INTERNATIONAL AND SELECTED NATIONAL LAW ON BIOPROSPECTING AND THE PROTECTION OF TRADITIONAL KNOWLEDGE

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KEYWORDS

Biodiversity
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Bioprospecting
Access to genetic resources
Benefit sharing
Traditional knowledge
Traditional knowledge registers
Patent
TRIPS

ABBREVIATIONS

CBD	United Nations Convention on Biological Diversity
ICJ	International Court of Justice
IP	Intellectual Property
IPR	Intellectual Property Right
MEC	Member of the Executive Council
MTA	Material Transfer Agreement
NGO	Non Governmental Organisations
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UN	United Nations
US	United States of America
WTO	World Trade Organisation

ABSTRACT

INTERNATIONAL AND SELECTED NATIONAL LAW ON BIOPROSPECTING AND THE PROTECTION OF TRADITIONAL KNOWLEDGE

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In this minithesis I discuss the subjects of bioprospecting and the protection of traditional knowledge.

At first the international approach to the subjects will be elaborately assessed. The focus is on the respective provisions of the United Nations Convention on Biological Diversity and the related Bonn Guidelines, stressing the matter of access to genetic resources and the fair and equitable sharing of benefits arising from their utilization. Enclosed in this discussion is the examination of different legislatory approaches to tackle the subject with an emphasis on national intellectual property rights laws and the role and potential merit of national registers of and databases for specific traditional knowledge.

The way national legislators have implemented the concerned obligations of the convention, and their peculiarities as for example the restriction of scope of law to indigenous biological resources, is exemplified with the respective Bolivian, South African as well as Indian laws.

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CHAPTER 1 - Introduction

I. Problem statement

Indigenous plans and traditional knowledge play an important role not only for the sustainable use of biodiversity in local communities but also for modern industry and agriculture. To a large extent, new pharmaceutical and agricultural products launched in the international market are derived from indigenous plants and knowledge. The inventors of such products, who are different from the original holders, usually apply for patents for the former. Since, in many domestic legislations the prerequisite of novelty does not include traditional, orally transmitted knowledge, the patents are granted as long as the other elements are given. As soon as the patent is granted, the patent holder acquires the exclusive right to commercially exploit his invention for a certain period of time. Although it would have provided the basis or at least the leads for the invention, the local community is often excluded from the commercial benefits.

The sharing of benefits, however, would promote equity and the vitality of local communities generating and developing such knowledge. Despite the fact that the CBD requires its parties to create conditions that facilitate access to genetic resources as well as preserve and maintain knowledge, only few countries have confronted this problem and have adopted provisions dealing with this matter. However, at this stage there is still no international legally binding regime ruling the topic.

II. Rationale for the study

Local communities usually do not apply for patents for their knowledge concerning, for example, the pharmaceutical use of a plant's active ingredients. The reasons for this are manifold. Often such intentions would fail due to the prerequisites of national patent legislation. The main purpose of this current research is to find out how and to what extent such traditional knowledge is already protected and how it could be protected respectively. The latter discussion will consist of analysing already advanced proposals, for example, the CBD-Bonn Guidelines. Therein the author will lay an emphasis on the subject of benefit sharing and the protection of traditional knowledge. The World Trade Organisation is aware of the problem but has not yet come to an agreement, since the opinions and proposed solutions of its members widely differ from each other. The proposals vary from contractual provisions advanced by the United States to disclosure requirements and *sui generis* protection systems advanced by concerned developing countries. Such *sui generis* protection

may limit legislative measures addressing access and benefit-sharing but can also embrace, amongst others, a comprehensive national biodiversity framework and comprehensive indigenous community rights laws. With regard to the protection of the respective knowledge of indigenous and local communities, the role of community-based registers of traditional knowledge, innovations and practices will need to be assessed.

With respect to the protection of but also accessibility to genetic resources it has to be discussed whether there is a conflict between provisions of the CBD that reaffirms (in its Preamble) that States have sovereign rights over their own biological resources and the WTO TRIPS agreement which requires the patentability of certain genetic material and its appropriation by private parties.

III. Theoretical assumptions

On the basis of the number of national provisions ruling the problem of bioprospecting and the protections of indigenous knowledge that have been adopted alone, it is suggested that the implementation of national legislation ruling this matter is still in development. A strong legal regime in combination with appropriate registers or databases of traditional knowledge might pursue the aim of allowing indigenous knowledge holders to share in the huge financial benefits that pharmaceutical or agricultural companies gain from commercializing such knowledge and launching products on the international market.

As indigenous communities seem to be overstrained by negotiating with pharmaceutical companies, national contact points that are familiar with the subject and that would have to be obligatorily included in the negotiation process between knowledge holder and future users, would seem to be another point that might ensure the equitable sharing of benefits through its utilization.

Since traditional knowledge, as the term suggests, develops over a long period of time there is usually nobody who could be deemed as the father of the certain knowledge. Insofar as this is not clear, the respective knowledge holder, for example, the indigenous healer, the local community or the state, that should receive granted participation also remains unclear. The local community seems to be the most appropriate beneficiary. However, one has to contemplate whether unlimited or, rather, unregulated financial participation with a concomitant rise in living standards and affiliation with the western world would run counter to the objective of the CBD, namely, the preservation and maintenance of traditional knowledge.

IV. Significance of the research

The interests of enterprises in the agricultural or pharmaceutical sector that deal with the invention and launch of new products are usually contrary to those of indigenous communities that provide the foundation stone for those inventions. The enterprise is interested in creating a new product at the most favourable price. The community, on the other hand, seeks for a return for either the delivering of genetic resources or the use of related traditional knowledge or both. Without legal obligations the enterprise will normally be reluctant to share the financial benefits arising out of the utilization. This research attempts to illustrate a possible way of bringing these diverging interests into balance.

More than 13 years after the Biodiversity Convention, neither have all biodiversity rich states adopted respective legislative measures nor is there an international legally binding regime, which rules that topic. This circumstance is not comprehensible when viewed against the reality that the former would entail financial benefits for their communities, something especially needed in developing countries. One reason for this might be the lack of human or financial capacity to install a respective legislation. If the international community, particularly developed nations, is willing to achieve the aim of an international use of the world's biodiversity hand in hand with a reasonable sharing of the benefits, it has to promote the implementation of appropriate national legislation, be it financially or through human resources.

V. Methodology / Scope of Study

This research discusses the subjects of bioprospecting and the protection of traditional knowledge.

Firstly, the international approach to the subject of bioprospecting and the protection of traditional knowledge will be elaborately assessed on the basis of the CBD. Thereby the emphasis will be laid on the matter of access and benefit-sharing. Furthermore, questions such as dispute settlement, as well as the rights and duties of states, and the peculiarities of developing countries will be assessed respectively.

Further, the international approach will be contrasted with already adopted national statutory provisions. The latter comprise the Bolivian Supreme Decree No. 24676, Regulation of Decision 391 on the Common Regime for Access to Genetic Resources, 1997, in connection with the Andean Community Commission Decision 391- Common Regime on Access to Genetic Resources, 1996 as well as the for Bolivia applying Andean Community Decision 486 - Common Intellectual Property Regime, 2000. One African and one Asian approach will

also be represented by means of the South African National Environmental Management: Biodiversity Act, 2004, the several times amended South African Patents Act, 1978, and the Indian Biological Diversity Bill, 2000, as well as the several times amended Indian Patents Act, 1970, respectively. Contrasting the approaches of the concerned states, the advantages as well as disadvantages of the respective regimes are sought to be determined.

VI. Anticipated outcomes

Indigenous communities through their surroundings tend to embrace the habitat of plants which especially in combination with traditional knowledge might be the solution for, amongst others, the healing of several human diseases. Some plants and their specific active ingredients are not even known by those indigenous communities themselves. In order to pursue the aim of tackling and solving mankind's current but also future health related problems, this biodiversity has to be preserved and the respective knowledge needs to be maintained.

Enterprises that avail themselves of those plants and knowledge have to let the concerned communities partake in the commercial benefits arising out of their utilization. Since the former usually aim at making the maximum profit, they are reluctant to do this voluntarily. This is why there is a need in countries that are rich in biodiversity, to establish area-wide legal regimes to enforce the participation. The basis for this by means of international guidelines is already provided. Now, it is up to the respective countries to implement national legislation that pursues the aim of access to biological resources and equitable sharing of benefits.

Since more and more indigenous communities approach, if not adopt the life style of the western world, their traditional knowledge has to be actively preserved for future generations. A suitable process seems to be the establishment of registers and databases for the recording of specific knowledge that must be protected against misuse. However, such a registration system alone has to be considered insufficient to protect traditional knowledge against misuse. Nevertheless, its merit might be the prevention of undue granting of patents due to lack of novelty. It does not, however, prevent the user from benefiting from this knowledge without sharing the benefits. This is why such registers or databases can only complement the protection of traditional knowledge, in connection with a strong legal regime that rules the latter.

VII. Chapter outline

1. CHAPTER 2 - Bioprospecting and the protection of traditional knowledge – the international approach

This part of the research will deal with the theoretical approaches to governing the subject of bioprospecting, in particular the matter of access and benefit sharing. The Chapter addresses the prerequisites for the examination of biological resources and related indigenous knowledge. In relation to this subjects such as dispute settlement, rights and duties, as well as peculiarities for developing countries will attract interest. The investigation is based on provisions of the CBD and the related Bonn Guidelines. In this context, furthermore, the contentious question of conflict between the CBD and the TRIPS Agreement will be investigated. Lastly, in this section the role of community-based registers of traditional knowledge, its possible merits and insufficiencies, will be addressed and investigated.

2. CHAPTER 3 – Bioprospecting and the protection of traditional knowledge – selected national approaches

States such as Bolivia, India and South Africa have adopted national legislation to tackle their obligation to address this topic.

Bolivia enacted the Supreme Decree No. 24676, Regulation of Decision 391 on the Common Regime for Access to Genetic Resources, 1997. Being a member of the Andean Community, the Andean Community Decision 486 - Common Intellectual Property Regime, 2000 is part of Bolivian law as well.

India enacted the Biological Diversity Bill in 2000. Intellectual property matters are partly regulated in the Biological Diversity Bill. In addition India has at its disposal the several times amended Indian Patents Act, 1970. Lastly, the South African approach is investigated by means of the Biodiversity Act, 2004 and the amended Patents Act, 1978. The approaches of these states will be subjected to a comparative analysis.

3. CHAPTER 4 – Conclusions and Recommendations

In this chapter some critical conclusions and recommendations will be brought forward.

CHAPTER 2 - Bioprospecting and the protection of traditional knowledge – the international approach

I. Bioprospecting

1. Definition of bioprospecting

Bioprospecting, literally the prospecting of biodiversity[1], is generally speaking the search in the wild for genetic and biochemical resources of value.[2] It embraces the collection of plants, animals and micro-organisms for scientific and or economic purposes, such as new drugs, crops, and industrial products, etc.[3]

Beginning in the 15th century, bioprospecting traditionally included, amongst others, selective plant and animal breeding and the utilisation of their products for traditional medicines. Nowadays bioprospecting has become important for research and development and is utilised in activities such as genetic modification, biological control, and the development of pharmaceutical products, agricultural chemicals and cosmetics.[4]

2. The Convention on Biological Diversity and the Bonn Guidelines

A) Introduction to the Convention

It was not until the 1980s that the international community dealt with the development of a global, comprehensive convention on biological diversity, which included the subject of bioprospecting. Initially, in the mid 1980s the World Conservation Union (IUCN) investigated the possibilities for a treaty on the subject and drafted appropriate articles to be included in a treaty. These were confined to the global action necessary to conserve biological diversity at the genetic, species and ecosystem levels.[5] Recognizing the need to intensify international efforts to protect biodiversity, the United Nations Environment Programme (UNEP) established an ad hoc working group to examine the possible form of an umbrella convention under which to bundle current activities in this field and related areas. The group

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[1] According to Art.2 CBD biological diversity means "the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems."

