS regulations voluntary guidelines can serve a useful purpose. The best guidelines are likely to be developed in consultation with as many of the stakeholders as possible. A well-known set of guidelines is the "Swiss draft Guidelines on Access and Benefit-sharing Regarding the Utilisation of Genetic Resources" (see below).

One problem with declarations, ethical guidelines, and codes of practice, of course, is that they are not legally binding. They are often effective only if the organisations concerned and its membership are willing to observe them. Because they sometimes do not, documents of this kind have been subject to criticism. Nevertheless, their existence may well make scientists more aware of their moral obligations. Furthermore, they may influence legislators who are drafting national and international laws and even serve as models for such laws.

7. An inventory of instruments in use or under development

7.1. Access and benefit sharing laws and legislative frameworks

7.1.1. Andean Community Common System on Access to Genetic Resources

Background and overview

The Andean Community[106] Decision 391, establishing a "Common System on Access to Genetic Resources" was the culmination of a two-year process which began in 1994 when the IUCN-World Conservation Union was invited to provide a technical report outlining the basic elements for a draft ABS system that could be drawn upon by government drafters. The first draft of the report was prepared soon after with an IUCN member NGO, the Peruvian Society of Environmental Law (SPDA). From the start it was intended that indigenous peoples and civil society organisations would participate in the process of developing the system through their attendance at workshops and expert meetings, and by requesting their comments on drafts.

But at a workshop in August 1994 which was attended by a large number of indigenous peoples organisations and other NGOs, a small number of these groups apparently mistook the second draft report intended for discussion only for an actual draft law, and sought to have it rescinded.

As a consequence of the controversy surrounding this incident, civil society involvement became more limited. At the same time, there were differences between governments concerning some basic provisions of the system leading to delays. But a text was finally agreed and adopted by the Andean Community member countries in 1996 as Decision 391.

Article 2 sets out the objectives of Decision 391, which are to regulate access to genetic resources and their derivatives in order to:

- Create the conditions for fair and equitable sharing of the benefits accruing from such access;
- Establish a basis for the recognition and appreciation of genetic resources, their derivatives and related intangible components, particularly where indigenous, Afro-American and local communities are involved;
- Encourage the conservation of biological diversity and sustainable use of biological resources containing genetic resources;
- Promote the consolidation and development of scientific, technological and technical capacities at local, national and subregional level; and
- Strengthen the negotiating capacity of the Member Countries.

Article 3 establishes the scope of the Decision, which applies to:

- genetic resources for which the Member Countries are countries of origin;
- their derivatives and intangible components; and

[106] Formally known as the Cartagena Accord and previously commonly referred to as the Andean Pact.

- the genetic resources of migratory species found for natural reasons in the territory of the member countries.

In conformity with the CBD, the Decision proclaims that member countries have sovereign rights over the use and exploitation of their genetic resources and the right to determine conditions of access. However, the Andean Community has gone further than the CBD by extending sovereign rights to the *derivatives* of these resources.

"Derivative" is defined in Article 1 as a molecule or combination or mixture of natural molecules, including raw extracts of living or dead organisms of biological origin, derived from the metabolism of living organisms. A derivative should thus be differentiated from a "synthesised product", which is a substance obtained by means of an artificial process, using genetic information or other biological molecules. This includes semi-processed extracts and substances obtained through treatment of a derivative using an artificial process. An example of a derivative would presumably be a herbal formulation, while a type of synthesised product would be a pharmaceutical compound modelled on a natural compound. By including derivatives within its purview, the Decision goes beyond the CBD, which regulates access only to genetic resources. Such derivatives may not necessarily contain functional units of heredity[107].

An "intangible component" refers to any knowledge, innovation or individual or collective practice of actual or potential value associated with the genetic resource, its derivatives or the biological resource containing them, whether or not it is protected by intellectual property systems.

As will be explained below these terms are extremely significant.

Core elements

(a) Prior informed consent

Although the Decision makes no explicit reference to PIC, applicants are required to afford competent national authorities with all information concerning the genetic resource and its derivatives with which they are familiar or in a position to know at the time of presenting the application. This information shall include the actual and potential uses of the resource, its derivatives or intangible components, its sustainability and risks which should arise from accessing it.[108] There is no requirement to provide such information to any other institution or stakeholder group.

(b) Mutually agreed terms

All access procedures must include an application (including a project proposal) and a contract[109]. Parties to such contracts are the applicant and the State represented by the

[107] Ten Kate, K., op. cit. (1997) 'The Common Regime on Access to Genetic Resources in the Andean Pact'. Biopolicy (Online Journal - URL: http://www.bdt.org.br/bioline/py), 2(6).
[108] Article 22.
[109] Article 16.

competent national authority. It is by means of contracts that terms of access are mutually agreed. Such contracts must include various conditions including the following[110]:

- Participation by nationals of the subregion in research activities into genetic resources, their derivatives and associated intangible components
- Support for research contributing to the conservation and sustainable use of biological diversity being carried out under the jurisdiction of the Member Country which is the country of origin of the genetic resource, or in any other country of the subregion
- Strengthening of mechanisms for the transfer of knowledge and technologies, including biotechnologies, which are culturally, socially and environmentally safe and healthy
- Strengthening and development of national or subregional institutional capacities connected with genetic resources and their derivatives
- Strengthening and development of the capacities of indigenous, afro-american and local communities with regard to the intangible components associated with genetic resources and their derivatives
- Obligatory deposit, in institutions designated by the Competent National Authority, of duplicates of all material collected
- Obligation to inform the Competent National Authority of the results of research carried out

Because only the State has the authority to grant access, other stakeholders are excluded from participation in these contracts. Nonetheless, all access contracts are required to take into consideration the rights and interests of suppliers of genetic resources and their derivatives, and of biological resources and their intangible components[111]. And if access is sought to genetic resources or their derivatives with an intangible component, an annex must be included in the contract providing fair and equitable sharing of the benefits arising from the said component. The annex will have to be signed by the supplier of the intangible component. It may also be signed by the competent national authority[112]. There is no clear indication that the supplier of an intangible component must be a representative of the indigenous, Afro-American or local community that is its source.

Other types of contract are also possible, though, such as (1) framework access contracts between the authority and universities, research centres or recognised researchers; (2) access contracts with ex situ conservation centres; (3) and access contracts with third parties which are likely to be ex situ conservation centres outside the Andean Community region concerning genetic resources whose origins are the member country.

The Decision also provides for accessory contracts for the purposes of developing activities connected with access to a genetic resource or its derivatives. Parties to such contracts are applicants and, for example, owners, holders or administrators of the property in which the bioprospecting is to be carried out, and ex situ conservation centres. These contracts are subordinate to the access contracts described earlier.

[110] Article 17.
[111] Article 34.
[112] Article 35.

(c) Roles, responsibilities and participation of stakeholders

Apart from the state as represented by the competent national authority, the roles, responsibilities and participation of the various other stakeholders are not described in any great detail except as parties to the contracts as presented earlier. But the following stakeholders are referred to[113]:

- Applicants for access;
- The member states of the Andean Community, represented by the competent national authority;
- Suppliers of genetic resources and their derivatives, and of biological resources and their intangible components;
- Suppliers of any knowledge, innovation or individual or collective practice of actual or potential value associated with the genetic resource, its derivatives or the biological resource containing them;
- Owners, holders or administrators of the property on which biological resources containing genetic resources are found;
- Ex-situ conservation centres;
- Owners, holders or administrators of biological resources containing genetic resources;
- National support institutions;
- Universities;
- Research centres;
- Recognised researchers;
- Other bodies carrying out activities involving access to genetic resources;
- 'Third party' suppliers.

(d) In-situ and ex-situ conservation and sustainable use

One of the objectives of the Decision is to encourage the conservation of biological diversity and sustainable use of biological resources containing genetic resources. How is such an objective to be realised through the regulation of access?

In Article 9, the States undertake to safeguard and facilitate, by means of the necessary contracts, access to technologies using genetic resources and their derivatives that are appropriate to the conservation and sustainable use of biological diversity and are not harmful to the environment. In addition, one of the aforementioned conditions to be provided in access contracts is research contributing to the conservation and sustainable use of biological diversity.
With respect to ex situ conservation it is noteworthy that two International Agricultural Research Centres exist in the Andean Community region: the International Centre of Tropical Agriculture (CIAT) and the International Potato Centre (CIP). It seems that CIAT and CIP will need to conform fully to the access regulations when they wish to conduct fieldwork. There is a possibility that the work of these Centres could be hampered if their activities become strictly regulated.

[113] Ten Kate, K., op. cit.

(e) Mechanisms for benefit-sharing, including technology transfer and joint research and development

Technology transfer has been dealt with earlier. But essentially, the Decision seeks to implement the relevant provisions of the CBD in various ways, including by requiring the incorporation of technology transfer requirements into the access contracts.

Joint research is referred to in Article 10 but only in the context of subregional co-operation and is therefore not linked to access procedures.

(f) Means to ensure the maintenance and protection of traditional knowledge, innovations and practices

With regard to traditional communities, the Decision recognises their historical contribution to biodiversity, its conservation, development and sustainable use, and the benefits provided by such contribution. It also acknowledges that the close interdependence between these communities and biodiversity must be strengthened.

Communities are not specifically mentioned as potential parties to any of the types of contract described above. But it is possible for them to be parties as suppliers of an intangible component or as owners, holders or administrators of the property on which the biological resource containing a genetic resource is found. To an extent then, the effectiveness of the Common System's support for community rights depends on the extent to which such communities already enjoy recognition of their land rights and are able to enforce these rights.

Given that a particular derivative may have been discovered through the application of an intangible component the question arises of whether the extension of national sovereignty to include derivatives might conflict with Article 8(j) of the CBD. For example, traditional remedies often consist of plant extracts. Should such extracts be the property (or patrimony as the case may be) of the nation, or of the shaman or community that originally produced it and used it for a particular disease? The tension here may be resolved if the intangible component is separated for legal purposes from the derivative with which it is associated. But if the derivative is of a type that does not occur naturally (such as a plant extract) it is difficult to see why states should claim sovereignty over it. The fact that the Decision excludes from its jurisdiction the exchange of genetic resources, their derivatives and the biological resources in which they are found, and related intangible components among traditional communities and for their own use, does not resolve the confusion.

(g) Intellectual property rights

The Decision states that any rights, including IPRs, to genetic resources, derivatives, synthesised products or related intangible components obtained or developed through non-compliance with these terms of access, shall not be recognised by the member states. Moreover, national IPR offices having evidence that products or processes for which protection is sought were obtained or developed from genetic resources or their

derivatives for which a member state is a country of origin, must require applicants to submit a copy of their access contract as a pre-condition for the concession of an IPR.

Of course, given that the Decision has no legal effect outside the Andean Community member states, it is difficult to see how such patents granted abroad could be challenged.

(h) Tangible property

The Decision separates genetic resources from biological resources. National sovereignty extends to genetic resources and their derivatives, but such a right is without prejudice to the systems of ownership applicable to the biological resources containing them, property on which they are located, or to any associated intangible component[114].

Progress in implementation[115]

The Decision has been barely operationalised at the national or international level. Only Bolivia has passed implementing regulations, but these have not yet been put into effect. Colombia and Venezuela have opted not to produce implementing regulations, but to apply Decision 391 directly.

Moreover, cooperation between the respective governments has been lacking, suggesting a lack of conviction that the cartel approach is superior to the 'go-it-alone' strategy whereby each country regulates access without reference to the interests of its neighbours. At the same time, the Decision was intended to be a genuine common system that set uniform rules for the whole region so that the interests of the region would take priority over national interests. It becomes difficult, then, for each country to adapt the rules to further its specific needs and interests.

7.1.2. The Costa Rica Biodiversity Law[116]

Background and overview

In April 1998, the Legislative Assembly of Costa Rica passed the *Ley de Biodiversidad*, or Biodiversity Law. The Costa Rican experience in drawing up the legislation was char-

[114] Articles 5 and 6.

[115] This sub-section draws on Ruiz, M. (2000) 'Regulating bioprospecting and protecting indigenous peoples knowledge in the Andean Community: Decision 391 and its overall impacts in the region'. Presented at UNCTAD Expert Meeting on Systems and National Experiences for Protecting Traditional Knowledge, Innovations, and Practices. Geneva, 30 October-1 November.

[116] This section draws on Dutfield, G. (2000) *Intellectual Property Rights, Trade and Biodiversity: Seeds and Plant Varieties*. Earthscan Books and IUCN, London; Dutfield, G. (2000) 'Developing and implementing national systems for protecting traditional knowledge: a review of experiences in selected developing countries'. Presented at UNCTAD Expert Meeting on Systems and National Experiences for Protecting Traditional Knowledge, Innovations, and Practices. Geneva, 30 October-1 November; and Solís, V. and Madrigal, P. (1999) 'Costa Rica's Biodiversity Law: sharing the process'. Prepared for the Workshop on Biodiversity Conservation and Intellectual Property Regime. New Delhi, India, 29-31 January. It also benefited from personal communications from Vivienna Solís (IUCN-ORMA) and Silvia Rodriguez (Universidad Nacional).

acterised by a great deal of stakeholder participation including the involvement of indigenous peoples and local communities.

The original proposal for the Law was made by an ex-politician and former president of the Environmental Commission of the Legislative Assembly, who enlisted the technical support of IUCN's Regional Office for Mesoamerica (IUCN-ORMA) to develop a draft. At the beginning of the process ORMA and the Environmental Commission agreed on a philosophical framework for the legislation and also its guiding principles, before beginning the first phase of consultations. These consultations included such stakeholders as indigenous peoples, small farmer groups, legal experts, scientists, civil servants and representatives of the private sector. The purpose was to establish the basic contents of the legislation before drawing up the first draft, which was published in June 1996.

Once the first draft had been circulated and comments and suggestions had been received, a more substantive draft was drawn up. But progress was stalled due to the wide and conflicting range of views.

The Environment Commission set up a Special Mixed Subcommission to draw up another draft of the law. This consisted of representatives of the following institutions and stakeholder groups:

- the National Indigenous Forum
- the Costa Rican Federation for Environmental Conservation (FECON)
- the National Small Farmers Forum
- the University of Costa Rica
- the National University
- the Union of Chambers for Private Business
- the National Biodiversity Institute (INBio)
- the Advisory Council to the Minister of the Environment and Energy (COABIO)
- the National Liberation Party (PLN)
- the Christian Socialist Unity Party (PUSC)

The draft was completed in November 1997, and was passed by the legislative assembly in April the following year. It became Law No. 7788 in May 1998.

To date this is perhaps the most ambitious and elaborate national law to implement the CBD. The Biodiversity Law was intended to fill a legal gap in the sense that while existing laws covered certain types of natural resources (e.g. wildlife and forests), there was no specific legislation on biological and genetic resources, and neither were there any specific access and benefit sharing regulations. The Law's overall objective is to conserve biodiversity, sustainably utilise resources, and distribute fairly the derived benefits and costs, and its 107 Articles cover the full range of issues contained in the CBD including: biosafety; conservation and sustainable use of ecosystems and species; access to genetic and biochemical elements of biodiversity; prior informed consent; protection of scientific and traditional biodiversity-related knowledge through intellectual property rights and/or *sui generis* systems; education and public awareness; technology transfer; environmental impact assessment; and incentives.

The Law has ten chapters of which one is devoted to "Access to genetic components and biochemicals and protection of associated knowledge", and another to "Education and public awareness, research and technology transfer". These two are the main ones dealing with access and benefit-sharing.

Article 7 deals with definitions. Within the definition of "biodiversity" is included "intangible elements", which are: traditional, individual or collective knowledge, innovation and practice with real or potential value associated with biochemical and genetic resources whether or not protected by intellectual property systems or *sui generis* register systems. The intangible element concept is the same thing as the intangible component of the Andean Community's Decision 391.

The Law sets up a National Biodiversity Management Commission (CONAGEBIO) to formulate and coordinate policy and to oversee implementation of the Law.

Core elements

(a) Prior informed consent

PIC is not defined except as the procedure by which providers of biological resources or associated intangible components – who may be the State, private owners, or local or indigenous communities – agree terms for access with users[117]. Consent is required from representatives of the place from where access is sought who may include the regional councils of Conservation Areas, landowners, or indigenous communities[118]. Applications for access are submitted to the Technical Office and need to be accompanied by the PIC of the appropriate stakeholder group[119].

(b) Mutually agreed terms

The only direct reference to mutually agreed terms appears in the definition of PIC, which establishes that PIC is the procedure through which mutually agreed terms for access can be negotiated. But Article 63 ("Basic requirements of access") implicitly links MATs to benefit-sharing. Permission for access requires that the terms of technology transfer and equitable distribution of benefits, when there are any, as agreed in the permits, agreements and concessions, as well as the type of protection of associated knowledge demanded by the representatives of the place where the access will occur.

In addition the party seeking access is expected to define the ways in which the said activities will contribute to the conservation of species and ecosystems.

[117] Article 7.
[118] Article 63.
[119] Article 65.

(c) Roles, responsibilities and participation of stakeholders

As was indicated earlier, a wide range of stakeholders was involved in developing the legislation. Not surprisingly, then, these groups are also involved in overseeing the implementation of the law through their participation in the work of CONAGEBIO. In fact, CONAGEBIO consists of representatives from various government ministries and agencies, the national protected areas system, the university sector, the private sector, and the national peasants' and indigenous peoples' associations.

(d) In-situ and ex-situ conservation and sustainable use

The Law links access to conservation and sustainable use in three ways. Applications for access should indicate possible environmental impacts[120], and its contribution to conservation[121]. And more specifically, 10 percent of the research budget of the party applying for access will have to be deposited in favour of the National System of Conservation Areas.

(e) Mechanisms for benefit-sharing, including technology transfer and joint research and development

The Law provides few details of the kinds of benefit that might be shared between users and providers. Also, there is no explicit requirement that benefits should be linked in any way to future commercialisation of genetic resources or traditional knowledge.

But technology transfer is indicated as a form of benefit-sharing to be included in the PIC procedures. And Article 88 ("Research and technology transfer related to biological diversity") commits the State to promoting information and scientific technical co-operation as well as access to technologies relevant to the conservation and sustainable use of biodiversity. Although Article 88 is not explicitly linked to access to genetic resources, it can be assumed that such technologies and co-operative relationships may best be achieved through the access procedures.

(f) Means to ensure the maintenance and protection of traditional knowledge, innovations and practices

Articles 82-85 deal specifically with the intellectual rights of indigenous peoples and local communities, implicitly acknowledging that a final solution to this issue has not been reached by stating that within 18 month period, CONAGEBIO will define a participatory process to elaborate an appropriate *sui generis* system. Even so, the State already expressly recognises and protects what is referred to as "*sui generis* community intellectual rights", i.e. the knowledge, innovations and practices of indigenous peoples and local communities. Similar in this respect to copyright, these rights have juridical recognition without the requirement of prior declaration or official registration.

[120] Article 72.
[121] Article 63.

The participatory process, which will include indigenous peoples and peasants, will determine the nature, extent and conditions of the *sui generis* community intellectual right, as well as the form the right will take, who will be entitled to hold the legal right, and who will receive its benefits. By means of this process, a registry will be made comprising those intellectual rights that communities wish to register with the Technical Office of the Commission. Such registration will be voluntary and free. The existence of such right claims in the registry will bind the Technical Office to the obligation to oppose the grant of IPR protection being requested for the same element or knowledge. It is not essential for the right to be officially registered for the refusal to be made provided that the reason is fully justified.

Moreover, the State will promote the recovery, maintenance and dissemination of traditional technologies and practices useful for conservation and sustainable use of biodiversity.

Finally, indigenous peoples and local communities are fully entitled to refuse access to their resources and knowledge for any reason.[122]

(g) Intellectual property rights

Articles 77-85 are devoted to the subject of intellectual and industrial property rights. This section of the Law begins with a statement recognising the need to protect knowledge and innovations through appropriate legal mechanisms, and refers specifically to patents, trade secrets, plant breeders' rights, *sui generis* community intellectual rights, copyrights and Farmers' Rights. Remarkably for a biodiversity law, parameters for the scope of IPR protection permitted by the State are drawn very explicitly. Excepted from IPR protection are the following:

1. DNA sequences;
2. plants and animals;
3. non-genetically modified organisms;
4. essentially biological processes for the production of plants and animals;
5. natural processes or cycles *per se*;
6. inventions essentially derived from knowledge associated with traditional biological or cultural biological practices in the public domain; and
7. inventions which, through their commercial exploitation in monopoly form can affect agriculture and livestock processes or products considered basic for nutrition and health of the country's inhabitants.

In order to ensure that these exceptions are observed, the National Seeds Office and the Intellectual and Industrial Property Registries are required to consult the National Biodiversity Management Commission[123], a State body set up by this Law, before awarding IPR protection for innovations involving biodiversity elements. In every case, a certificate of origin issued by the Technical Office of the Commission and statement of prior informed consent will have to be presented with the IPR application. Such consent may

[122] Article 66.