[2] Kate, K. ten, 1995, *Biodiversity Prospecting Partnerships : The role of providers, collectors and users*, Biotechnology and Development Monitor, No. 25, p. 16-21, [Online], Available http://www.biotech-monitor.nl/2507.htm, last accessed 01.05.2006

[3] Hall, K., 2003, *Bioprospecting Background Paper: What is Bioprospecting and what are our International Commitments?*, p.2, [Online], Available http://www.med.govt.nz/ers/nat-res/bioprospecting/general-information/what-is/what-is.pdf, [hereinafter Hall], last accessed 01.05.2006

[4] ibid., p.2

[5] Glowka, L, et al., 1994, *A Guide to the Convention on Biological Diversity*, Gland and Cambridge: IUCN, p.2, [hereinafter Glowka]

considered that the existing conventions only addressed specific questions of biodiversity protection, for example, the threat of trade in endangered species and, therefore, that these did not meet the needs of global biodiversity conservation.[6] By early 1990, the working group agreed on the need for a new global framework treaty on biodiversity conservation. One year later the formal negotiations were taken up in the renamed Intergovernmental Negotiating Committee for a Convention on Biological Diversity (INC). Finally, after contentious negotiations which were often close to breaking down[7], the convention was adopted on 5 June 1992 at the UN Conference on Environment and Development in Rio de Janeiro. 18 months later, on 29 December 1993, the convention entered into force as the first binding global treaty that covered biodiversity comprehensively.

The convention embraces three major objectives, the conservation of biological diversity, the use of natural resources in a sustainable way, and the fair and equitable sharing of benefits deriving from the utilization of genetic resources, through appropriate access to genetic resources.[8]

The aspect of access and benefit sharing is of particular importance in the field of bioprospecting and forms its major issue.

B) Provisions of particular interest and the Bonn Guidelines

Renewing a basic principle embedded in the Preamble of the convention, Art.15 (1) CBD recognizes the sovereign rights of States over their natural resources and endorses the authority to determine access to national governments, subject to national legislation.

This approach stands in contrast to the principle of free access to genetic resources which had prevailed until the convention was negotiated. This change is due to controversy over the control of genetic resources: developing countries called for national control and in the negotiating of the convention this view was held by the majority of the prospective member states.

The determining point for the new approach is based on the view that the principle of national sovereignty over natural resources includes sovereignty over genetic resources.[9]

Art.15 (4) and (5) CBD set out that access, where granted, shall be on mutually agreed terms and be subject to prior informed consent of the provider as contracting party.

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[6] Glowka, above no.5, p.2
[7] ibid., p.2
[8] Art.1 Convention on Biological Diversity
[9] Conference of the Parties to the Convention on Biological Diversity, 1995, *Access to Genetic Resources and Benefit-Sharing: Legislation, Administrative and Policy Information*, UNEP/CBD/COP/2/13, p.4, [Online], Available: http://www.biodiv.org/doc/meetings/cop/cop-02/official/cop-02-13-en.wpd, [hereinafter COP to the CBD, *Access to Genetic Resources...*], last accessed 01.05.2006

Moreover, the control of access to the genetic resource gives the provider the opportunity to negotiate the terms for benefit sharing.[10]

The latter is mainly ruled in Art.15 (7) CBD. Accordingly the parties shall take appropriate measures to warrant the fair and equitable sharing of benefits arising out of the genetic resources' utilization. What is problematic in this respect is the fact that the obligations set out in Art.15 (7) CBD leave discretion with the parties to implement the provision. And, however, the clear identification of a genetic source which the benefit derives from is not always possible. This, will be shown below, is especially the case if the used genetic material is based on several sources.[11]

Another aspect of access and benefit sharing is the issue of access to and transfer of technologies. According to the United Nations Conference on Trade and Development, technology transfer is defined as the "transfer of systematic knowledge for the manufacture of a product, for the application of a process or for the rendering of a service".[12]

At the early stage of the negotiations primarily developed countries adopted a declining attitude towards the inclusion of provisions on technology transfer. The opposing view was held mainly by developing countries that considered the inclusion to be an essential element of the convention as a counterpart to the provisions on the access to genetic resources. In the end, the latter position prevailed and developed countries obliged.[13] Negotiating the final text of the convention, developed countries were particularly afraid of any formulation that might be interpreted as an obligation to compel their private sector to transfer technology[14] and therefore placed importance on intellectual property rights.[15] Nevertheless, Art.16 CBD creates a basic obligation to provide and facilitate respectively access to and transfer of technology.

Although the convention has been in force since 1993, it was not until 1999 that serious work was taken up by an ad-hoc Working Group with the mandate to develop guidelines and other approaches to these provisions and to assist parties and stakeholders in addressing certain elements relevant to accessing genetic resources and benefit sharing.[16] The efforts lead to the

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[10] Glowka, above no.5, p.5
[11] COP to the CBD, *Access to Genetic Resources...*, above no.9, p.16
[12] Secretariat of the Convention on Biological Diversity United Nations Environment Programme, 1997, *Traditional Knowledge and Biological Diversity*, UNEP/CBD/TKBD/1/2, p.6, [Online], Available: http://www.biodiv.org/doc/meetings/tk/wstkbd-01/official/wstkbd-01-02-en.pdf, [hereinafter Secretariat of the CBD UNEP, *TK and BD*], last accessed 03.05.2006
[13] Glowka, above no.5, p.84
[14] ibid., p.84
[15] ibid., p.5 et seq.
[16] WIPO-UNEP *Study on the Role of Intellectual Property Rights in the Sharing of Benefits Arising from the Use of Biological Resources and Associated Traditional Knowledge*, p.24, [Online], Available http://www.wipo.int/tk/en/publications/769e_unep_tk.pdf, last accessed 03.05.2006

Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization. The name is derived from the location of the intergovernmental meeting in October 2001 where the first draft was prepared. The guidelines were finally adopted by the Conference of the Parties to the Convention by some 180 countries in April 2002. Their provisions are of a legally non-binding nature and offer guidance for parties, governments and other stakeholders in the implementation of the relevant provisions of the CBD related to access and benefit sharing. Therewith the guidelines are intended to provide assistance in establishing legislative, administrative or policy measures on that topic and/or when negotiating contractual arrangements in that range.[17]

B1) Art.15 Convention on Biological Diversity

As mentioned above Art.15 CBD sets out a framework for the implementation of obligations and rights with regard to the matter of access to genetic resources and the sharing of benefits deriving from their utilization. Paragraphs 1 and 2 aim at establishing a balance between the right of national governments to determine access and their obligations to facilitate access by member parties. Paragraphs 4 and 5 address the mutual access agreement subject to prior informed consent of the provider of the genetic resources. Lastly, paragraphs 6 and 7 govern the return of benefits arising out of the subsequent use of the respective resources. These may include participation in scientific research on the supplied resource, the sharing of research results as well as commercial and other benefits. More specific benefits are addressed in Art.16 (3) and Art.19 (1) et seq. CBD. These will be discussed in turn below.

B1.1) Paragraph 1

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

In Art.2 CBD genetic resources are defined as genetic material of actual or potential value. The Bonn Guidelines cover these but exclude human genetic resources from their application.[18] Though the term "their" suggests it, Art.15 CBD does not grant the state a property right over the resources. The latter are merely referred under the state's jurisdiction. The matter of ownership is to be determined by national legislation.[19]

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[17] Secretariat of the Convention on Biological Diversity, 2002, *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization*. Montreal: Secretariat of the Convention on Biological Diversity, Introduction, [hereinafter Bonn Guidelines]
[18] Bonn Guidelines, above no.17, I.C.9.
[19] Glowka, above no.5, p.76

B1.2) Paragraph 2

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

The parties shall endeavour to facilitate access by other member parties. This obligation may encourage other states, especially biodiversity-poorer states that are dependent on access to genetic resources, to join the convention.[20] The duty to facilitate access, however, relates to access for environmentally sound uses, for example, uses that do not run counter to the objectives of the convention. The assessment of soundness is left to the discretion of the party that supplies the resource. Furthermore parties are not allowed to place restrictions on access which are contrary to the convention's objectives. As mentioned above, this new approach stands in contrast to the long prevailing concept of unrestricted access to genetic resources, at least for plant genetic resources. The former approach was based on the generally accepted international principle that these resources are a heritage of humankind and therefore available to anyone for any purpose.[21] The concept was implemented in Art.1 1983 Food and Agricultural Organisation of the United Nations – International Undertaking on Plant Genetic Resources. However, the principle of unrestricted access was narrowed over time by factors such as intellectual property rights over plant varieties and genetic material.

Viewed from the perspective that no state is self-sufficient in genetic resources, particularly in the field of agriculture, it is essential to maintain the exchange of genetic resources within the world community.[22]

With regard to the obligation to endeavour to facilitate access to genetic resources, the Bonn Guidelines promote the designation of one national focal point for access and benefit sharing in each party. The information should be made available through the clearing-house mechanism according to Art.18 CBD. The focal point is supposed to provide applicants for access to genetic resources with information about necessary procedures, including competent national authorities.[23] The latter could be a committee drawn from relevant agencies and interest groups[24] and may be responsible for granting access to and for giving advice on, for example, the negotiating process, monitoring, evaluation and approval of access and benefit sharing agreements as well as the effective participation of different stakeholders, in particular

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[20] Glowka, above no.5, p.76
[21] COP to the CBD, *Access to Genetic Resources...*, above no.9, p.4
[22] Glowka, above no.5, p.77
[23] Bonn Guidelines, above no.17, II.A.13.
[24] COP to the CBD, *Access to Genetic Resources...*, above no.9, p.23

indigenous and local communities.[25] Indigenous communities, peoples, and nations may be defined as those, "having a historical continuity with 'pre-invasion' and pre-colonial societies that developed on their territories, consider themselves distinct from other sectors of the societies now prevailing in those countries, or parts of them. They form at present non-dominant sectors of society and are determined to preserve, develop and transmit to future generations their ancestral territories, and their ethnic identities, as the basis of their continued existence as peoples, in accordance with their own cultural pattern, social institutions and legal systems".[26]

Since the contracting parties are obliged to facilitate access to genetic resources without imposing restrictions that run counter to the convention's objectives, disputes arise, for instance, if one party prevents another's access for undue reasons.

In cases of disputes between contracting parties regarding rights and duties arising under the CBD, Art.27 comes into play. According to the latter, any conflict under the convention has to be settled according to its binding and non-binding procedures, giving priority to the latter like e.g. negotiations or mediation.[27]

B1.2.1) Art.27 (1),(2) Convention on Biological Diversity

The first two paragraphs read as follows:

> 1. In the event of a dispute between Contracting Parties concerning the interpretation or application of this Convention, the parties concerned shall seek solution by negotiation.
> 2. If the parties concerned cannot reach agreement by negotiation, they may jointly seek the good offices of, or request mediation by, a third party.

Through binding disputing contracting parties to seek a solution through negotiation the convention follows a fundamental and traditional rule of conflict resolution.[28] Jointly made decisions are usually more accepted by the concerned parties than those reached by a third party, since the parties hold the outcome of the decision in their own hands. If this process does not lead to a settlement of the dispute, the disputing parties may opt to seek the good offices of, or mediation by a third party. If the negotiation and or mediation do not result in a decision satisfying both disputing parties, paragraph 3 comes into play.