[123] The Commission will consist *inter alia* of government ministers and representatives of the national protected areas system, the university sector, the private sector, and the national peasant (campesino) and indigenous peoples associations.

include that of indigenous authorities in cases where bioprospecting takes place on their lands.

(h) Tangible property

With respect to property rights, lands and the resources on them may be owned by the State, private landowners or local communities. However, the Law separates the physical elements of biodiversity from their intangible informational aspects. While biodiversity components *per se* are subject to the exclusive sovereignty of the State[124], the *properties* of these components can be owned by nobody, not even those who discover or may be aware of these properties.

Progress in implementation

The Biodiversity Law still has not been implemented and the situation is somewhat confused. It is expected that the Law will be subject to some amendments. Furthermore, some of the functions of CONAGEBIO[125] have been challenged by the Ministry of Environment and Energy on the grounds that they allegedly violate the constitution. As a consequence of this situation, CONAGEBIO has not been able to receive funds. In spite of this, CONAGEBIO has set up a subcommision to draw up norms for access to genetic and biochemical resources. A draft of the first part of the norms (dealing with general provisions and access permits) was submitted to CONAGEBIO in April 2000 and subsequently published. The second part of the norms deals with intellectual property and community intellectual rights. External funding support is being solicited to initiate the participatory process to develop these norms.

7.1.3. Philippines Executive Order 247 and Its Implementing Rules and Regulations (IRR)[126]

Background and overview

The Philippine ABS experience is significant firstly because it was the first country to introduce bioprospecting regulations, and secondly because it set a trend for such kinds of national system to be developed through processes of consultation with civil society organisations and indigenous and local communities.

Executive Order No. 247 became law in 1995. An Executive Order is different from an Act of the Congress in that it comes from the executive branch of government. This might suggest that it was developed without much civil society participation. On the contrary, it was the result of a consultative process involving a wide range of stakeholders.

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[124] Article 2.

[125] And that of another institution, the National System of Conservation Areas (SINAC).

[126] This section draws on the preliminary results of a project of the International Institute for Environment and Development project on Participation in Policies on Access to Genetic Resources and Traditional Knowledge.

The original suggestion for such a law came from the Philippine scientific community, in fact a network of natural product chemists. And it was these scientists working for universities who produced the first draft. They then invited a lawyer working for an NGO (Antonio La Viña) to revise it. This initial drafting group was then joined by the National Academy of Science and Technology, an institution affiliated to a government department. The first consultations were held with academics and university scientists, subsequently with government officials and scientists, and were then opened up to include other government departments, NGOs, organisations representing the indigenous communities, and the (mostly Philippine) private sector.

Shortly after the Executive Order was signed by President Ramos in May 1995 work began on the Implementing Rules and Regulations. This was the task of a new regulatory body established by EO 247 to enforce and implement its provisions: the Inter-Agency Committee on Biological and Genetic Resources (IACBGR). When La Viña was appointed DENR Under-secretary in January 1996 he was given overall responsibility for drafting the IRRs. Drafts were circulated for comments to government departments, universities, the national private sector, and also to some NGOs and POs. The final version was signed in June that year by the DENR Secretary.

The purpose of EO 247 is to regulate the prospecting of biological and genetic resources so that these resources are protected and conserved, are developed and put to the sustainable use and benefit of the national interest. Its scope covers the prospecting of all biological and genetic resources in public domain, including natural growths in private lands, intended to be utilized by both foreign and local individuals, entities, organizations, whether government or private.[127]

Core elements

(a) Prior informed consent

According to the IRRs prior informed consent refers to the consent obtained by the applicant from (i) the local community, (ii) indigenous people, (iii) protected area management board or (iv) private land owner concerned, after disclosing fully the intent and scope of the bioprospecting activity, in a language and process understandable to the community, and before any bioprospecting activity is undertaken[128].

Unlike Decision 391 and similar to the Costa Rica law, PIC is not required at the level of the State. Rather, applications for academic or commercial research relating to bioprospecting must be accompanied by a PIC Certificate issued by one (or more) of the above types of entity. Nonetheless, the amount of detail to be provided to the IACBGR before access can be granted amounts to a de facto PIC requirement.

[127] IRRs Section 3.
[128] IRRs Section 2.

(b) Mutually agreed terms

Permission for bioprospecting depends on a research agreement between the bioprospector and the government. For an agreement to be granted, a research proposal must be submitted to the government, with a copy submitted to any community that may be affected. There are two kinds of research agreement: the Academic Research Agreement (ARA) and the Commercial Research Agreement (CRA). Certain minimum terms apply to all agreements, while a number apply specifically to ARAs and CRAs.

The applicants for a research agreement of either kind must agree to a list of seventeen minimum terms and conditions.[129] These deal with such matters as:

- The deposit of voucher specimens and samples
- Access to specimens deposited in international genebanks for Filipinos and Philippine government entities
- Controls on export and transportation of biological and genetic material
- Periodic reports on the collections made
- The availability of commercial products derived from Philippine resources to the national government and local communities concerned
- Submission of a list of species collected, utilised or are currently developing
- Equitable sharing of immediate, medium and long-term benefits resulting from the bioprospecting activities among the government, communities concerned and the entity that is party to the research agreement
- The requirement that all bioprospecting research, including technological development of a product derived from the collected biological and/or genetic resources by any foreign individuals or entities be conducted in collaboration or cooperation with Philippine scientists from domestic institutions
- The requirement that technologies developed from research on Philippine endemic species be made available royalty-free for commercial and local uses to the national government
- The requirement that a separate agreement be made for the transfer of royalties, benefits and technologies

With respect to ARAs, an important condition is that collected data and materials are for the exclusive use of the parties and are not transferable to commercial entities unless the agreement is reclassified as a CRA.

As for CRAs, one of the most important conditions is that if a technology or a commercial product is developed and marketed out of the biological and/or genetic resources/specimens collected in the Philippines, an equity or remittance, in the amount to be mutually agreed upon by the parties concerned, shall be equitably shared with the Philippine government, or with the protected areas fund if the materials or resources come from the protected areas or with the concerned indigenous people, local community who gave the PIC and with the individual person who modified such material or resource that came from private property.

[129] IRRs Section 8.

(c) Roles, responsibilities and participation of stakeholders

Due to the comprehensive nature of the IRRs, the Philippine system is relatively explicit about the roles, responsibilities and participation of the various stakeholder groups. Thus, parties to ARAs envisaged by the Implementing Rules and Regulations include:

- Philippine universities and academic institutions;
- domestic governmental entities; and
- intergovernmental entities.

Parties to CRAs are:

- private persons;
- corporations; and
- foreign international entities.

In addition, the IACBGR consists of a broad cross-section of such groups and others. According to Section 6 of EO 247, the IACBGR is constituted by under-secretaries of two government departments: the Department of Environment and Natural Resources (DENR) and the Department of Science and Technology (DOST); and representatives of: the Departments of Agriculture, Health and Foreign Affairs, the Philippine academic science community, the National Museum, an NGO active in biodiversity protection, and a People's Organisation (PO) with membership consisting of indigenous cultural communities and/or their organisations to be selected by the PO community.

(d) In-situ and ex-situ conservation and sustainable use

The IRRs make few references to conservation or sustainable use of biodiversity. With respect to research agreements, it is stipulated that in the case of benefit-sharing arrangements, beneficiaries must include the local communities, indigenous peoples or protected areas concerned *and be allocated for conservation measures*. In the case of CRAs, benefits from commercialisation should go to the Integrated Protected Areas Fund if the biological or genetic material came from a protected area.

(e) Mechanisms for benefit-sharing, including technology transfer and joint research and development

According to the IRRs, benefit sharing refers to the sharing of results of bioprospecting activity and benefits arising from the utilisation or commercialisation of the biological or genetic resources fairly and equitably with the indigenous cultural community/local community/protected area/private land owner concerned and the national government by the Principal/Collector. Among the results and benefits that may be shared are payment for access to specimens, royalties, data, technology, capacity building, training, and joint research.

(f) Means to ensure the maintenance and protection of traditional knowledge, innovations and practices

According to the IRRs, Indigenous Cultural Communities or Indigenous Peoples (IPs) refers to a homogenous society identified by self-ascription and ascription by others, who have continuously lived as community on communally bounded and defined territory, sharing common bonds of language, customs, traditions and other distinctive cultural traits, and who, through resistance to the political, social and cultural inroads of colonization, became historically differentiated from the majority of Filipinos.

The preamble of EO 247 affirms that it is in the interests of the State's conservation efforts to identify and recognise the rights of indigenous cultural communities and other Philippine communities to their traditional knowledge and practices when this information is directly and indirectly put to commercial use. Similarly, the IRRs refer to the CBD and its recognition of the close and traditional dependence of many indigenous and local communities embodying traditional lifestyles on biological resources, and the desirability of sharing equitably benefits arising from the use of traditional knowledge, innovations and practices relevant to the conservation of biological diversity and the sustainable use of its components.

However, while EO 247 and the IRRs regulate access to biological and genetic resources on the ancestral lands and domains of indigenous cultural communities and indigenous peoples, they do not refer directly to the transfer to bioprospectors of associated traditional knowledge, innovations and practices. So while the interests of these peoples and communities in the resources existing on their lands and domains are supported through the PIC procedure and the requirement that benefits from commercialisation should be shared with them, procedures for strengthening their rights over their knowledge, innovations and practices are not apparently provided for.

(g) Intellectual property rights

The EO 247 hardly deals with IPRs, except that one of the duties and functions of the IACBGR is to study and recommend to the President and the Congress appropriate laws on the utilisation of biological and genetic resources including new laws on intellectual property rights.

(h) Tangible property

The preamble of EO 247 asserts that wildlife, flora and fauna, among others, are owned by the State and the disposition, development and utilisation thereof are under its full control and supervision. However, the State's sovereignty rights are not absolute, in that prospecting is only permitted within the lands of private owners and the ancestral lands and domains of indigenous cultural communities with the prior informed consent of such land owners and communities, obtained in accordance with communities' customary laws.

Progress in implementation

In terms of implementation of EO 247 and the IRRs, given the pioneering nature of both the process and the regulations themselves, one should not be too surprised that difficulties have arisen. There is for example concern that the rules and regulations are too complex and bureaucratic. This may well be true because since 1995 only two research permits have been issued.

7.1.4. The Draft Indian Biological Diversity Bill, 2000

Background and overview

The draft Biological Diversity Bill was drafted by the Ministry of Environment and Forests in 2000. It remains unclear at this stage whether or not the Bill will become law, and if it does to what extent it will be amended.

As with the Costa Rica Law, the scope of the Bill extends beyond access and benefit-sharing. The primary objective of the proposed legislation is to address the issue concerning access to genetic resources and associated knowledge by foreigners and equitable benefit sharing, but there are several other objectives as well. These are:[130]

(i) to regulate access to biological resources of the country with the purpose of securing equitable share in benefits arising out of the use of biological resources; and associated knowledge relating to biological resources,
(ii) to conserve and sustainably use biological diversity;
(iii) to respect and protect knowledge of local communities related to biodiversity;
(iv) to secure sharing of benefits with local people as conservers of biological resources and holders of knowledge and information relating to the use of biological resources;
(v) conservation and development of areas important from the standpoint of biological diversity by declaring them as biological diversity heritage sites;
(vi) protection and rehabilitation of threatened species;
(vii) involvement of institutions of self-government in the broad scheme of the implementation of the Act through constitution of committees.

In its present form, the Bill would set up institutions at national, state and local levels: The National Biodiversity Authority (NBA), the State Biodiversity Boards (SBBs), and the Biodiversity Management Committees. The NBA would be chaired by an eminent and knowledgeable person, and consist of eight representatives of government ministries, and five non-official members who would be specialists and scientists.

The NBA would have the power to grant or refuse authorisation from foreigners and foreign companies (including India-based firms not wholly owned and managed by Indians) to access biological resources occurring in India or associated knowledge for purposes of

[130] The Biological Diversity Bill, 2000 – Bill No. 93 of 2000, Statement of objectives and reasons.

research or commercial use.[131] It would also require authorisation for transfer to foreigners or foreign companies of results of research relating to any biological resources occurring in or obtained from India.[132] Government-approved collaborative research projects involving transfer or exchange of biological resources or related information between institutions, including Government sponsored institution of India, and such institutions in other countries are excepted from these rules.

The SBBs would be established by each of the state governments. The composition would be similar to that of the NBA, consisting of state-level counterparts. One of the functions of the boards would be to regulate commercial use or surveys or collections of biological material carried out *by Indians*.[133]

Biodiversity Management Committees would exist at the local level, which would deal primarily with promoting conservation, sustainable use and documentation of biodiversity including chronicling biodiversity-related knowledge. The Committees would be able to levy fees on bioprospectors.

Core elements

(a) Prior informed consent

There is no explicit reference to PIC in the Bill. To obtain approval from the NBA to carry out a collection of biological material and/or associated knowledge or to transfer research results abroad, an application must be submitted. But the Bill gives no details of the information that must be provided in the application.

Domestic collectors must give prior intimation to the relevant SBB of their intention to commercially use, collect or survey biological resources. The Boards have the right to prohibit or restrict such activities that are deemed to be detrimental or contrary to the objectives of conservation and sustainable use of biodiversity or equitable sharing of benefits arising out of such activity.[134]

(b) Mutually agreed terms

Section 21 requires the NBA to ensure that the terms and conditions subject to which approval is granted secures equitable sharing of benefits arising out of the use of accessed biological resources, their by-products, innovations and practices associated with their use and applications and knowledge relating thereto in accordance with *mutually agreed terms and conditions* between the person applying for such approval, local bodies concerned and the benefit claimers. With respect to the SBBs, the Bill provides no such requirement. Apart from the stipulation concerning conservation, sustainable use and equitable sharing, no other conditions are expressed.

[131] Chapter 5.
[132] Chapter 5.
[133] Chapter 6.
[134] Chapter 6.

(c) Roles, responsibilities and participation of stakeholders

The stakeholders referred to in the Bill are the foreign and domestic collectors, the central, state and local governments as represented by the new institutions to be set up, and the local people holding biodiversity-related knowledge. The central government has responsibilities much wider than ABS, including the development of national strategies, plans and programmes for the conservation and sustainable use of biodiversity.

(d) In-situ and ex-situ conservation and sustainable use

The links between ABS and conservation and sustainable use of biodiversity are to be achieved in two ways. First, a National Biodiversity Fund is to be created that will be used to channel benefit to claimants and for the conservation of biological resources and the development (including socio-economic development) of areas from where such biological resources or associate knowledge have been accessed. And applications for access made to SBBs as we saw earlier should not be detrimental or contrary to conservation, sustainable use and equitable benefit-sharing. It is also noteworthy that the national strategies, plans and programmes for which the central government is responsible may include promotion of in situ conservation and ex situ conservation of biological resources.

(e) Mechanisms for benefit-sharing, including technology transfer and joint research and development

The NBA has some discretion in determining the specific forms that benefit sharing should take, but the following are specifically referred to as obligations that industrial users be required to accept:

(a) grant of joint ownership of intellectual property rights to the National Biodiversity Authority or where benefit claimers[135] [sic] are identified, to such benefit claimers;
(b) transfer of technology;
(c) location of production, research and development units in such areas which will facilitate better living standards to the benefit claimers;
(d) association of Indian scientists, benefit claimers and the local people with research and development in biological resources and bio-survey and bio-utilization;
(e) setting up of venture capital fund for aiding the cause of benefit claimers;
(f) payment of monetary compensation and other non monetary benefits to the benefit claimers as the National Biodiversity Authority may deem fit.

Apart from the exception from the access regulations of certain collaborative research programmes, the Bill does little to encourage joint research involving foreign institutions. But to safeguard the interests of Indian researchers, it is proposed that there should be free access for Indian people to biological resources for domestic non-commercial use including for research purposes.[136]

[135] Defined by the Bill as "conservers of biological resources, their by-products, creators and holders of knowledge and information relating to the use of such biological resources, innovations and practices associated with such use and application."
[136] Statement of objectives and reasons.

(f) Means to ensure the maintenance and protection of traditional knowledge, innovations and practices

According to Chapter 9, the central government shall endeavour to respect and protect the knowledge of local people relating to biological diversity as recommended by the National Biodiversity Authority through measures, such as registration of such knowledge at the local, state or national levels, and other measures for protection, and a *sui generis* system. It is also stated that traditional knowledge is proposed to be protected.[137] However, no mechanisms for implementation are provided.

But the Bill does introduce measures to oppose patents on traditional knowledge (see below).

(g) Intellectual property rights

IPRs are linked to both access procedures and benefit-sharing. Chapter 2 requires prior permission of the NBA before an application for IPR protection[138] in or outside India of any invention based on any research or information on a biological resource obtained from India may be submitted. In cases where such approval is granted, the NBA may impose benefit sharing fee or royalty or both or impose conditions including the sharing of financial benefits arising out of the commercial utilisation of such rights.

The NBA may take measures to oppose the grant of IPRs in any country outside India on any biological resource obtained from India or knowledge associated with such biological resource.[139]

(h) Tangible property

The Bill in its current form is silent on such matters as national sovereignty and property rights relating to biological material and the lands on which such material exists in its natural conditions.

[137] Statement of objectives and reasons.
[138] Only Plant Variety Rights applied for in India are excepted since these are a matter for separate legislation.
[139] Chapter 4.

7.1.5. OAU African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources

Background and overview[140]

In March 1998, the Scientific, Technical and Research Commission of the Organization of African Unity (OAU/STRC) task force on community rights and access to biological resources met to develop a Draft Model Legislation on Community Rights and Access to Biological Resources as a basis for national legislation and an Africa-wide convention.
In June 1998, governmental delegates at the OAU Ministerial Meeting in Ouagadougou agreed to recommend that member governments:

(i) give due attention as a matter of priority to the need for regulating access to biological resources, community knowledge and technologies and their implication for intellectual property rights as entrenched in the international trade regime of the TRIPS Agreement;
(ii) adopt the draft Model Legislation on access to biological resources and call on Member States to initiate the process at national level involving all stakeholders in accordance with national interest and enacted into law;
(iii) initiate a process of negotiation among African countries to formulate and adopt an African Convention on Biological Diversity with emphasis on conditions for access to biological resources and protection of community rights; and
(iv) develop an African Common Position to safeguard the sovereign rights of Member States and the vital interests of our local communities and forge alliance with other countries of the South on the revision of TRIPS in 1999.

The draft model legislation was further developed and expanded by experts from East and Southern African countries meeting in June 1999 in Lusaka, Zambia. Seeking to implement in an appropriate way for the African continent CBD Articles 8(j), 15(1) and 15(2), the IUPGR, and the TRIPS requirement that plant varieties be protected under an IPR system, the result was a much more substantial document titled the African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources.

The African Model legislation, then, is not just an ABS instrument or an IPR one, but is both. Its 68 Articles are divided into seven parts, which are:

1. Objectives
2. Definitions and scope
3. Access to biological resources
4. Community rights
5. Farmers' Rights

[140] For the purpose of this study the following outline concentrates on the analytical description of those elements which aim at the implementation of the CBD´s access and benefit sharing stipulations. Accordingly, the plant variety related regulations of the OAU Model Legislation are not at the centre of the analysis presented here. It should be mentioned, however, that its stipulations regarding the protection of plant varieties have been criticised by various sources for being inconsistent and needing further elaboration.

6. Institutional arrangements
7. Plant breeders' rights

Its main aim is to ensure the conservation, evaluation and sustainable use of biological resources, including agricultural genetic resources, and knowledge and technologies in order to maintain and improve their diversity as a means of sustaining the life support systems. But there are 11 specific obligations in total which cover recognition of the rights of local communities and breeders, regulation of access to biological resources and community knowledge and technologies, promotion of benefit sharing mechanisms, and various others relating to participation, community rights, capacity-building, conservation and sustainable use of plant genetic resources, agricultural sustainability, and food security.

Core elements

(a) Prior informed consent

PIC is necessary for access not only to biological resources but also to the knowledge, innovations, practices or technologies of local communities. Consent should be acquired from the State and the concerned local communities, ensuring that women are also involved in decision making. Those seeking access to PIC must apply to the National Competent Authority, and must provide the following information[141]:

i) the identity of the applicant and the documents that testify to her/his legal capacity to contract;
ii) the resources to which access is sought, including the sites from which it will be collected, its present and potential uses, its sustainability and the risks which may arise from access to it;
iii) whether any collection of the resource endangers any component of biological diversity and the risks which may arise from the access;
iv) the purpose for which access to the resource is requested including the type and extent of research, teaching or commercial use expected to be derived from it;
v) description of the manner and extent of local and national collaboration in the research and development of the biological resource concerned;
vi) the identification of the national institution or institutions which will participate in the research and be in charge of the monitoring process;
vii) the identity of the location where the research and development will be carried out;
viii) the primary destination of the resource and its probable subsequent destination(s);
ix) the economic, social, technical, biotechnological, scientific, environmental or any other benefits that are intended, or may be likely to, accrue to the country and local communities providing the biological resource as well as the collector and the country or countries where he/she operates;
x) the proposed mechanisms and arrangements for benefit sharing;
xi) description of the innovation, practice, knowledge or technology associated with the biological resource; and

[141] Article 4.

xii) an environmental and socio-economic impact assessment covering at least the coming three generations, in cases where the collection is in large quantities.