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[25] Bonn Guidelines, above no.17, II.B.14.(a),(c),(g)
[26] WIPO, 2001, *Intellectual property needs and expectations of traditional knowledge holders:* WIPO report on fact-finding missions on intellectual property and traditional knowledge (1998-1999), Geneva, p.23, [hereinafter WIPO, *Intellectual property needs*]
[27] Glowka, above no.5, p.118
[28] ibid., p.118

B1.2.2) Art.27 (3) Convention on Biological Diversity

It reads:

> When ratifying, accepting, approving or acceding to this Convention, or at any time thereafter, a State or regional economic integration organization may declare in writing to the Depositary that for a dispute not resolved in accordance with paragraph 1 or paragraph 2 above, it accepts one or both of the following means of dispute settlement as compulsory:
> (a) Arbitration in accordance with the procedure laid down in Part 1 of Annex II;
> (b) Submission of the dispute to the International Court of Justice.

The contracting parties are free to declare at any time to pursue the resolution of a respective dispute by means of arbitration according to Annex 2 and/or submission to the ICJ if the above mentioned non-binding negotiations or mediation fail. Either procedure under Art.27 (3) CBD leads then to a binding decision for the disputing parties.

In this respect the convention is aware of the imperative of a judicial control mechanism if the dispute cannot be settled by negotiations and/or mediation. Thereby, the judicial instruments act as organs of states. For example, NGOs or private third parties are not involved in the mechanism.[29] Thus, a private entity, unsuccessfully seeking for access to genetic resources, would be excluded from this dispute settlement mechanism.

Since the amicable settlement of the dispute is given preference by the convention, even in cases where the parties accepted the finding of resolutions according to subparagraph (a) and (b), they still first have to try to achieve a non-judicial settlement.[30] The decision according to subparagraph (a) is reached by an arbitration tribunal. The latter consists of two arbitrators which are respectively appointed by the parties and another one, amicably appointed by the so appointed.[31] That is, in this procedure the parties can still take influence on the body settling the dispute.

As far as the party decides to regard the submission of the dispute to the ICJ as compulsory, they lose the opportunity to exert influence. However, the prerequisite for both procedures according to subparagraph (a) and (b) is that both disputing parties have accepted the same procedure. If the latter is not the case, paragraph 4 comes to application.

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[29] Rest, A, 1999, *Enhanced Implementation of the Biological Diversity Convention by Judicial Control*, Environmental Policy and Law, 29/1, [Online], Available: http://iospress.metapress.com/media/h83awvxuxg6xb8xh8r4h/contributions/p/r/v/l/prvlkugwrntxlrb8.pdf , last accessed 13.04.2006

[30] Glowka, above no.5, p.118

[31] Annex II, Part 1, Art.2, Paragraph 1 CBD

B1.2.3) Art.27 (4) Convention on Biological Diversity

It reads:

> If the parties to the dispute have not, in accordance with paragraph 3 above, accepted the same or any procedure, the dispute shall be submitted to conciliation in accordance with Part 2 of Annex II unless the parties otherwise agree.

If disputing parties find no resolution through the means of negotiation or good offices , or through mediation by a third party and they furthermore do not accept the same judicial procedure as arbitration of submission to the ICJ, the dispute must be submitted to conciliation. The procedure is ruled in part 2 of Annex II of the convention.
Accordingly, a conciliation commission shall be created upon the request of one of the disputing parties.[32] The commission is basically composed of members appointed by the parties and a president, chosen of the so appointed. So again, the parties can take influence in the resolution of the dispute. Only if it lacks an appointment of the members, the Secretary-General of the UN undertakes the task of appointing.[33] The decision taken by the commission is a proposal for the resolution of the dispute,[34] i.e. it constitutes a non-binding decision to the disputing parties. This decision the disputing parties shall consider in good faith.[35]

B1.3) Paragraph 3

> For the purpose of this Convention, the genetic resources being provided by a Contracting Party, as referred to in this Article and Articles 16 and 19, are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.

According to Art.2 CBD a country of origin of genetic resources is a country which possesses those genetic resources in *in-situ* conditions. The latter are defined under Art.2 CBD as conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.
The second category of resources provided to parties in Paragraph 3 excludes those cases in which the resources were obtained from the provider before the convention entered into force.

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[32] Annex II, Part 2, Art.1 CBD
[33] Annex II, Part 2, Art.3, 4 CBD
[34] Annex II, Part 2, Art.5 CBD
[35] Annex II, Part 2, Art.5 CBD

Therewith the convention incorporates the principle of "non-retroactivity". This entails, on the on hand, that a contracting party which provided genetic resources prior to the entry into force cannot claim the benefit-sharing provisions of Art.15, 16 and 19 CBD. This holds true for the past, as well as the future use of these resources. On the other hand, parties that obtained these resources are not obliged to facilitate access to them. Furthermore, as a reverse of the above mentioned not given claim, the party which uses the resource is not required to share the benefits arising out of its utilization.[36]

Likewise excluded from the convention's application is the case, if the genetic resources are obtained from the country of origin by illegal means after the convention's entry into force.

For illustration purposes shall serve the following facts of an imaginary case. A contracting party obtained genetic resources from another country of origin, being party to the convention, without its required prior informed consent. If the illegal acting state provides the genetic resources later to another, a third contracting party, the country of origin has no legal claim, based on the convention, to share the benefits arising out of their utilization.[37]

As long as in an imaginary supply chain, at least one side, i.e. either the providing party or the first obtaining and then providing party or an only obtaining party, or two or all of them got illegally into possession of the genetic resources, the respective party cannot invoke the convention's provisions of Art.15, 16 and 19 CBD. As soon as in this supply chain both parties to the contract act lawfully, the convention's protection and claims gain application for the invoking party. Insofar the good faith of both contract parties overcomes the tarnish that adheres to the genetic resource.

B1.4) Paragraph 4

> Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.

The formulation "mutually agreed terms" entails the requirement of negotiation between the contracting party granting access to the genetic resource and the party which desires access to and use of the latter. The respective party can be an individual, a company, an institution but also a community or state.[38]

The purpose of this paragraph is to warrant the negotiation not only of the authorization for access to genetic resources but at the same time of an agreement on a return of benefits arising

[36] Glowka, above no.5, p.79
[37] ibid., p.79
[38] ibid., p.80

out of its utilization.[39] The reason, therefore, is that it is unlikely and difficult to negotiate benefit-sharing details independent of or after negotiating the access conditions.[40] As soon as the party having asked for access obtains the authorization, it will likely be reluctant to agree on a benefit sharing scheme. The latter will probably go along with costs and efforts with no advantages for the party seeking access.

The Bonn Guidelines call on the parties to support measures, as appropriate, to enhance the capacity of indigenous and local communities to represent their interests fully at negotiations.[41] This is due to the fact that there may be significant differences in bargaining power between parties to such agreements.[42] Moreover, even if the state, as opposed to the specific community, is the owner of the area where bioprospecting is going to take place, the involvement of affected indigenous and local communities is sought to be warranted. The effective participation of relevant stakeholders could be promoted by providing them with information, particularly regarding scientific and legal advice.[43]

While implementing the mutually agreed terms, users of genetic resources should respect the customs, traditions, values and customary practices of those concerned communities.[44] Thus, the provider party is required to let the communities actively take part in the negotiations while the user is merely obliged to take their rights and interest into account.

To promote the involvement of relevant stakeholders the guidelines advance appropriate consultative arrangements, such as national consultative committees providing for the participation of relevant stakeholders representatives.[45] A further step to be considered by the members of the convention to ensure the fair and equitable conclusion of the agreement between the provider and user of the genetic resources is the establishment of a national focal point.[46] This would allow a coordination and elaboration of the respective agreements with the parties.

The primary advantages of a focal point are threefold: First, potential users of a convention member's genetic resources could be provided with information about access rules and regulations. They would obtain this information from a central body, specialised in the matter. This in turn would be beneficial to the competent treatment of different potential resource users. Second, the delay of access determinations could be avoided by streamlining them.

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[39] COP to the CBD, *Access to Genetic Resources...*, above no.9, p.7 et seq.
[40] Glowka, above no.5, p.80
[41] Bonn Guidelines, above no.17, II.C.16.(a)(vii)
[42] COP to the CBD, *Access to Genetic Resources...*, above no.9, p.8
[43] Bonn Guidelines, above no.17, III.20.(a)
[44] ibid., II.C.16.(b)(ii)
[45] ibid., III.19
[46] Glowka, above no.5, p.80

Lastly, the making of arbitrary decisions is more likely to be avoided. The given advantages would enable the contracting parties to pursue the convention's objective to ensure the facilitation of access to genetic resources and not to restrict the latter. Bodies carrying out this function could be a governmental agency as well as a government or university related research institute. Following the general tendency of privatisation and outsourcing, likewise a private contractor or an independent private, non-profit organization acting as an intermediary on the government's behalf could be put in charge of this task.[47]

The mechanism for determining the focal point's range of responsibilities would depend on the legal form of the body. National legislation, implemented through administrative regulations or policy outlines, would be the appropriate means if the body is to be a governmental organisation. The scope of responsibilities of a non-profit organization as well as a private contractor could be determined by contract.

The authority of the focal point could embrace, at first, the negotiation of integral parts of the contract, for example, the terms of access and the return of benefits on behalf of the party to the contract. Furthermore, the execution of the contract, like the collection and disbursement of potential financial returns or other compensation of the users, as well as the enforcement of the access agreement could be comprised of the focal point's tasks. In addition, in order to connect and bundle theoretical and practical tasks, the focal point could coordinate and carry out functions such as collecting and characterising genetic resources.[48] The better understanding of the use and value of the resource that it has would improve the position of the focal point in the negotiation process and in the end promote the equitable balancing of duties and rights of the parties to the contract.

Regardless of the question of whether or not the government decides to establish a national focal point, the legislation that rules the access will have to differentiate between genetic resources owned by the state and those owned by others. In any case, the legislation should clearly indicate that the party seeking access has to negotiate an access agreement with the owner and whether the state has to join the negotiations compulsory or at least comprehensive reviews of their results must be done.[49]

The Bonn Guidelines call on the parties to support measures, as appropriate, to enhance the capacity of indigenous and local communities in order represent their interests fully at negotiations.[50] For example, even if the state rather than the community is the owner of the

[47] Glowka, above no.5, p.80
[48] ibid., p.80
[49] ibid., p.80
[50] Bonn Guidelines, above no.17, II.C.16.(a)(vii)

area where bioprospecting shall take place, the participation of affected indigenous and local communities is sought to be warranted.

B1.5) Paragraph 5

> Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.

Paragraph 5 requires the party that is seeking access to genetic resources to acquire an informed consent from the providing party previous to access and subsequent export of the resources. The affirmative act is based on the information which the potential resource user provides.

The mutual agreement between the parties ruled in Paragraph 4, precedes the consent but could be accomplished within consent procedure. The prior informed consent requirement gives the providing party the authority and opportunity on the one side to require the potential user to gain the approval previous to the access and on the other side to require the user to sketch out the consequences of access.