This is very detailed compared to most other ABS instruments.

(b) Mutually agreed terms

Access permits may be academic research permits, commercial research permits, or commercial exploitation permits.[142] The difference between these types of permit is not made clear. Article 11 sets out the terms for all access applicants whether for academic or commercial purposes as follows:

1) The National Competent Authority shall subject all applications for access to a biological resource, a community innovation, practice, knowledge or technology to the *prior informed consent* of the concerned community or communities.
2) The National Competent Authority shall determine the appropriate conditions to be met under the written agreement referred to in Article 8, by *academic and research institutions, public agencies and inter-governmental institutions*.
3) The application for *access for research purposes* shall clearly state the objective of the research and the relation of the applicant to industry. Neither the sample nor the associated information shall be transferred without a material transfer agreement reserving the prior rights of the State and/or community or communities.
4) Where the institutions referred to in this Article change their activities to be predominantly the commercialisation of a biological resource, the National Competent Authority shall cause the conditions and terms to be varied accordingly

Collectors are required to comply with the following minimum requirements:

i) to adhere to a limit set by the National Competent Authority on the quantity and specification of the quality of the biological resource that the collector may obtain and/or export;
ii) to guarantee to deposit duplicates of, with complete field information on, each specimen of the biological resource or the records of community innovation, practice, knowledge or technology collected with the duly designated governmental agencies and, if so required, with local community organizations;
iii) to inform immediately the National Competent Authority and the concerned local community or communities of all findings from research and development on the resource;
iv) not to transfer the biological resource or any of its derivatives or the community innovation, practice, knowledge or technology to any third party without the authorization of the National Competent Authority and the concerned local community or communities;
v) not to apply for any form of intellectual property protection over the biological resource or parts or derivatives thereof and not to apply for intellectual property rights protection over a community innovation, practice, knowledge or technology without the prior informed consent of the original providers;
vi) to provide for the sharing of benefits;

[142] Article 12.

vii) access shall be conditioned upon a commitment to contribute economically to the efforts of the State and concerned local community or communities in the regeneration and conservation of the biological resource, and the maintenance of the innovation, practice, knowledge or technology to which access is sought;
viii) submit to the National Competent Authority a regular status report of research and development on the resource concerned and where the biological resource is to be collected in large quantities on the ecological state of the area; and
ix) abide by the relevant laws of the country particularly those regarding sanitary control, biosafety and the protection of the environment as well as by the cultural practices, traditional values and customs of the local communities.

As with PIC, these terms apply to all collectors and collecting institutions whether national or foreign.

(c) Roles, responsibilities and participation of stakeholders

The stakeholders referred to in the Model Legislation in the context of ABS are as follows:

- The State as represented by the National Competent Authority
- Collectors
- Local communities including farming communities, and their women members
- Academic research institutions, public agencies and inter-governmental institutions

It is the first three whose roles and responsibilities are most clearly delineated. For example, with respect to the National Competent Authority, its duties as set out in Article 58 are to:

i) create and operate a regulatory mechanism that will ensure effective protection of Community Intellectual Rights and Farmers' Rights, and the regulation of access to biological resources;
ii) carry out the process of consultation and participation of local communities, including farming communities, in the identification of their rights as provided for under the customary practices and laws of the communities;
iii) identify types of Community Intellectual Rights and Farmers' Rights;
iv) identify and define the requirements and procedures necessary for the recognition of Community Intellectual Rights and Farmers' Rights;
v) develop criteria and mechanisms to standardise procedures;
vi) develop a system of registration of items protected by Community Intellectual Rights and Farmers' Rights according to their customary practices and law;
vii) issue licenses for the exploitation and commercialisation of biological resources, including protected species, varieties or lineages, and community innovations, practices, knowledge and technologies;
viii) identify relevant technical institutions that will assist local communities, including farming communities, in the categorisation and characterisation of their biological resources, innovations, practices, knowledge and technologies.

With respect to the local communities, the State is required to respect their rights over the following[143]:

i) their biological resources;
ii) the right to collectively benefit from the use of their biological resources;
iii) their innovations, practices, knowledge and technologies acquired through generations;
iv) the right to collectively benefit from the utilisation of their innovations, practices, knowledge and technologies;
v) their rights to use their innovations, practices, knowledge and technologies in the conservation and sustainable use of biological diversity;
vi) the exercise of collective rights as legitimate custodians and users of their biological resources.

Plant breeders are another important stakeholder group, though they are not involved in the ABS sections of the legislation.
Several other institutions are established to implement the legislation as a whole. These are

- A National Inter-Sectoral Coordination Body
- A Technical Advisory Board
- A National Information System
- A Community Gene Fund

(d) In-situ and ex-situ conservation and sustainable use

The legislation applies to biological resources in both in situ and ex situ conditions and has among its objectives to promote the conservation, evaluation and sustainable utilisation of biological resources. But it does not deal with conservation or sustainability issues in great depth.

(e) Mechanisms for benefit-sharing, including technology transfer and joint research and development

Benefit-sharing is defined as "the sharing of whatever accrues from the utilisation of biological resources, community knowledge, technologies, innovations or practices". But mechanisms for benefit-sharing are not well elaborated; neither are the various possible forms that benefit sharing might take detailed. However, the PIC procedures require applicants to inform the National Competent Authority of the intended or expected benefits.

Article 12 stipulates that the State and the community or communities shall receive a share of the earnings derived from when any biological resource and/or knowledge collected generates, directly or indirectly, a product used in a production process. At least 50 percent of such benefits are to be channelled to the concerned local community or

[143] Article 16.

communities in a manner which treats men and women equitably. These benefits are to be guaranteed through a written contract between the State and the collector.[144]

(f) Means to ensure the maintenance and protection of traditional knowledge, innovations and practices

The African Model Legislation is quite ambitious in its treatment of traditional knowledge, innovations, practices and technologies. It adopts two terms: community rights and Farmers' Rights.

Community rights include the rights of communities (a) to their knowledge, innovations, practices and technologies, as well as to collectively benefit from their utilisation, and to use them in the conservation and sustainable use of biodiversity, and (b) to exercise their collective rights as legitimate custodians and users of their biological resources, and to collectively benefit from their use. The State recognises and protects these rights as they are enshrined and protected under the norms, practices and customary law of the concerned local and indigenous communities.[145]

According to Article 26, Farmers' Rights include the right to:

a) the protection of their traditional knowledge relevant to plant and animal genetic resources;
b) obtain an equitable share of benefits arising from the use of plant and animal genetic resources;
c) participate in making decisions, including at the national level, on matters related to the conservation and sustainable use of plant and animal genetic resources;
d) save, use, exchange and sell farm-saved seed/propagating material of farmers' varieties;
e) use a new breeders' variety protected under this law to develop farmers' varieties, including material obtained from genebanks or plant genetic resource centres; and
f) collectively save, use, multiply and process farm-saved seed of protected varieties.

(g) Intellectual property rights

Apart from the section of the legislation dealing with plant breeders' rights, Article 9 states that patents over life forms and biological processes are not recognised and cannot be applied for. Consequently, the collector cannot apply for patents over life forms and biological processes relevant to the regulation of access and use of a biological resource, community innovation, practice, knowledge and technology, and the protection of rights therein. Neither can any other form of IPR protection be applied for in respect of biological resources or parts or derivatives thereof, or over a community innovation,

[144] Article 22.
[145] Article 16.

practice, knowledge or technology without the prior informed consent of the original providers.[146]

(h) Tangible property

The African Model Legislation does not mention any other property than intellectual property. In common with – and possible inspired by – Third World Network's Community Intellectual Rights Act, the legislation avoids the word property in its description of the rights of local communities. On the other hand, holders of community rights are legitimate custodians and users of their biological resources. Nonetheless, 'local community' is defined as a human population in a distinct geographical area, *with ownership over its biological resources, innovations, practices, knowledge, and technologies* governed partially or completely by its own customs, traditions or laws.

7.2. Contracts and other legal agreements

7.2.1. Third World Network Model Contract between the Collector and the Government

The Third World Network's Contract between the Collector and the Government deals with the collection of biological resources, specifically the procedures and conditions for authorisation of collections and the sharing of benefits.

There is no explicit reference to PIC in the Contract. However, the collector is required to provide certain information, namely:

- the types of material to be collected in terms of species and quantities;
- the plan for the evaluation, storage and use of the material collected;
- the use or uses to which the collected material will be put; and
- the benefit the host country/community may derive from the collection of the germplasm;
- financial arrangements for the collection;
- the names, address and particulars of their collaborators;
- details of any agreement with said collaborator, and the names of persons assisting in the said collection and the particulars of two persons nominated by the collaborators to accompany the collecting mission.

The terms that collectors must accept consist of actions that must be carried out during and after collection. For example, during collection the collector must collect no more than 100-150 grams of the resource for initial screening[147], and must inform local communities about the purpose of the mission, how and where samples of the collected biological resources could be obtained by the local community, and their entitlement to obtain duplicate samples from the collector. One of the obligations after collection is to inform the appropriate authorities about any impending threat to plant populations, or evidence of accelerated genetic erosion, and make recommendations for remedial action.

[146] Article 8.
[147] Unless there is written permission to collect more than this.

Benefits to be shared are both monetary and non-monetary. With respect to the former, where natural product extracts are supplied by the collector to commercial organisations, 60 percent of any income will be paid to local communities or the government, as appropriate. And at least 51 percent of royalties obtained from creation or invention of a marketable product will likewise be transferred to a local community or the government. Technology transfer is not mentioned, but joint research is a requirement in that collaborators must join in the work in the laboratories or trial sites where any specimen collected is the subject of any experimentation or study.

Apart from preventing improper patenting, there are no provisions concerning maintenance and protection of traditional knowledge, which is the subject of a complementary model law developed by TWN: the "Community Intellectual Rights Act".

As for IPRs, the language is not entirely clear but patents cannot be filed anywhere in respect of collected specimens or their parts, properties, activities or derivatives which utilise the knowledge of indigenous groups or communities.

7.3. Codes of conduct and voluntary guidelines

Ethical guidelines (or codes of ethics) are statements that clarify what is ethically acceptable behaviour for scientists when performing their work. Although they have no legal effect, they reflect a consensus among concerned scientists. Consequently, the expectation is that they will be observed. Declarations may be quite similar but tend to express general principles rather than specific guidelines.

In 1988, the International Society of Ethnobiology established a set of principles for ethnobiological research involving indigenous peoples. The Declaration of Belém was the first such statement to call for compensation for native peoples for the utilisation of their knowledge and their biological resources.

Since then a growing number of ethical guidelines and declarations of scientific and professional organisations have been developed. Two good examples are the International Society of Ethnobiology's "Code of Ethics and Standards of Practices", and the Biodiversity and Ethics Working Group of Pew Conservation Fellows' "Proposed Guidelines for Researchers and Local Communities Interested in Accessing, Exploring and Studying Biodiversity".

7.3.1. The ISE Code of Ethics and Standards of Practice

At its Fourth Congress in 1994, the International Society of Ethnobiology (ISE) agreed to develop a code of ethics, and invited a Maori lawyer[148] to develop a draft. The draft document was debated at two further congresses and a final version was adopted at the ISE's sixth congress in New Zealand in 1998.

The purposes of the Code of Ethics are twofold:

[148] Mr. Maui Solomon.

1. to optimise the outcomes and reduce as much as possible the adverse effects of research (in all its forms, including applied research and development work) and related activities of ethnobiologists that can disrupt or disenfranchise indigenous peoples, traditional societies and local communities from their customary and chosen lifestyles; and
2. to provide a set of principles to govern the conduct of ethnobiologists and all members of the International Society of Ethnobiology (ISE) engaged in or proposing to be engaged in research in all its forms, especially collation and use of traditional knowledge or collections of flora, fauna, or any other element found on community lands or territories.

Among the principles established by the Code are:

- full disclosure
- prior informed consent and veto
- confidentiality
- respect
- compensation and equitable sharing
- restitution

The Standards of Practice, which are incorporated as part of the Code, elaborate on these principles with some fairly explicit procedures pertaining to research, collections, databases and publications. All such activities are conditional upon the agreement of the potentially affected communities subject to full disclosure, prior informed consent and their approval with respect to:

- the relevant equitable benefit-sharing from, compensation for, restitution for, and ownership of the collection, database or publication; and
- all potential uses of such research, collections, databases or publications, including derivative forms they may take such as films, videotapes, audiotapes, public broadcasts, translations, and communication through the electronic media, including the internet or world wide web.

With respect to intellectual property rights, the Standards of Practice stipulate that an understanding or agreement must be reached between the person or organization undertaking such [ethnobiology] project and each community or person who significantly contributed to such collection, database or publication project regarding attribution, credit, authorship, co-authorship, and due acknowledgement to contributors.

7.3.2. The Pew Conservation Fellows' Proposed Guidelines for Researchers and Local Communities Interested in Accessing, Exploring and Studying Biodiversity

The Proposed Guidelines are intended to apply to scientific research on biodiversity whether commercial or non-commercial and extractive or non-extractive. The underlying principles are as follows:

- Research should be an educational process leading to mutual learning among researchers and the collaborating individuals, communities and institutions.
- Just as the propriety rights of scientific knowledge are well established and respected, such rights are due to the producers and providers of traditional knowledge and contemporary innovations from local communities.
- Research should be based on respect for the local cultural values and norms.
- Benefits should accrue to all partners in a fair and equitable manner.
- Informed consent should be obtained within limits of practicality.

The Guidelines relate specifically to initial disclosure of information; involvement and negotiation; compensation and other terms of access; and the actions of professional societies, academic institutions and funding agencies. As for intellectual property rights and benefit-sharing, the Guidelines propose that the community's right to any organism or part thereof extracted by any biotechnological or other method must not be exhausted merely by publication or collection. The community can assign these rights or associated intellectual property rights to anyone it feels appropriate.

They also state that professional societies, academic institutions and funding agencies should help set up a system of registration of innovations / practices so that IPRs of local communities or innovators are not compromised.

7.3.3. Swiss Draft Guidelines on Access and Benefit Sharing Regarding the Utilization of Genetic Resources

The Swiss draft Guidelines on Access and Benefit Sharing Regarding the Utilization of Genetic Resources were initially presented in outline form at the first meeting of the Panel of Experts on Access and Benefit-sharing in October 1999. The completed draft was then circulated at the fifth meeting of the Conference of the Parties to the CBD in May 2000.

According to the Introduction, the draft Guidelines' primary function is to serve as a point of reference for all stakeholders involved in access to genetic resources and their utilisation, and in the fair and equitable sharing of benefits arising from their utilisation.

The scope of the Guidelines includes genetic resources covered by the CBD but not those covered by the FAO Global System for the Conservation and Utilization of Plant Genetic Resources.

Article 11 deals with PIC but does not define the concept. Neither does it suggest any information that should be provided in order to make the consent 'informed'. Each providing country will have to set up a transparent PIC system. Consent will have to be acquired from the 'donor' (the agency representing the provider country) and indigenous and local communities. Oddly, PIC is treated as being primarily a responsibility for providing countries.

The Guidelines state that the following activities must be carried out on mutually agreed terms:

1. Scientific research and development by users with the participation of the providing country
2. The making available of the findings of scientific research and development to the stakeholders involved in the transfer of the genetic resources in question
3. The sharing of benefits arising from the commercialisation and other utilisation of genetic resources between the user and the stakeholders involved in their transfer

With respect to activity 1, Annex A provides some possible elements for MATs:

- Regular reporting of users on the state of the relevant scientific research and development on genetic resources;
- Collaboration in education and training;
- Collaboration in scientific research and development programs;
- Participation in product development;
- Joint ventures;
- Co-authorship of publications;
- Trust Funds.

Concerning activity 2, the following elements are suggested in Annex B:

- Regular reporting of users on the state of the relevant scientific research and development on genetic resources;
- Admittance to ex situ facilities of genetic resources and to databases;
- Admittance to taxonomic, biochemical, ecological, horticultural and other information and data;
- Joint ventures;
- Co-authorship of publications.

Possible MAT elements regarding activity 3 presented in Annex C include:

- Transfer of knowledge and technology, in particular knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilisation of biological diversity.
- Collaboration in education and training;
- Collaboration in scientific research and development programs;
- Participation in product development;
- Joint ventures;
- Admittance to ex situ facilities of genetic resources and to databases;
- Joint ownership of patents and other relevant forms of intellectual property rights;
- Providing means for a fund at the local, national, regional or multilateral level;
- Fee per sample collected or otherwise acquired;
- Licence fee in case of commercialisation;
- Royalties.
- Trust Funds

The Guidelines barely mention intellectual property, except that holders of IPRs based on genetic resources are encouraged to share them with the stakeholders that contributed to the conservation of these genetic resources or to the scientific research and development based on these genetic resources.

8. Analysis

This analysis focuses mainly on the ABS laws and legislative frameworks presented in Chapter 7 Section (a). It should be emphasised from the start that hardly any of these instruments have been fully implemented. Therefore it is still too early to provide definitive conclusions concerning the effectiveness of the ways they deal with the various elements *in actual practice*. Nevertheless, some provisional remarks can be made with respect to the potential advantages and disadvantages of the provisions relating to the elements.

8.1. Prior informed consent

The instruments vary in terms of (a) whether or not they define PIC, and (b) from whom PIC must be obtained: the competent national authority, the local community or landowners, or more than one of them.

Concerning the former, the OAU Model Law provides the most details about the information that would be required for the consent to be properly informed. This extent of information should not be too onerous for applicants. The other instruments appear somewhat deficient regarding this particular element.

With respect to the latter, Decision 391 requires applicants to acquire the prior informed consent only of the State, while the Philippines Executive Order 247 and the Costa Rica Biodiversity Law do not require the State to give its prior informed consent at all, though of course the approval of its representative body is still necessary for access to be granted. Applicants under the OAU Model Law requires PIC of both the State and the local communities. It seems fair that local communities should have the opportunity to be fully informed about access applications, especially when applicants also desire to acquire traditional knowledge related to the resources of interest to them.

8.2. Mutually agreed terms

With some instruments the terms of access vary according to whether the intended bioprospecting is for academic or commercial purposes. This is the case for the Filipino regulations and the African Model Law. It seems reasonable that the terms should be less demanding for academic research than for commercial research. The problem is that drawing a distinction between such kinds of research is not always easy to do. On the other hand, subjecting basic research to onerous terms may be detrimental to the national interest since it may inhibit the carrying out of such research, especially if the regulations apply equally to domestic and foreign applicants.

8.3. Roles, responsibilities and participation of stakeholders

Again, the different instruments vary in the extent to which the various stakeholders are referred to and have their roles and responsibilities clearly delineated. It is not clear at

this stage whether it is better to describe the roles of each stakeholder comprehensively or not to do so and leave room for more flexibility.

8.4. In-situ and ex-situ conservation and sustainable use

Consistency with the CBD requires that conservation and sustainable use – with benefit-sharing – should be treated as being the most important objectives of any ABS regulations. Access to genetic resource should go further than simply not harming biodiversity but should actually promote conservation and sustainable use. Among such possible means of supporting conservation and sustainable use referred to in the instruments are through access to technologies appropriate to conservation and sustainable use, research, the earmarking of access fees or benefits from commercial use for the national protected areas system, and the creation of a fund.

8.5. Mechanisms for benefit sharing, including technology transfer and joint research and development

ABS regulations should be a component in a country's strategic plan for sustainable development. Therefore benefits derived from the scientific and commercial use of biodiversity should not just be for the short term, but for medium and long term capacity-building as well. However, not all the instruments place any great emphasis on technology transfer and joint research. Decision 391 is quite detailed in this respect as it seeks to build such capacity at local national and regional levels. The Indian Biological Bill's mechanisms for benefit-sharing can be considered quite demanding. It is possible that foreigners may be deterred from seeking access though only time will tell whether such a concern is well-founded. The African Model Law provides few specifics concerning the nature of the benefits to be shared except monetary benefits. It is possible that non-monetary benefits such as technology transfer and joint research may actually be preferable to cash transfers.

8.6. Means to ensure the maintenance of traditional knowledge and innovations

All of the instruments consider the maintenance of traditional knowledge to be important. But mechanisms to implement such a priority tend to be lacking. The instruments offer a range of approaches such as requiring benefits to be shared with traditional knowledge holders and their communities, making communities parties to access contracts, and the development of a *sui generis* system to protect the intellectual rights of traditional communities. Generally such *sui generis* systems are not well elaborated. But this is to be expected. Since there are few existing models for such systems, developing an effective system will require a great deal of consultation with both legal experts and potential users. This is likely to take quite a long time to carry out, perhaps longer than it takes to develop the basic ABS framework. The Costa Rica approach, then, may be the most pragmatic one.