Information that is required to be provided to the competent authority could be the type and quantity of genetic resources to which access is required, or the time frame and location of access activity and an evaluation of how the activity may impact on conservation and sustainable use of biodiversity. The latter would be the critical point to determine the relative costs and benefits of granting the access.[51]

The potential user could, furthermore, be asked to specify how and by whom the obtained resource will be used afterwards.[52] This information may be crucial for the assessment of whether, and under which terms and conditions, the access will be granted.[53] While the consent may be granted initially for specific uses, any change of the latter including the transfer to third parties should be preceded by a new application for prior informed consent.[54]

The Bonn Guidelines emphasize that while implementing the mutually agreed terms, users of genetic resources should ensure that use of genetic resources for purposes other than those for which they were required may only take place after new prior informed consent and mutually agreed terms are given.[55] Moreover it clarifies that, if users supply genetic resources to third parties, they have to obey any terms and conditions regarding the acquired material. The third

[51] Bonn Guidelines, above no.17, IV.C.2.36.(b),(c),(g),(e)
[52] ibid., IV.C.2.36.(f),(j)
[53] Glowka, above no.5, p.81
[54] Bonn Guidelines, above no.17, IV.C.2.34
[55] ibid., II.C.16.(b)(v)

party has to be provided with relevant data on their own acquisition, including prior informed consent and conditions of use. To safeguard the interests of the primary provider party, the mutually agreed terms could require the insurance that the third parties enter into similar agreements except for taxonomic and systematic research that is not related to commercialization.[56] Finally, the user that provides other parties with the acquired resources should record and maintain data on this supply.[57]

However, the formulation "unless otherwise determined by that party" suggests that the prior informed consent is the norm, except where the party to the contract providing the resources decides to differ from that norm. Failing to establish the necessary legal system, the providing party abandons the ability to control the access of the potential party seeking the resources and the sharing of the benefit deriving from their utilization.

The formulation "unless otherwise" furthermore implies that it is up to the parties not only whether they require a prior informed consent or not but also whether to confine the range of genetic resources requiring such a consent. Thus, it is free to exclude certain categories of genetic resources from the necessity of prior informed consent. This reflects the above mentioned principle of the states' sovereignty over their biological resources.

While parties receiving genetic resources are not bound by specific obligations under Art.15, its language - providing that access "shall be on mutually agreed terms" and "shall be subject to prior informed consent" - indicates that the general obligation to ensure access according to the article's requirements is not limited to provider parties alone.[58] Although it is to the interest of the providing party to confine unrestricted, free access, to genetic resources and to negotiate the terms of benefit sharing; national legislation ruling that topic only in the providing state seems not to be sufficient to give full effect to the consent requirement. If, for instance, a pharmaceutical company gains access to genetic resources in another country without the prior informed consent of the latter, it will not be hindered to proceed with the utilization and commercialization in its own country if there is no legislation enacted that deals with this problematic. This is why national legislation in both the providing and the using country seems to be necessary.

Measures to be considered in respect of the receiving parties could involve the requirement that imported genetic resources have special export permits that provide for evidence of prior informed consent having been granted by the provider party. Moreover, the importers could be obliged to maintain records of imported genetic resources, showing their origin, date of

[56] Bonn Guidelines, above no.17, IV.D.2.44.(f)
[57] ibid., II.C.16.(b)(viii)
[58] COP to the CBD, *Access to Genetic Resources...*, above no.9, p.24

receipt, and other related information.[59] Since parties providing genetic resources can be using parties at the same time, the national legislation should cover both cases, applicable to nationals and non-nationals equally.[60]

How detailed the legislation will look like is left to the parties. If the latter are the provider of genetic resources they can determine the minimum or general requirements of access, leaving flexibility to the parties to negotiate more specific terms such as the sharing of benefits. These minimum standards for access would create a uniform starting point for further negotiations, minimizing delays and limiting arbitrary decision making.[61]

The national legislation could at first define the scope of application, i.e. what kind of genetic resources, *in-situ* and or *ex-situ* are concerned, whether public or private owned and what kind of users, commercial or non-commercial, are subject to the provisions. In that regard, the Bonn Guidelines specify that prior informed consent for access to *in-situ* genetic resource must be obtained through the provider party's competent national authority(ies) as far as required by that party.[62] Since the consent may be required from different levels of government, i.e. the national, provincial or local level, the provider's requirements therefore should be specified.[63] For *ex-situ* collections, the guidelines suggest that the duty to obtain the consent from the competent national authority(ies) and or the body governing the Collection is still required.[64]

As far as the legal rights of indigenous and local communities are associated with the genetic resources being accessed, the prior informed consent of these communities should be obtained, subject to national policies and laws.[65] Thus, the guidelines emphasize the pursuit of warranting the participation of all concerned stakeholders.

Secondly, the legislation could establish the necessary information for an access determination, inclusive of environmental assessment data, and as a practicable future use of the resources. Whether or not and under what conditions the access would be granted would decisively depend on this information.

Further points may embrace the requirement of an access fee or license. The legislator can adopt restrictions on future and third party use and transfer, limits on collecting, as well as specifications for environmentally sound uses.[66] Thus, the party can determine and confine

[59] COP to the CBD, *Access to Genetic Resources...*, above no.9, p.24
[60] Glowka, above no.5, p.81
[61] ibid., p.81
[62] Bonn Guidelines, above no.17, IV.C.2.28
[63] ibid., IV.C.2.29
[64] ibid., IV.C.2.32
[65] ibid., IV.C.2.31
[66] Glowka, above no.5, p.81

the chain of users, as well as the channels for future utilization. The latter may consist of possession, cultivation but also further transfer.[67]

Moreover, the national legislation may establish the government's policy on research collaboration, benefit sharing and intellectual property rights. With regard to the latter, contracting parties having users under their jurisdiction, should take appropriate measures to support compliance with prior informed consent by encouraging the disclosure of the country of origin of the genetic resources in applications for intellectual property rights.[68]

In a similar manner the legislator could set export restrictions and provide for administrative or judicial penalties for export without prior informed consent.[69] Lastly an appeal process could be designed for cases where access is denied.[70]

Against the background of the parties' obligation to endeavour to facilitate access to genetic resources (Art.15 (2) CBD), the legislation should strive for a simplicity of process in order to avoid cumbersome rules and delays. The competent authority could grant the access by means of issuing, for example, a permit or licence. Such issuance could moreover be recorded in a national registration system.[71]

A party, the user of genetic resources, could enact legislation requiring the importer to elucidate that both the importation and subsequent utilization are corresponding to the prior informed consent of the providing party and with respect to the property rights in that party.[72]

Likewise the legislation of the state that is providing the resource, the provisions of the state where the resources are used, could require the user to compose periodic reports of subsequent use to the providing party.

Finally, the system should be of legal certainty and clarity and provide for access at minimum cost.[73] To warrant the effectiveness of the whole system, the providing party must dispose of access to the court system of the using party, providing penalties and remedies for importation and utilization without prior informed consent.[74] These concerns can furthermore be ruled out and specified in dispute settlement provisions in the finally material transfer agreements between the provider and the user of the genetic resources.[75]

B1.6) Paragraph 6

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[67] Glowka, above no.5, p.81
[68] Bonn Guidelines, above no.17, II.C.16.(d)(ii)
[69] COP to the CBD, *Access to Genetic Resources...*, above no.9, p.24
[70] Glowka, above no.5, p.81
[71] Bonn Guidelines, above no.17, IV.C.2.39
[72] Glowka, above no.5, p.81
[73] Bonn Guidelines, above no.17, IV.C.1.26.(a),(b)
[74] Glowka, above no.5, p.82, Bonn Guidelines, above no.17, V.E.60
[75] Bonn Guidelines, above no.17, Appendix I.C.7

> Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties.

The paragraph aims at involving parties that provide genetic resources in all research based on the latter, conducted by user parties to the contract. Thus it is intended to build and extend scientific research capacity and knowledge of the providing party, a form of soft transfer of technology. Furthermore, joint research within the provider party makes the participation of local researchers more likely and with it increases its scientific research capacity to use its genetic resources. To reach this aim, the party to the contract seeking genetic resources is asked to ensure that their governmental agencies which are involved in the concerned scientific research promote the development of joint research programmes with the providing party and, if possible, in the state where the resources originate from.[76] Basically, the party seeking access is not willing to conduct joint research with the providing party and therewith sharing certain knowledge, unless it receives no benefits out of it. This is especially the case, if the providing party is not disposed of especially educated personnel. To compensate this general reluctance, parties seeking for genetic resources could create funding incentives and conditions encouraging governmental research agencies to cooperate in research projects benefiting both users and provider parties of the resources. The same goes for governmental institutions, namely, not conducting the research but granting public money to the private sector, such as organisations, universities, business and industry.[77]

The provisions received no specification through the Bonn Guidelines. They merely clarified that users should, as much as possible, endeavour - thus in contrast to the provision of the CBD an increased effort - to carry out their use of the genetic resources in, and with the participation of, the provider party.[78] To facilitate a decision finding of the party providing the genetic resources, the application for access should require an indication about where the research and development will take place, how it is to be carried out and which local research and development bodies will be involved.[79]

However, doing so, it is essential for the parties to such an access agreement to treat the results of research on genetic resources confidentially. This is based on the fact that parties seeking access will often seek to keep research results secret until they can obtain patent protection over the resulting invention. If research results are disclosed prior to the date of

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[76] Glowka, above no.5, p.82
[77] ibid., p.82
[78] Bonn Guidelines, above no.17, II.C.16.(b)(vii)
[79] ibid., IV.C.2.36.(g),(h),(i)

application for a patent, its filing respectively, competitors may use the information to develop a competing product and patent the same invention or a similar one.[80]

B1.7) Paragraph 7

> Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.

The last paragraph of Art.15 is the central provision with regard to the sharing of benefits arising out of the utilization of genetic resources. It requires each party to the contract, regardless of its economic state of development, to take appropriate measures aimed at the fair and equitable sharing of benefits with the providing party on mutually agreed terms. The benefits comprise research and development results as well as commercial or other utilization benefits. The references to Art.16 and 19 CBD flesh out the potential benefits. Thus they firstly include access to and transfer of technology which makes use of the respective resources. Secondly, benefits like the participation in biotechnological research activities especially by developing countries providing the genetic resources. The same goes for priority access to the results and benefits deriving from the biotechnological use of the genetic resources.[81] A discussion of the provisions of Art.16 and 19 CBD further below.

The majority of agreements according to the paragraph will be concluded between a contracting party as the provider of genetic resources and a private entity. Hence, the paragraph takes into account that most of the benefits to share will occur and be generated in the private sector. Doing so, it requires the parties to the contract to take appropriate measures not to require but rather to aim at the sharing of benefits on the base of a mutual agreement.[82] Since the use of genetic resources varies widely, it is hardly possible for governments to enact provisions both covering all imaginary benefits which should be shared and specifying the modalities to be applied.[83] Rather, the benefit sharing has to be the result of a mutual agreement. The provision thus implies the conducting of negotiations in each individual case.