8.7. Intellectual property rights

While the Filipino ABS regulations deliberately avoid IPRs, some of the other instruments place great emphasis on this topic. Some ABS frameworks are premised on the conviction that expansive intellectual property rights encourage exploitative behaviour. Therefore, the right to acquire IPR protection needs to be constrained. Other regulations start with the same premise but rather than place limits on IPRs, they introduce certain administrative requirements into the IPR system to make it more supportive of the ABS regulations. Such is the case of Decision 391, which requires IPR applicants to include a copy of the access contract. The Costa Rica Law both constrains the rights and introduces administrative requirements into the IPR system. It is not clear which particular approach is the best one. There is a danger that limiting the freedom of companies and researchers to secure IPR protection will drive applicants away. On the other hand, there is no doubt that some patents are improperly awarded since the inventions they describe are almost the same as the traditional knowledge or genetic resource acquired by the patent-holding institution. It does seem reasonable, then to deal with IPRs in some way or another in ABS regulations.

8.8. Tangible property

National sovereignty over genetic resources does not mean that individuals and groups cannot own the land on which the genetic resources exist or the biological material in which they may be discovered. Some of the instruments explicitly separate ownership of genetic materials from biological resources and land.

Part III: Proposals and Recommendations

This final part of the study provides some final conclusions and recommendations on the basis of the findings from the discussion on key issues presented in Part I and on the overview, inventory and analysis of the existing and proposed ABS regulations described in Part II.

It begins by providing some examples of proposals and recommendations provided by members of stakeholder groups (Chapter 9). Chapter 10 provides a brief discussion on policy approaches. More specific policy recommendations are provided in Chapter 11.

Before going further it is important to repeat the point made earlier, that very few ABS regulations have been fully implemented, making it difficult to evaluate their effectiveness reliably. Nonetheless, it should be possible to identify principles, guidelines, procedures and rules that are likely to be successful, and which warrant the consideration of all CBD Parties. Part III is an attempt to do this.

9. Normative recommendations formulated by stakeholders

9.1. Industry

At the 5th meeting of the Conference of the Parties to the CBD in May 2000, the Japan Bioindustry Association circulated a policy statement on access to genetic resources and benefit-sharing.[149] The intention was for the statement to be useful as a source of voluntary guidelines. The statement is not very detailed but emphasises the following:

1. That prior informed consent can be effected through various types of agreement, such as purchase agreements, contract research agreements, and joint research agreements. The Japan Bioindustry Association considers joint research to be preferable, but depending on whether providers have the ability and willingness to participate.
2. That non-monetary benefits such as education, training and technology transfer are especially important.
3. That provider country obligations to facilitate access for environmentally-sound uses by users and not to impose undue restrictions should be supported through 'a pragmatic and effective procedure'.

The Danish life-science corporation, Novo Nordisk, has probably gone further than most companies in the ABS context by making public commitments concerning prior informed consent, mutually agreed terms, *and patenting*. The company's statement, "Novo Nordisk requirements for the use of and access to genetic resources"[150], states that:

> Novo Nordisk will proactively contribute to the implementation of the objectives of the Convention. In order to do this we have formulated the following guiding principles, which we will do our utmost to live up to for all material covered by the CBD (the CBD came into force in December 1993):
>
> - No microbial strain or natural material obtained without proper prior informed consent from the country of origin will be included in screening.
> - All materials screened should be covered by contracts and/or material transfer agreements.
> - Conditions should be on mutually agreed terms and should include benefit sharing, intellectual property rights and technology transfer arrangements where appropriate.
> - Contracts should be cleared by the proper authority in the country of origin.
> - The country of origin will be mentioned in relevant publications and patent applications.

In 2000, the European Chemical Industry Council (CEFIC) issued a public statement titled "The Chemical Industry Comments on the Legal Protection of Traditional Knowledge and Access to Genetic Resources".[151]

With respect to access to genetic resources, CEFIC states as follows:

[149] http://www.jba.or.jp
[150] http://www.novo.dk
[151] http://www.cefic.org

> In order to support and promote the objectives of the CBD and facilitate the decision-making of companies in respect of access to genetic material, CEFIC suggests that the implementation texts [i.e. the national ABS regulations] should specifically:
>
> - create conditions to facilitate access to genetic resources for environmentally sound uses and not impose restrictions that run counter to the objectives of the CBD,
> - specify any mandatory requirements set by the country for obtaining mutually agreed terms and prior informed consent, or the clear and unambiguous indication that such conditions are not mandatory in the country,
> - provide rules setting out minimum requirements in respect of the sharing, in a fair and equitable way, of the results of research and development and the benefits arising from the commercial and other utilisation of genetic resources and any other conditions to obtain mutual agreement,
> - designate a responsible contact point in each country where companies could address their requests.

While this adds little to Article 15 of the CBD, it makes clear that industry has a preference for legal clarity with respect to its rights and responsibilities, and that access procedures be established so that companies know who to apply to and what the conditions are.

As with the Japan Bioindustry Association, the recommendations are targeted at provider countries. If these statements are anything to go by, industry in developed countries sees no need for supportive user measures to be implemented by countries to which genetic resources are sent. This contrasts with the CBD-COP, the Expert Panel on Access and Benefit-sharing, and many NGOs, which all emphasise the need for 'user measures' in countries where genetic resources are used.

9.2. Scientists and scientific organisations

Few scientists and scientific organisations have published recommendations concerning ABS. One of the few is the Natural History Museum of London, whose trustees in 1996 approved a bioprospecting policy. The policy states in part that:

> In drawing up bioprospecting agreements, we will take account of the rights, interests and practices of indigenous peoples. We expect that, by working co-operatively with local organisations, we will help to strengthen the taxonomic capacity of the country providing the biological resources."[152]

However, since then many scientists involved in basic non-commercial research oriented, for examples to education and taxonomy, have expressed concern that regulations for non-commercial research not be excessively restrictive. They have also suggested that some of the first generation of ABS regulations may actually hinder basic research, and that this is likely to be detrimental to the interests of the countries providing the access.

[152] Natural History Museum 'Bioresource: bioprospecting policy', 1996.

9.3. Ex-situ-collections

The International Agricultural Research Centres operating under the aegis of the Consultative Group on International Agricultural Research (CGIAR) have become concerned about ABS and the effects of intellectual property rights on the global circulation of genetic material. Two of these centres, the International Maize and Wheat Improvement Centre (CIMMYT) and the International Plant Genetic Resources Institute (IPGRI) have produced policy statements focusing mainly on intellectual property rights.[153] IPGRI's has a section dealing specifically with mechanisms for access and benefit-sharing. It states as follows:

1. IPGRI supports the establishment of an effective multilateral system for the exchange of plant genetic resources that supports the conservation, development and sustainable use of plant genetic resources through, inter alia, benefit sharing and the recognition of Farmers' Rights in accordance with the provisions of the FAO-International Undertaking.
2. IPGRI also adheres to the use of Germplasm Acquisition Agreements and Material Transfer Agreements for the acquisition and distribution of germplasm and related information, and the use of bilateral agreements as a mechanism for recording terms of access and benefit sharing, as appropriate.
3. IPGRI supports efforts to bring about an equitable balance between intellectual property rights and the protection of traditional knowledge in relation to the use of plant genetic materials, with a view to foster conservation, sustainable use and benefit sharing.

The emphasis on multilateral systems is different from the CBD's general orientation towards bilateralism, which is based on recognition of national sovereignty. Ideally, ABS regulations should accommodate the interdependency of countries with respect to genetic resources for food and agriculture, a situation that differs from genetic resources for the pharmaceutical industry. In the latter case providers and users can more easily be differentiated. Providers tend to be – though are by no means always – biodiversity-rich developing countries. Users are most commonly research-based firms that operate primarily in the developed countries.

9.4. Representatives of indigenous peoples' organisations

Indigenous peoples tend to be quite wary about bioprospecting. While they have not issued statements specifically on ABS, a number of declarations resulting from international conferences organised by indigenous peoples have favoured a moratorium on bioprospecting. While this is unlikely to be a view shared by all indigenous groups around the world, it evidences the lack of confidence many indigenous groups feel, both in ABS regulations and in the willingness of companies to treat them fairly. Clearly confidence-building measures are needed including regulations based on close collaboration with indigenous groups and their representative organisations.

[153] CIMMYT's is titled 'International Maize and Wheat Improvement Centre Policy on Intellectual Property'. (See http://www.cimmyt.org). IPGRI's is 'IPGRI Policy on Intellectual Property' (see http://www.ipgri.cgiar.org).

9.5. Civil Society Organisations

Perhaps the most influential and well-informed proposals on ABS emanating from civil society are produced at meetings of the Global Biodiversity Forum (GBF). The GBF was originally proposed by the International Union for Conservation of Nature, World Resources Institute and the United Nations Environment Programme. The GBF holds sessions immediately prior to inter-governmental meetings relating to biodiversity such as the CBD-COPs[154] and is usually convened by the above organisations and other (mostly non-governmental) organisations. GBF meetings usually provide statements that are presented at these meetings.

The 15th session of the GBF was held in Nairobi in May 2000 just before COP-5. One of the workshops, organised jointly by a wide range of stakeholders[155], was on "Instruments for Access and Benefit-Sharing from Genetic Resources". In the context of developing and implementing effective and equitable access and benefit sharing measures, the following conclusions and recommendations are provided:

1 As a matter of urgency, all Parties should designate a national focal point and/or competent national authority with a clear mandate to determine matters related to access and benefit sharing.
2 Access legislation in countries providing genetic resources should be flexible in order to avoid high transaction costs and implementation difficulties. Some 50 countries are currently developing such measures. To assist Parties in this regard, the Secretariat and other relevant bodies should be directed to undertake review of existing national measures, in order to identify successful approaches and potential problems.
3 As recognized by the Expert Panel on Access and Benefit-sharing, regulatory flexibility in countries providing genetic resources is directly related to the adoption of complementary measures in countries in which genetic resources are used. In particular, legal and other measures should ensure that genetic resources have been obtained in compliance with applicable access legislation of the providing country. Development of such measures is essential to facilitate cooperation between provider and user countries in the enforcement of ABS measures.
4 Access legislation and other measures should fully incorporate effective protection of the traditional knowledge of indigenous and local communities as mandated by Article 8(j) and related provisions.
5 As recognized by the CBD Expert Panel on Access and Benefit-sharing, Parties should take into account and allow for the development of a multilateral system to facilitate access and benefit-sharing for plant genetic resources for food and agriculture in the process of developing ABS measures. In doing so, Parties' ABS measures should provide flexibility to remain members to join regional and/or crop-based systems of exchange.
6 In order to ensure that access legislation meets all objectives of the Convention and is consistent with Parties' national priorities, such legislation and other measures

[154] Conference of the Parties.
[155] The joint organisers were: World Resources Institute, International Plant Genetic Resource Institute, The Royal Botanic Gardens – Kew, Indigenous Peoples Biodiversity Network, Peruvian Society for Environmental Law, Indonesian Indigenous Peoples National Organisation, Kechua-Aymara Association for Sustainable Livelihoods, and World Wide Fund for Nature.

should be developed within the context of national biodiversity strategies and action plans.