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[80] COP to the CBD, *Access to Genetic Resources...*, above no.9, p.26
[81] Glowka, above no.5, p.82
[82] ibid., p.82
[83] ibid., p.83

This does not prevent contracting parties from developing principles and basic requirements for such an agreement. Those measures could comprise the development of standardized material agreements and benefit sharing arrangements for similar resources and similar uses.[84] These could contain permitted uses of the covered genetic resources, their products or derivates, bearing in mind their potential uses.[85]

For different resources and for different uses, such as taxonomy, collection, research or commercialization, the parties to the convention could develop appropriate contractual arrangements and model agreements, respectively.[86]

As mentioned above, the achievement of a mutual access agreement between the parties according to Art.15 (4) CBD could be combined with the consent procedure under Art.15 (5) CBD. Likewise the negotiation leading to the agreement on the sharing of benefits could be integrated in that procedure. A case by case approach to negotiations not dependent on a rigid provision set by the government would facilitate and pursue the aim of the paragraph, to find an agreement on what is fair and equitable in the respective situation.[87]

Since it is not possible to determine the concrete benefits arising out of the utilization of the genetic resource, the crucial point will be what the parties consider the perceived value of the provided material to be. The latter depends on both the nature of the provided genetic resource and the kind of proposed subsequent utilization. Of particular importance in this regard is the question whether the prospective user pursues a commercial utilization. The better the providing party can independently determine or estimate the potential use or value of the genetic resource, the stronger its position in the negotiation process will be.[88] The Bonn Guidelines therefore set out that an application for access to genetic resources should require information on kinds and types of benefits that could result from obtaining access to the resource, including benefits from derivates and products arising from the commercial and other utilization of the resource. An indication of whether and to what extent arrangements of benefit sharing are already concluded, could be called for to complete the above mentioned list.[89]

In practice, in many cases it will not be possible to obtain all or even any of the user-related information at the time the access negotiations take place. In cases when genetic resources

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[84] Bonn Guidelines, above no.17, IV.D.1.42.(b)(iv)
[85] ibid., Appendix I.B.2
[86] Bonn Guidelines, above no.17, IV.D.1.42.(d),(e)
[87] Glowka, above no.5, p.83
[88] ibid., p.83
[89] Bonn Guidelines, above no.17, IV.C.2.36.(l),(m)

have yet to be collected and the end-product or the final user is not yet certain the party seeking for access is just unable to provide the specific information.[90]

Likewise, as I mentioned briefly above, difficulties arise in instances where a certain end-product consists of genetic resources from several providers. In the field of agricultural applications, comprising conventional plant breeding, quantifying a genetic resource's percental contribution to a new plant variety will be unfeasible in the majority of the cases. Contrary to this, the contribution of a single component to an end-product like bio-pesticides is rather quantifiable. As long as the end-product can be split into its constituent components, one could quote the contribution of a single component on the basis of its mass fraction.[91] However, whether the actual share in active agents, which could also be decisive for the determination of value, corresponds to the simple mass proportion is doubtable.

There are also cases imaginable, in which the genetic resources turn out to be of no value at all for the user party. To avoid disputes, the party providing the resources should include provisions guaranteeing no warranties on identity and or quality of the provided material.[92]

Despite these difficulties, an effective sharing of benefits can still be negotiated and achieved. The transfer of technology, especially the conducting of joint research and the sharing of research results can be carried out without necessarily knowing how the use of the respective resource will look like at the end. The same goes for advanced payments or per sample fees.[93] Advanced payments are crucial as they can create immediate incentives for conservation and respond to the often urgent financial needs of developing countries and local communities.[94] Standing alone, the advance payments and sample fees bring about the advantage that both parties know at the time the negotiations take place, how much the user party will have to pay and what profit the provider party will gain. Moreover, against the background that the commercialization of an end-product can last years, the provider receives financial benefits for the short term. However, the disadvantage is that the provider possibly loses a potential share of bigger commercial benefits if the end-product is launched to the market successfully. The solution to the problem could provide a combination of advanced payments and possible future profit sharing such as minimum royalties as a percentage of net sales.[95]

The Bonn Guidelines determine generally that the mutually agreed terms should cover near-term, medium-term and long-term benefits, including the above mentioned up-front

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[90] Glowka, above no.5, p.83
[91] ibid., p.83
[92] Bonn Guidelines, above no.17, Appendix I.B.6
[93] Glowka, above no.5, p.83
[94] COP to the CBD, *Access to Genetic Resources...*, above no.9, p.21
[95] Glowka, above no.5, p.83

payments, milestone payments and royalties. At the same time the time frame of benefit sharing should be definitely stipulated[96] to pursue clarity and calculability.

Another possibility is to take into account an unforeseen development as the accommodation of adjustments in respect of unpredictable end-products, applications or other contingencies due to long lasting research or the transfer to third parties.[97]

To enable the sharing of unforeseen benefits it is decisive that the parties stipulate that the party using genetic resources accommodates the provider party with the necessary information about the subsequent use of the resources. As mentioned above, in case of intended transfer to third parties the agreement between provider and first user party could contain a provision ruling that in such a case the prior informed consent of the providing party prior to the transfer has to be awaited. This would offer the original provider the opportunity to negotiate a mutual agreement with the third party.[98]

Another step in warranting or at least promoting the user's compliance with the mutually agreed terms embraces the establishment of a national monitoring process to assess whether the use of genetic resources is in compliance with the terms of access and benefit sharing as well as whether the research and development process and, importantly, applications for intellectual property rights relating to the provided material are in conformity with the latter terms.[99] For that purpose, the party providing the genetic resources can negotiate, as a form of non-monetary benefits, the place of human and material resources at its disposal to strengthen the capacities for the administration and the enforcement of access regulations.[100]

In order to avoid misunderstandings and disputes as far as possible, the parties to the access agreement should determine a clear definition of potential short and long term benefits, a clear arrangement of how the latter shall be distributed, and lastly the ownership structure of the collected genetic resources.[101]

Another aspect of benefit sharing to be considered is the question of distribution of benefits. The guidelines specify that the benefits should be shared fairly and equitably with all those who have contributed to the resource management, scientific and or commercial process. Those may include governmental, non-governmental or academic institutions as well as indigenous and local communities. However, the distribution should be practised in a way

[96] Bonn Guidelines, above no.17, IV.D.2.47
[97] Glowka, above no.5, p.83
[98] ibid., p.83
[99] Bonn Guidelines, above no.17, V.C.47.(a),(b),(c)
[100] ibid., Appendix II.2.(i)
[101] Glowka, above no.5, p.83

that promotes conservation and the sustainable use of biological diversity,[102] the first two main objectives of the CBD.

Despite the reasonable desire for participation in the commercial benefits, the Bonn Guidelines emphasize that contracting parties of origin of genetic resources should seek to ensure that commercial and other use of the latter should not prevent traditional use of genetic resources.[103]

Recognizing that parties and stakeholders may be users as well as providers of genetic resources, the guidelines call on contracting parties which are "countries of origin" in terms of Art.2 (4) CBD or lawful possessors of those resources to review their taken measures to ensure their full compliance with Art.15 CBD.[104] Furthermore, those parties are required to establish mechanisms to warrant that their decisions with regard to access and benefit sharing are made available to relevant indigenous and local communities and relevant stakeholders.[105]

B1.8) Relationship TRIPS-CBD

As set out in this chapter, the CBD establishes the basic principle of the state's sovereignty over its natural resources. This aspect gives rise to the problematic question of the relationship between the CBD and the TRIPS.

Considering that the TRIPS requires its member states to provide for protection of plant varieties by means of patents or *sui generis* systems and that they at least enable the patent grant for certain genetic resources like plants and animals,[106] some states hold the view that there is an inherent conflict or at least potential for conflict between these two instruments. It is argued that to enable private parties the appropriation of such genetic resources by means of patents contradicts the sovereign rights of the states over their resources.[107] Moreover, as set out above, the CBD requires prior informed consent and benefits sharing in the field of bioprospecting, whereas the TRIPS requires or enables genetic resources to be patentable without recognizing and protecting these provisions.[108] It is therefore suggested to amend the TRIPS to incorporate these CBD requirements. Applicants could be required "to disclose the

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[102] Bonn Guidelines, above no.17, IV.D.2.48
[103] ibid., II.C.16.(a)(iii)
[104] ibid., II.C.16.(a)(i)
[105] ibid., II.C.16.(a)(vi)
[106] Art.27 (3)(b) TRIPS
[107] WTO Council for Trade-Related Aspects of Intellectual Property Rights, 2002, *The Relationship between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge*, p.1, [Online], Available: http://docsonline.wto.org/DDFDocuments/t/IP/C/W356.doc, last accessed 18.05.2006
[108] WTO Council for Trade-Related Aspects of Intellectual Property Rights, 2002, *Minutes of Meeting Held in the Centre William Rappard on 21 and 22 September 2000*, Para 144, [Online], Available: http://docsonline.wto.org/DDFDocuments/t/IP/C/W368.doc, last accessed 18.05.2006

source and country of origin of any biological resources or traditional knowledge used in inventions, and to demonstrate that they had obtained prior informed consent from the competent authority in the country of origin and entered into fair and equitable benefit-sharing arrangements".[109] As long as the respective patent application is inconsistent with the provisions set out in Art.15 CBD the granting of the patent shall be denied.[110]

The opponents of these arguments advance that there is no conflict between the Agreement and the Convention since both have different objects, deal with different subjects, and can be implemented in a mutually supportive way at the national level.[111]

As long as the criteria for patentability are applied correctly, the grant of valid patents over inventions that use genetic material is ensured. Those patents do not run counter the compliance with the CBD's objects of the countries' sovereignty over their genetic resources, or prior informed consent and benefit sharing.[112]

In support of this opinion, the example of isolated or modified genetic material is submitted. Holding a patent on such neither amounts to ownership of the material itself, nor gives it property rights to the source the material is originating in. Such a patent only provides the patentee with the right to prevent others from certain actions, such as producing, marketing and using the material. Its source itself remains unaffected by the patent.[113] A life form in its natural state would not satisfy the criteria for patentability set out in the TRIPS.[114] Those are novelty, inventive activity and capability of industrial application.[115]

With regard to the proposal to include disclosure provisions in the TRIPS it is expressed that "intellectual property rights do not aim to regulate the access and use of genetic resources, to regulate the terms and conditions for bioprospecting or the commercialisation of IPR-

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[109] WTO Council for Trade-Related Aspects of Intellectual Property Rights, 2006, *The Relationship between the TRIPS Agreement and the Convention on Biological Diversity – Summary of Issued Raised and Points Made*, S.14, [Online], Available: http://docsonline.wto.org/DDFDocuments/t/IP/C/W368R1.doc, [hereinafter WTO, *Relationship TRIPS-CBD, summary 2006*], last accessed 19.05.2006

[110] WTO Council for Trade-Related Aspects of Intellectual Property Rights, 2000, *Communication from India*, S.4, [Online], Available: http://docsonline.wto.org/DDFDocuments/t/IP/C/W196.DOC, last accessed 19.05.2006

[111] WTO Council for Trade-Related Aspects of Intellectual Property Rights, 2005, *Article 27.3(B), Relationship between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore, Communication by the United States*, S.3, [Online], Available: http://docsonline.wto.org/DDFDocuments/t/IP/C/W449.doc, [hereinafter WTO, *Relationship TRIPS-CBD,US communication*], last accessed 19.05.2006

[112] WTO, *Relationship TRIPS-CBD, summary 2006*, above no.109, S.8

[113] WTO Council for Trade-Related Aspects of Intellectual Property Rights, 2000, *Review of the Provisions of Article 27.3(b), Further Views of the United States- Communication from the United States*, p.4, [Online], Available: http://docsonline.wto.org/DDFDocuments/t/IP/C/W209.doc, [hereinafter WTO, *Review of Art. 27.3(b) TRIPS, US Communication*], last accessed 19.05.2006

[114] WTO Council for Trade-Related Aspects of Intellectual Property Rights, 2001, *Review of the Provisions of Article 27.3(b) of the TRIPS Agreement, Communication from the European Communities and their member States*, S.8, [Online], Available: http://docsonline.wto.org/DDFDocuments/t/IP/C/W254.doc, [hereinafter WTO, *Article 27.3(b) TRIPS, EC Communication*], last accessed 20.05.2006

[115] Art.27 (1) TRIPS

protected goods and services". Moreover the patent provisions are not aimed at enforcing a third country's ABS legislation. The task of patent authorities is to examine whether an invention meets the national patentability criteria.[116]

As long as the grant of a bad patent emerges, "post-grant opposition or re-examination proceedings could be used to rectify those rare cases when patents are issued erroneously."[117]

Lastly, in order to fight erroneously issued patents from a basis of traditional knowledge, it is submitted that one manner of pursuing this aim is through the establishment of databases of such knowledge. As long as the public and especially patent examiners have access to such databases, the likelihood of the granting of bad patents would decrease.[118] This approach is not free of jeopardy for the knowledge holder as will be elaborated later in this minithesis.