7 In order to build the consensus and capacity required for effective ABS policies and measures – and to promote fairness and equity – development of ABS measures must systematically incorporate the participation of a wide range of stakeholders.

8 Parties should recognize the importance of non-binding measures complementary to legislation, such as mediation and dispute resolution mechanisms, codes of conduct, guidelines, model legislation and model contracts.

9 The COP should adopt and Parties should heed the conclusions and recommendations of the CBD Panel of Experts on Access to Genetic Resources, and should provide the mandate and funding for continued work by the Panel.

While the statement contains many noteworthy conclusions and recommendations, perhaps the most significant ones that are not well covered in similar documents are: (a) that regulatory flexibility in provider countries is linked to complementary user measures in user countries, and that such measures are essential for cooperation to enforce ABS measures; and (b) that Parties should take into account and allow for the development of a multilateral system to facilitate ABS relating to plant genetic resources for food and agriculture. Therefore, there should be sufficient regulatory flexibility to allow participation in international systems of exchange of crop germplasm in the interests of food security.

10. Developing effective policy approaches to access and benefit-sharing

ABS regulations should accommodate the interests of all groups that have a legitimate stake in how the system is designed, and not just the most economically-dominant groups. This is not just a matter of justice but also of effectiveness. Top-down regulatory approaches that lack the support of the local communities are bound to fail. ABS regimes need to embody a decentralised approach that empowers democratic local-level institutions with rights to control access, and that encourages their participation. Channelling benefits from commercial use of genetic resources to such institutions is much more likely to result in favourable outcomes than the more top-down conservation approaches that are still prevalent in many countries.

But ultimately, regulations are judged not so much by what they say but whether they actually fulfil their objectives in the real world. Bearing this important point in mind, the purpose of this chapter is to assist in the design of effective ABS systems by identifying those expectations that are likely to be fulfilled and those that probably cannot be.

10.1. Unrealistic expectations of an ABS system

Starting with the unrealistic expectations, a number of issues need to be understood.

First, the idea that individual countries will enjoy a markedly improved bargaining position because they have stringent ABS regulations in place is probably unrealistic. This is the case for genetic resources both for pharmaceutical use and for food and agriculture. And while the situation may improve for countries acting together to create a quasi-cartel (as with the Andean Community countries), expectations should not be pitched too high. There are several reasons to doubt that setting up such 'genetic resource OPECs' is feasible. First, many species have an extremely wide geographical distribution. Second, genetic resources are reproducible and highly portable, making it difficult to track their movements. Third, it is information within the resource rather than the resource itself that has value. Fourth, whereas oil is a single natural resource with proven value, groups of countries would be trying to control not one but many resources almost none of which have any significant commercial applications. And it can take many years after discovering a piece of genetic information from, say, a plant to identify a genuine commercial application, especially if this would require the information to be combined with other pieces of genetic information from different species and even (biological) kingdoms. At the same time, these countries would continue needing to access other resources from non-cartel members, especially genetic resources for food and agriculture.

Second, it is highly unlikely that any ABS system will eradicate the unauthorised collection of genetic material and use of traditional knowledge. The best that can be hoped is that it will reduce abuses.

Third, biodiversity is not 'green petroleum'. No country will become fabulously wealthy no matter how effectively it harnesses its genetic endowments and biodiversity-related traditional knowledge for development.

10.2. Realistic expectations of an ABS system

Having made the above points, carefully designed ABS regulations can undoubtedly provide some positive outcomes, especially with supportive measures in place in user countries. While it is the task of Chapter 11 to provide specific recommendations, the rest of this chapter offers some general points concerning realistic expectations.

ABS systems can and should help biodiversity-rich countries to increase their share of the benefits arising from commercial use of their genetic resources while creating incentives to conserve and sustainably utilise the resource base. This should be their overriding objective. And with well-crafted policies in place, such an aspiration is a realistic one.

But biodiversity-rich countries cannot achieve this merely by exporting biological samples and extracts. Rather they should aspire – either as alternatives to, or in combination with, the export of samples and extracts – to: (1) improve and integrate their life-science research and development and production capacities; and (2) to identify, develop and market high-value primary and semi-processed products.

For many biodiversity-rich developing countries, option 2 is more likely to be a feasible option, at least in the short term. This is because pursuing option 1 demands substantial investments in training, education, and advanced R&D facilities. While some developing countries are relatively advanced in science, technology and industrial development, many others are not and cannot expect improvements to take place overnight.

Efforts to enhance the scientific and technological bases of all developing countries requires appropriate regulatory and legal frameworks providing rewards and incentives for innovation and investment, of which ABS regulations must be a central component. There are limits to what ABS regulations can achieve. But being realistic about ABS does not mean being unambitious.

The challenge for current developing country providers of genetic resources is to exploit their legal control by:

1. identifying technological fields or industrial or market sectors where they may be able to compete internationally;
2. acquiring and/or channelling the necessary investments to develop and market high value products; and
3. putting in place the institutional reforms needed to ensure that efforts to conserve biodiversity and utilise biological resources do not conflict but are mutually supportive.

While science-based research-intensive industries and technologies like pharmaceuticals and the new biotechnologies are extremely important for adding value to such countries' genetic resources, competitive high value-added products can be developed without cutting-edge scientific knowledge and equipment. High-value products may succeed in the market based on knowledge acquired from such sources as traditional communities. Products derived from genetic resources will command high prices in international markets only if they are knowledge-intensive, but this does not by definition require them to be science-based, high-tech, R&D intensive, expensive to develop and produce. In fact,

various kinds of knowledge must be acquired and used for any product to succeed in the increasingly competitive global economy. These need not be science and technology-related at all. These kinds of knowledge include: product design; process engineering; quality control; management and maintenance routines; knowledge about markets and investment opportunities; and skills and capabilities needed to undertake changes in products and processes, create networks, and sustain partnering activity.[156]

So what benefits can realistically be attained from ABS systems that would provide an impetus for such capacity-building at local and national levels?

First, non-monetary benefits such as joint research, training and technology transfer are essential. And many private users of genetic resources appear willing to provide these. On the other hand, monetary benefits are likely to be small, except in the rare case of a blockbuster drug derived from a gene or compound discovered on a bio-prospecting expedition.

Second, it is realistic to expect users to provide immediate, medium and long-term benefits rather than just one of these. While long-term benefits may ultimately be more useful, needs are likely to be urgent, and so immediate benefits can be essential.

Third, non-commercial research can be highly beneficial, since basic research such as taxonomy is fundamental to future commercial use of biodiversity. Foreign universities and research institutes often have long-term relationships with in-county counterpart institutions. ABS should encourage and strengthen such relationships while ensuring that the in-country institutions are able to benefit to the maximum extent possible, especially with respect to scientific capacity-building and training. Again it is realistic to expect positive outcomes here.

[156] Mytelka, L. K. and Tesfachew, T. (1998) The Role of Policy in Promoting Enterprise Learning During Early Industrialization: Lessons for African Countries. UNCTAD, Geneva.

11. Policy recommendations

11.1. International level

As Article 15 of the CBD makes clear, ABS is a responsibility of both provider and users. Therefore international cooperation is essential. User countries can support the ABS regulations of provider countries by such measures as:

1. Creating legal obligations for importers of genetic resources to provide documentary evidence that the resources were acquired in conformity with the applicable regulations of the providing country.

2. Subject to the requirements of the TRIPS Agreement and where appropriate, requesting that patent applications based on use of genetic resources include a declaration of the origin of the source material. This will ensure greater transparency and help build confidence in the patent system, especially among those concerned that patents legitimise so-called biopiracy. In the future, it may also be worthwhile to consider the possibility of introducing administrative requirements for filing patent applications based on use of genetic resources and/or traditional knowledge. These might, for example, require inclusion of: (i) a sworn statement as to the genetic resources and associated knowledge, innovations and practices of indigenous peoples and local communities utilised, directly or indirectly, in the research and development of the subject matter of the IPR application; and (ii) evidence of prior informed consent from the country of origin and/or indigenous or local community, as appropriate.[157]

3. Build upon this study by undertaking a comprehensive review of all ABS systems in operation and under development, and identifying advantages and disadvantages of the various types of legal instrument, strategies and provisions based on practical experiences and from the viewpoints of the various stakeholders.

11.2. National level

Responsibility for regulating access to genetic resources lies with those countries where the resources exist. In general terms, the design of national ABS systems should address the following points:

1. ABS systems should have very clear objectives that are ambitious but realistic. Capacity building in the area of conservation and sustainable use of biodiversity, including commercial use, should be among the key objectives.

2. They should be flexible and transparent.

3. They should be reviewed on a regular basis. On the basis of such reviews, modifications should be considered if deemed necessary.

[157] See Tobin, B. (1997) 'Certificates of origin: a role for IPR regimes in securing prior informed consent'. In: Mugabe, J., Barber, C.V., Henne, G., Glowka, L. and La Vina, A. (eds.) *Access to Genetic Resources: Strategies for Sharing Benefits*. ACTS Press, Nairobi, pp.329-340.

4. They should be based on a realistic understanding of how, and to what extent, the life-science-based industries use genetic resources commercially, and how far they depend on bioprospecting. There is a great deal of anecdotal evidence but a lack of reliable data on this.

5. They should encourage equitable and ethically-sound bioprospecting. Therefore they should not be excessively demanding and bureaucratic and thereby discourage such activities.

6. They should particularly encourage non-commercial research collaboration.

7. They must establish properly functioning institutions such as a competent authority and a focal point.

8. They should not undermine, but should rather support, multilateral systems of exchange such as those likely to be established for certain crop species.

9. They should provide and set minimum standards for immediate, medium-term and long-term benefit-sharing. The benefits should not be defined too narrowly in the regulations but should be left to the discretion of parties to benefit-sharing negotiations.

11.3. Level of societal actors

The active involvement of all stakeholders is essential for ABS systems to work in practice. Disadvantaged groups especially should benefit from the systems. Therefore:

1. The development of ABS systems should involve the active participation of all stakeholder groups so that the views of all these groups are adequately and fairly represented.

2. Benefits should not just go to governments but should be distributed to research institutions, landowners, communities etc., as appropriate.

3. Where possible, ABS regulations should devolve decision-making power to the local level as long as the relevant local and community institutions are able to carry out these added responsibilities competently and appropriately.

4. They should ensure that indigenous and local communities are able to negotiate with those seeking access from a position of strength and that CBD Article 8(j) is fully implemented in this and other contexts.