Ultimately it has to be ascertained that there is no inherent conflict between TRIPS and CBD. Even though genetic material of a biological resource might be patentable under certain circumstances, the sovereignty of the state, the source of origin of the resource, over the source is not affected. In addition to this, this view is supported by the fact that there is no national patent legislation known that provides for patent grants for genetic resources in their natural occurring, that is uncultivated, state. A proper definition of the patentability criteria with a strong patent revision regime can furthermore avoid or at least counter the grant of bad patents. However, it has to be admitted that in the field of patent applications, the requirement of proof of prior informed consent and benefit sharing is at least desirable to promote the respective objectives of the CBD. It is not decisive that the primary objective of IPR legislation is to entitle the holder of the respective right to exercise various exclusive rights depending on the subject of the right. However, the IPR regime could be used to promote the ABS objectives of the CBD. It must be recalled, however, that the number of countries that have instituted ABS regulations is still limited and that this is why an ABS certificate or the like could sometimes not be submitted by IPR applicants,[119] of course, this can be countered by pointing out that of course such a certificate could only be required if the country providing the biological resources issues those.

B2) Art.16 (3),(5) Convention on Biological Diversity

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[116] WTO, *Article 27.3(b) TRIPS, EC Communication*, above no.114, S.21
[117] WTO, *Relationship TRIPS-CBD,US communication*, above no.111, S.31
[118] WTO Council for Trade-Related Aspects of Intellectual Property Rights, 2004, *Article 27.3(B), Relationship between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore, Communication by the United States*, S.29, [Online], Available: http://docsonline.wto.org/DDFDocuments/t/IP/C/W434.doc, last accessed 21.05.2006
[119] WTO, *Article 27.3(b) TRIPS, EC Communication*, above no.114, S.22

As mentioned above Art.16 deals with the access to and transfer of technology. Of particular interest in the field of benefit sharing is Art.16 (3). It reads as follows:

> 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 and consistent with paragraphs 4 and 5 below.

Paragraph 3 deals with the transfer of technology which makes use of genetic resources.
The parties are not obliged to actually transfer technology using such resources to parties providing the latter. However, they are required, independent from their development status, to implement appropriate actions, a framework with the aim of allowing access to and transfer of technology - making use of genetic resources to contracting parties providing those resources - takes place.[120]
Furthermore, unlike other provisions in the field of access and benefit sharing, the paragraph does not only impose obligations on contracting parties which are potential parties to an access agreement themselves or whose private sector might be, whether as a providing or using contractual partner. The provision is broader. Each contracting party - regardless whether developed or undeveloped - which has at its disposal technology for making use of genetic resources shall take appropriate measures with the aim of providing access to and transfer of such technology to contracting parties providing those resources. So, the assumption of possibly initiating a contractual relationship between parties disposing of the respective technology and parties which do not is of no significance.
It is true, that the range of receivers of technology is not limited. However, the emphasis is laid on the obligation towards developing countries.[121]
The aim of the provision is to let the transfer of technology take place. How the parties fulfil this obligation is left to their discretion. A party could require its governmental agencies to transfer technology which they dispose of. The same obligation could be imposed on anyone receiving subsidies or other public financial benefits and disposing of such technology. If the latter requirement is not yet fulfilled, the beneficiary could be obliged to develop the respective technology, for example, to grant the financial support on condition of the

[120] Glowka, above no.5, p.90
[121] ibid., p.90

development of the asked technology. Another way to pursue the distribution of the respective technology is to purchase technology developed by the private sector and to deliver it subsequently to the party providing the resources. Lastly incentives could be provided to promote the private sector to transfer the technology directly to the recipient.[122] The latter approach will certainly have to go hand in hand with financial incentives for the provider of the technology, since there is no reason to believe that the private sector would provide the technology voluntarily without any benefit.

The transfer of the technology shall be carried out on the basis of mutually agreed terms. This agreement can be achieved in the course of the negotiation of an access agreement, although, as mentioned above, the latter constitutes no condition for the transfer of the respective technology.

Furthermore, paragraph 3 refers to Art.20 and 21 CBD. These contain regulations on the financial mechanism of the convention to be established and monitored by the conference of the parties. That means that, if necessary, the transfer of technology can be connected with, for example, the use of funds.

Moreover, the transfer of technology must be in accordance with international law. This includes international intellectual property law. The latter is the subject of paragraph 5 which reads:

> 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.

The formulation "may have an influence" leaves the question of whether the impact on implementing the convention is to be considered as positive or negative open. The parties are rather obliged to cooperate to warrant that those intellectual property rights do not run contrary to the convention's objectives. This should be reflected in both international and national legislation. The latter could comprise the development of contractual agreements embracing provisions for the use of intellectual property rights which include joint research, the obligation to implement rights on inventions obtained and to provide licences by common consent.[123] According to the degree of contribution those intellectual property rights could

[122] Glowka, above no.5, p.90
[123] Bonn Guidelines, above no.17, IV.D.1.43.(c)

also be jointly owned by both the providing and the using party.[124] Ultimately, the parties are free to negotiate material transfer provisions assigning, transferring or excluding the right to claim any property rights, including intellectual property rights over the provided genetic resources.[125]

In the past, developing countries advanced that strong patent rights compromise the transfer of technology, in particular, since protected technology is dearer and its use restricted. As such, technology is less affordable to developing countries resulting in their economic development being curbed. Industrialised nations, on the other hand, hold a strong protection of intellectual property rights necessary to promote technological transfer to developing countries. Furthermore, such legal system would provide an incentive for local innovation. In the meantime the debate is fading, since many developing countries, in particular Latin American and East Asian, have introduced or strengthened their protection of intellectual property. This is to a certain extent due to the pressure placed on those countries by developed nations as well as the increased capability of many developing countries to produce technologies, appropriate to be or already protected, for the international market.[126]

B3) Art.19 Convention on Biological Diversity

Art.19 is a provision the specifically deals with the handling of biotechnology and the distribution of its benefits. In doing so it renews some obligations already imposed on the contracting parties by Art.15 and 16 CBD but at the same time enhances the former. Paragraph 1 aims at the provider party's participation in biotechnological research. Paragraph 2 rules the provider's access to the results and benefits derived from biotechnologies.

B3.1) Paragraph 1

> Each contracting Party shall take legislative, administrative or policy measures, as appropriate, to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research, and where feasible in such Contracting Parties.

Paragraph 1 pursues the establishment of biotechnological research capacity through contracting provider parties, especially developing countries, through their own participation

[124] Bonn Guidelines, above no.17, IV.D.1.43.(d)
[125] ibid., Appendix I.C.9
[126] Glowka, above no.5, p.91

in research as a form of soft technology transfer.[127] As addressed above, Paragraph 1 renews but also enhances the obligation imposed on the contracting parties by Art.15 (6) CBD in the field of biotechnological research. Art.15 (6) CBD requires the parties only to endeavour to develop and carry out scientific research based on genetic resources with the participation of the provider party. The obligations set out in Art.15 (6) CBD are thus merely an effort. Paragraph 1 goes beyond that. The contracting parties are required to take appropriate measures to create a framework through which "effective participation" can take place. Art.15 (6) CBD requires the "full participation" in research. The substitution of effective for full makes clear the intent that the participation is to be of substantive nature. Full participation would already be granted if the provider party would be allowed to join the research as an observer. In contrast, effective participation pursues cooperative efforts, the joint setting of goals and attaining of results being mutually beneficial to both the provider as well as user party of genetic resources.[128]

Likewise set out in Art.15 (6) CBD, the biotechnological research should be carried out in the realm of the providing party if possible. This is aimed at building up endogenous technical and technological capacity in contrast to the sending of researchers to the user party where the latter would just participate in a joint research. Moreover this procedure could result in hard technologies' transfer to the provider party to facilitate the research. Subsequently, the provider party's own personnel has been trained and, moreover, as far as negotiated, the technical equipment being used for the research can remain in the country for future research.[129]

The text of the convention does not determine that the measures to be taken have to be valid for the private sector as well. Thus it is up to each party to the convention whether the extension to the private sector is considered necessary to fulfil the objectives of this provision. Private sector involvement could be facilitated by providing incentives. If private biotechnological research on genetic resources is funded by public money, the provider of the fund could condition the grant on the provider of the resources' effective participation in research.[130]

Eventually, as mentioned above in the discussion of Art.15 (7) CBD, the party providing access to the resources can provide for research participation by including this aspect in the negotiation of the access agreement. Since the research in the resources does not necessarily

[127] Glowka, above no.5, p.96
[128] ibid., p.96
[129] ibid., p.96
[130] ibid., p.96

have to take place immediately after the resources being provided, a notification prior to the conduct of the research can be stipulated.[131]

Furthermore, it has to be pointed out that in contrast to the obligations set out in Art.16 (3) CBD there is a correlation between the provision of genetic resources and the granting of effective participation in the research in the particular resource. Participation in biotechnological research, as mentioned above, is a form of transfer of soft technology, and therefore has to be granted only to a party of an access agreement which provides the genetic resources. Thus the requirements for the obligation arising from Paragraph 1 is much stronger than those from Art.16 (3) CBD.

B3.2) Paragraph 2

> Each Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms.

Providing for the entitlement to benefits and the requirement of mutually agreed terms, the provision parallels Art.15 (7) and 16 (3) CBD. The terms "results" and "benefits" are not defined in the convention. However, in common language use, results are the end product of the biotechnological research. This embraces any scientific or technological data, product or process, produced for profit or not. Benefits consist of the advantages arising out from the use of the results such as technical or technological information or any commercial profits. The words "promote and advance" were chosen to avoid any commitment of the parties to impose an obligation on its respective private sector. The contentious formulation was advanced and conditioned by most developed countries, even though major biotechnological research is conducted in the private sector. Again, whether the latter is included is left to the discretion of the parties. Pursuing the objectives of the convention the limits are set by what is reasonably practicable. Thus, the parties to the convention are at least expected to provide for incentives for the private sector to grant priority access to results and benefits arising from biotechnologies. "Priority access" in this regard indicates preferential treatment. Likewise set out in Art.15 (7) and 16 (3) CBD the access has to be on mutually agreed terms. Again, this aspect should preferably be linked with the negotiation for the resource access agreement.[132]

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[131] Glowka, above no.5, p.97
[132] ibid., p.97

II. The protection of traditional knowledge

1. Definition of traditional knowledge

Traditional knowledge embraces the knowledge, innovations and practices of indigenous and local communities relevant for the conservation and sustainable use of biological diversity.[133] "Traditional" does not mean that the knowledge is antiquated. Rather, the term refers to the way it is acquired and used.[134] It has developed from experience gained over years, centuries, even up to millenniums and has been adapted to the respective local culture and environment. However this does not necessarily exclude that such knowledge constantly evolves.[135] On the contrary it is being created every day, "evolving as a response of individuals and communities to the challenges posed by their social environment"[136]. It tends to be collectively owned and is transmitted orally from one generation to the next by means of stories, songs, folklore and proverbs. Traditional knowledge is not limited to agricultural practices like the development of plant species and animal breeds. It also comprises cultural values, beliefs, rituals and local language.[137] However, in this elaboration the focus is put on its practical nature in fields such as agriculture and health.

2. Is there a need for protection?

Traditional knowledge's application is by no means restricted to indigenous communities. Modern society has already benefited and can still benefit from such knowledge, especially in the achievement of sustainable development. A large proportion of the world's crop diversity is in the hands of farmers following ancient farming and land use methods capable of conserving biodiversity as well as providing other local benefits such as reduced insect and disease incidence.[138] Moreover, nearly all plant derived drugs in modern Western medicine

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[133] Secretariat of the Convention on Biological Diversity United Nations Environment Programme, *Article 8(j): Traditional Knowledge, Innovations and Practices What the Convention says about Traditional Knowledge, Innovations and Practices*, [Online], Available: http://www.biodiv.org/programmes/socio-eco/traditional/what.asp, last accessed 17.05.2006

[134] Dutfield, G., 1999, *The Public and Private Domains: Intellectual Property Rights in Traditional Ecological Knowledge*, WP 03/99, OIPRC Electronic Journal of Intellectual Property Rights, 1., [Online], Available: http://www.oiprc.ox.ac.uk/EJWP0399.html, [hereinafter Dutfield], last accessed 12.05.2006

[135] Krumenacher, T. J., 2004, *Protection for Indigenous Peoples and Their Traditional Knowledge: Would a Registry System Reduce the Misappropriation of Traditional Knowledge*, Marquette Intellectual Property Law Review, No. 8, p.146, [Online], Available: http://www.heinonline.org/HOL/Page?handle=hein.journals/marq8&id=147&collection=journals, [hereinafter Krumenacher], last accessed 13.05.2006

[136] WIPO, *Intellectual property needs,* above no.26, p.212

[137] Secretariat of the Convention on Biological Diversity, *Traditional Knowledge and the Convention on Biological Diversity*, p.1, [Online], Available http://www.biodiv.org/doc/publications/8j-brochure-en.pdf, last accessed last accessed 13.05.2006

[138] WIPO, *Intellectual property needs,* above no.26, p.213 et seq.

were not discovered coincidentally but from their use in traditional societies.[139] This shows clearly that the protection of traditional knowledge can provide both environmental benefits as well as possible commercial applications.

The passing on of information, how to use a certain natural resource for the good of humankind, is desirable but has to go hand in hand with the holder's participation in the benefits, no matter of which kind.

The latter aspect clarifies that the protection of traditional knowledge not only comprises its preservation and maintenance but also the reduction and exclusion, respectively, of its misappropriation. That is, the protection has both a substantial as well as legal component.

That there is a need for protection against misappropriation is based on the fact that often, for instance, ancient herbal remedies are identified by Western scientist and finally used for the launch of high-priced pharmaceuticals without the consent of the knowledge holder or their adequate participation in the benefits,[140] and without an appropriate sharing of the benefits arising from the utilization of traditional knowledge.

However, there are also critical voices, opposing any form of legal protection of traditional knowledge. This opinion is based on the view that traditional knowledge is by its nature in the public domain and should not be the subject of exclusive rights.[141] Further points of criticism, especially with regard to the legal protection by means of IPR, will be specified below.

3. The Convention on Biological Diversity

A) Art.8 (j) CBD

Most indigenous and local communities are situated in biodiversity-rich areas where moreover the vast majority of the world's plant genetic resources are found. Living consistent with nature, many of these communities have cultivated and used biodiversity sustainably for thousands of years. Skills and techniques for conservation and sustainable use of natural resources, developed by them, provide valuable information to the world community for biodiversity policies.[142]

As set out in the preambular paragraph 12 CBD, the international community has recognized the close and traditional dependence of many indigenous and local communities embodying

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[139] Glowka, above no.5, p.49
[140] Krumenacher, above no.135, p.143 et seq.
[141] WIPO, *Intellectual property needs,* above no.26, p.216
[142] Secretariat of the Convention on Biological Diversity United Nations Environment Programme, *Article 8(j): Traditional Knowledge, Innovations and Practices Introduction*, [Online], Available: http://www.biodiv.org/programmes/socio-eco/traditional/default.aspx, [hereinafter Secretariat of the CBD, *Article 8(j): TK Introduction*], last accessed 03.05.2006

traditional lifestyles on biological resources. Knowledge, related to the genetic resources of a particular habitat which lacks of appliance falls into oblivion if the habitat with its flora and fauna is destructed. Therewith, if communities and practices of indigenous and local people die out, the vast store of accumulated knowledge is lost for good. Hence, the loss of biological diversity involves not only a loss of genes, species and ecosystems but eventually also of cultural diversity.[143] Facing these consequences of progressing environmental pollution and destruction, the contracting parties recognized the link between indigenous communities and the respective biological resources surrounding them in several places. However, the central provision addressing the subject is provided in Art.8 (j).

It reads:

> Each Contracting Party shall, as far as possible and as appropriate: ...
> (j) Subject to its national legislation, 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 their 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 utilization of such knowledge, innovations and practices;

The provision requires the contracting parties not only to maintain traditional knowledge but also to extend its application and to equitably share the benefits deriving from its utilization. Specifying indigenous and local communities as "embodying traditional lifestyles" the contracting parties expressed their intention to exclude the article's application to people of traditional descent but who no longer live in communities practicing their traditional lifestyles.[144]

One way to conserve traditional knowledge is to protect and promote the customary use of biological resources under recognition of conservation and sustainability aspects, as called for in Art.10 (c) CBD.[145] The rate of erosion of traditional biodiversity-related knowledge held by indigenous and local communities has never been as high as in the current generation. It is therefore crucial for the development of appropriate incentives to secure the appliance of traditional knowledge within and beyond this generation. Doing so, it is furthermore most important to develop and apply these measures in a manner that maintains community and

[143] Glowka, above no.5, p.48
[144] ibid., p.48
[145] ibid., p.48

ecological balance. That is, even if the respective knowledge is held only by a small group of community members or only one single person, measures are not to be aimed at rewarding only this specific group or individual so as to avoid the risk of repercussions for community stability.[146]

In many cases, government policies such as modern biological resource management have resulted in the loss of diversity in cultural and biological respects. An example for the former is the creation of protected areas designed to exclude surrounding populations, disenfranchising indigenous and local communities from the biological resources which they may depend on to make their income and or to keep up their cultural identity. Hunting of a certain species in that area, practiced over centuries, becomes poaching and traditional agriculture in that area an illegal encroachment.[147] This example shows that potentially the protection of the environment can result in the suppression and finally deactivation of traditional knowledge. This interdependence has to be considered by national governments and the adverse impact to be minimised as far as possible, for example, by including the communities in the work and maintenance of the respective protected area. Thereby compatible customary uses and traditional knowledge, compatible with conservation and sustainable use requirements could be encouraged within a supervisory framework of checks and balances.[148] Local communities' participation could be achieved in manifold ways. One possibility to involve them is through recruiting 'locals' with a background of customary use of biological resources for the park staff. Another way to accomplish their inclusion is the delegation of day to day management responsibility from the national or provincial to local level. Doing so, appropriate customary uses, traditional knowledge and cultural institutions could complement modern practices and institutions to improve protected area management.[149] Thus, the contracting parties are firstly called for screening their policies and to identify and eliminate their adverse impact with regard to the loss of biological diversity through the erosion of cultural diversity.

Over the centuries many traditional communities have developed a lifestyle in harmony with the nature surrounding them. Ultimately those communities control the biological resources of their environment.[150] That is why there is a danger to the surroundings not only by e.g. economic companies exploiting habitats but also by the communities themselves. That is, if communities are concerned with rapid population growth and or poverty, their members are

[146] Secretariat of the CBD UNEP, *TK and BD*, above no.12, p.14 et seq.
[147] Glowka, above no.5, p.60
[148] Secretariat of the CBD UNEP, *TK and BD*, above no.12, p.18
[149] Glowka, above no.5, p.61
[150] ibid., p.60

often forced to exploit their surroundings in a way that lacks the above mentioned harmony. If a habitat is sustainably managed by a community consisting of 1000 members, this sustainability is disordered if the population doubles in a short space of time. The new members need foodstuff, which have to be cultivated. This need for acreage is often for account of former natural habitats and not seldom leading to land degradation. If poverty arises or increases, the members of indigenous communities are forced to find new revenues. If the only revenue is their surrounding, the concerned will start to increase its exploitation, sometimes with fatal effects. Thus, the contracting parties have to recognise and fight threats to habitats not only from alien origin but also those threats rooted in the respective habitats themselves. Thereby, the contracting parties are invited to introduce modern techniques and practices to help those concerned communities to overcome problems which they traditionally did not have to deal with.[151]

As mentioned above, the contracting parties are not only asked to maintain traditional knowledge but furthermore to promote its wider application. This obligation, however, is qualified by the necessary approval and involvement of the respective knowledge holder. It is, however, vague as to who is deemed to be the holder of this knowledge. It could be the respective community itself but also a member of the latter, such as a farmer or the local healer.[152]

Moreover the contracting parties considered it desirable to equitably share the benefits arising from the use of traditional knowledge relevant to the conservation of biological diversity and the sustainable use of its components, both fundamental objectives of the Convention. Thus, the parties acknowledged the great economic and non-economic value of traditional knowledge to modern society and the holders' entitlement to decide how to share the knowledge and under what conditions.

In resent years, genetic resource related traditional knowledge has often been used by modern industry to develop and launch new products and techniques without participation and consent of the holders of such knowledge. Moreover they have not received any of the resulting benefits.[153]

To enable the wider application of the knowledge and at the same time warranting the equitable sharing of the benefits is the big challenge to the contracting parties. Besides the above mentioned problems concerning the precise determination and valuation of the deriving

[151] Glowka, above no.5, p.61
[152] ibid., p.48
[153] Secretariat of the CBD, *Article 8(j): TK Introduction*, above no.142

benefits it can prove difficult to determine precisely who shall enjoy the benefits. This is due to the problem of exact determination of who has to be considered as the knowledge holder.[154] It seems to be most appropriate to regard the whole community as the holder[155], since, although it is not explicitly required in the paragraph, the benefits have to be shared with the knowledge holder. Considering that the knowledge usually developed over many years and several members of a community may have contributed to develop it, it seems to be unfair to grant this benefit only to one member of the community and not to the whole community.

B) Ways to protect traditional knowledge

On its forth meeting, the Conference of the Parties decided to establish an Ad Hoc Open-Ended Inter-Sessional Working Group with the aim to address the implementation of Art.8 (j) CBD and related provisions.[156] This involves the mandate to make concrete proposals and to develop guidelines on how to translate the commitments mentioned above into reality.
Its work comprises amongst others the development of elements of a *sui generis* system, for example, a system "of its own kind", for the protection of traditional knowledge, innovations and practices. The analysis recognises different approaches to such a system, which are not mutually exclusive.[157] Besides the Working Group, numerous scholars as well as the World Intellectual Property Organisation have dealt with this subject. Their suggestions are taken into account in the following proposals for solution of the problem.

B1) National intellectual property rights laws

Appropriate measures to deal with the subject are at first national intellectual property rights laws which incorporate *sui generis* elements for the protection of traditional biodiversity related knowledge. As set out above, applicants for intellectual property rights could, for instance, be required to disclose the source of genetic resources and associated traditional

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[154] Glowka, above no.5, p.48, et seq.
[155] Hansen, S.A., VanFleet, J.W., 2003, *Traditional Knowledge and Intellectual Property: A Handbook on Issues and Options for Traditional Knowledge Holders in Protecting their Intellectual Property and Maintaining Biological Diversity*, p.3, [Online], Available: shr.aaas.org/tek/handbook/handbook.pdf, [hereinafter Hansen, VanFleet], last accessed 15.04.2006
[156] Conference of the Parties to the CBD, *Decision IV/9, Implementation of Article 8(j) and related provisions*, Paragraph 1., [Online], Available: http://www.biodiv.org/decisions/default.aspx?dec=IV/9, last accessed 16.04.2006
[157] Ad Hoc Open-Ended Inter-Sessional Working Group on Article 8(j) and Related Provisions of the Convention on Biological Diversity, 2003, *Development of Elements of a Sui Generis System for the Protection of Traditional Knowledge, Innovations and Practices*, p.3, [Online], Available: http://www.biodiv.org/doc/meetings/tk/wg8j-03/official/wg8j-03-07-en.pdf, [hereinafter Working Group on Article 8(j) CBD, *Elements of a Sui Generis System*], last accessed 17.04.2006

knowledge and to provide evidence of prior informed consent of the knowledge holder.[158] The citation of intellectual origin in such application would particularly demonstrate "respect" for the contribution of the traditional knowledge holder, also required under Article 8 (j) CBD, and desired by indigenous groups and leaders.[159] In cases where the applicant refuses to disclose the source and/or cannot prove the consent, the application would have to be rejected if there are reasonable grounds for the assumption of misappropriation. The latter approach is considered as defensive protection, in other words, the preventing "of third parties from obtaining or exercising invalid intellectual property rights over traditional knowledge".[160] This approach could furthermore be internationally standardised through an international certification system. In accordance with this, countries providing genetic resources and/or related traditional knowledge would issue certificates signifying that the seeking party obeyed all obligations to the source country and the relevant knowledge holder, such as prior informed consent, equitable benefit sharing, and, where appropriate, other conditions imposing limitations on the utilization of the genetic resources or knowledge. Applying for a patent without including these certificates would then automatically result in the rejection of the application.[161] However, this approach is not free of criticism. It is argued, that "imposing additional requirements on all patent applicants only increases the cost of obtaining patents that would have a greater adverse effect on individual inventors, non-profit entities, and small and medium sized businesses, including those in developing countries."[162] These arguments are not convincing, as it is not to be expected that the simple declaration of source and the submission of copies of authorization for the respective act cause a high financial burden.

Positive Protection, on the other hand, embraces the creation of rights in traditional knowledge to protect and promote it, including the opportunity to take action or seek remedies for illicit uses.[163] As mentioned above, such positive protection is not free of criticism. It is argued that traditional knowledge is by its nature in the public domain. That is why it should not be legally protected by exclusive rights, since this would hinder the management and free flow of information.[164] Others argue that concepts of ownership and

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[158] Working Group on Article 8(j) CBD, *Elements of a Sui Generis System*, above no.157, p.3; Dutfield, above no.134, Appendix 1.1.
[159] COP to the CBD, *Access to Genetic Resources...*, above no.9, p.28
[160] Haira, A., 2005, *Using Intellectual Property Rights to Protect Traditional Knowledge*, p.19, [Online], Available: http://www.med.govt.nz/buslt/int_prop/traditional-knowledge/seminars/anne-haira/presentation/presentation.pdf, [hereinafter Haira], last accessed 16.05.2006
[161] Dutfield, above no.134, Appendix 1.1.
[162] WTO Council for Trade-Related Aspects of Intellectual Property Rights, 1999, *Review of the Provisions of Article 27.3(b), Communication from the United States*, p.6, [Online], Available: http://docsonline.wto.org/DDFDocuments/t/IP/C/W162.doc, last accessed 19.05.2006
[163] Haira, above no.161, p.19
[164] WIPO, *Intellectual property needs,* above no.26, p.216

property rights are strange to indigenous and local communities. Accordingly, if the knowledge is not considered by the holders themselves as anybody's property, nobody's rights are infringed by publishing or commercially exploiting it. In response to this it has to be argued that concepts such as ownership and property rights or at least close equivalents do exist in the majority of if not all traditional societies.[165]

A further basic approach why IPRs are unsuitable is that they protect new knowledge created by individuals and do not recognise collective rights. However, this generalized view ignores the fact that in some cases there are individuals able to distinguish themselves from the community as the informal creator or inventors of such knowledge. Moreover, IPRs are not per se individualistic against the background that numerous inventions and creations are generated in firms by groups of persons, which is recognized by the IP regime.[166]

Difficulties, again, arise since commonly traditional knowledge cannot be traced to a specific holder as a community or single person. Hence, if there is no group of people to whom the knowledge is attributable, there is none to which such rights can be vested. But even if the holder is clearly identifiable, there are practical obstacles making patenting an unattractive option. This is due to the assumption that it is most unlikely that potential applicants could afford the acquisition as well as the defence of a patent.[167] Although this circumstance is true for most of the communities, the cost argument does not render the whole system unfair. This is in particular the case if firstly the expenses are reduced, an approach already practiced in certain national patent offices with regard to independent inventors and small and medium-sized enterprises. Secondly, if communities or individuals that are willing to make use of but lack the practical experience with the formal IP system receive assistance.[168] Such support, for instance, by means of information and training on the system could be offered and carried out by national IP offices and other agencies designed to facilitate access to the national IP system.[169]

Some opponents of patent protection of products derived from traditional knowledge advance that once it is granted to another party, like a foreign company, members of the community out of which the knowledge was gained are prevented from further use of the knowledge. This does not hold true as long as only the invention, i.e. what the third party made out of the knowledge as a basis, gains protection. The members of the community are thus not prevented from further use of the knowledge. As long as the knowledge received no further

[165] WIPO, *Intellectual property needs,* above no.26, p.220
[166] ibid., p.219
[167] Dutfield, above no.134, 3.
[168] WIPO, *Intellectual property needs,* above no.26, p.222, 223, 227
[169] ibid., p.227

development but nevertheless passed the novelty test of national IP-legislation, it is important but also practice in numerous countries, to consider "prior use" exceptions allowing people already exploiting an invention to continue after the knowledge becomes subject to a patent held by a third party.[170] The same goes for cases in which one indigenous community applies for the grant of a patent of its traditional knowledge with regard to other communities holding the same knowledge, again, as far as the application passes the novelty test. If the national legislation does not provide for such an exception and the applied patent is granted in the country where the community using the knowledge is situated, the concerned community would indeed be deprived from its continued free use. However, those cases are no examples for the non-suitability of IPR law for the protection of traditional knowledge but rather for non-appropriate definition of the novelty criterion in the examination of a patent application.

B2) Legislatory measures ruling access and benefit sharing

Another possibility in tackling this subject is to take legislatory measures entrenching the access and benefit sharing provisions of the CBD. In this regime provisions addressing the protection of traditional knowledge, especially issues of ownership and access to the knowledge could be included. In cases where access is sought for genetic resources and related knowledge, provider states could require their prior informed consent and additionally the consent of the respective knowledge holder.[171] Of course, the latter is superfluous if the state determines itself as the holder of the knowledge. Where the contracting parties include the respective provisions is up to them. Appropriate options vary from frameworks for the conservation and sustainable use of biological resources to comprehensive indigenous/local community rights laws or comprehensive *sui generis* cultural heritage protection laws.[172] In any event, the indigenous community, where the respective knowledge is actually held, has to receive advice and assistance in respect of the national legislation as well as agreements on access and benefit sharing,[173] to strengthen their position in the negotiation of such agreements with third parties.

B3) Main Elements of a *sui generis* system

The Working Group eventually does not favour one specific approach to the appropriate protection of traditional knowledge. What it does is to identify main elements to be

[170] WIPO, *Intellectual property needs,* above no.26, p.222
[171] COP to the CBD, *Access to Genetic Resources...*, above no.9, p.28
[172] Working Group on Article 8(j) CBD, *Elements of a Sui Generis System*, above no.157, p.4 et seq.
[173] WIPO, *Intellectual property needs,* above no.26, p.232

considered as components of a *sui generis* system, as appropriate to national needs and circumstances.

The main objectives of such a system form have already been discussed above; subjects such as the control of access to and use of traditional knowledge, the exercise of the right to require prior informed consent, the equitable sharing of its benefits as well as the maintenance of continued customary use of the knowledge.[174]

Besides providing relevant definitions, the system should clarify the respective rights of indigenous and local communities over genetic resources and associated knowledge as well as determine the ownership of said resources. The latter, as mentioned above, can be vested in the state, a local body or the community itself, or even several communities respectively,[175] but also individuals. The matter of ownership can be crucial for the determination, whose prior consent has to be obtained, for example, whether the approval of the provider state suffices or whether the concerned community also or instead of the state needs to declare its approval, and then who would primarily be entitled to benefit sharing. In doing so, the parties to the convention can use the respective guidance provided in the Bonn Guidelines. This concerns especially matters of prior informed consent systems with the involvement of a competent authority, the elaboration of mutually agreed terms as well as benefit sharing,[176] see above.

Furthermore the system may set the conditions for the granting of rights, amongst others, clarifying which traditional knowledge will be protected, its content, acquisition, duration as well as transfer and licensing.[177]

The approaches to duration of the rights are twofold: One way is to establish protection for traditional knowledge for an indefinite time, giving consideration to its intergenerational and incremental nature. Another one is to limit the protection for a certain period, for example 50 years from the first commercial exploitation of the protected knowledge.[178] However, in these cases the legislator will have to consider that patents on products or processes, depending on his own legislation, usually expire after 20 years. Usually after being expired, the content of the patent becomes part of the public domain and is not protected any longer. A way to solve this problem is through adapting the term of protection to the respective 'term of protection of used traditional knowledge' to either the whole product or process or as far as it is separable to the part relating more directly to the knowledge component.

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[174] Working Group on Article 8(j) CBD, *Elements of a Sui Generis System*, above no.157, p.10
[175] ibid., p.10 et seq.
[176] ibid., p.11
[177] ibid., p.11
[178] ibid., p.12

Furthermore, as part of the *sui generis* system, the establishment of registers and databases of traditional knowledge could be taken into consideration. This aspect will be assessed in the next subparagraph.

Since intellectual property rights, no matter of which kind, are useless unless they can be enforced, the parties to the convention should provide for effective and expeditious remedies against its unauthorized use. As far as there is cause for concern that the communities holding the knowledge are unable to enforce their rights, the administration of rights could be exercised by a governmental institution. As far as the state is in charge of granting prior informed consent, administrative and judicial review should be warranted for the assessment of possible environmental, cultural and social impacts.[179] Moreover, since biopiracy and the misappropriation of traditional knowledge often appear in an international context, problems are likely to arise if the concerned party cannot prosecute or hold liable the perpetrator. Hence, there is need for a multilateral framework ensuring the protection of all stakeholders involved, i.e. the protection of foreign expressions of traditional knowledge. The basis for this treatment may be national reciprocity but should not be limited to this, as countries that do not have indigenous or local communities or that do not recognize their rights should be included in the framework.[180]

B4) Registry systems of traditional knowledge

As set out above, the CBD leaves it to the contracting parties to decide how to maintain and protect the traditional knowledge of their indigenous and local communities.

Another manner through which this aim can be pursued on the one hand while not excluding other measures on the other hand, is the establishment of registry systems of traditional knowledge, in other words, official collections of documentation that describe traditional knowledge.

B4.1) Pros

Once such a register has been created, firstly, it permanently catalogues the respective knowledge, preventing it from falling out of use and being lost completely. Secondly, interested parties can be provided with information about traditional knowledge, available in the registry, in exchange for a fee.[181] Thus, registries would be conducive to Art.8 (j) CBD's objective of promoting the wider application of such knowledge. Thirdly, such registries could provide a resource for patent examiners worldwide to identify traditional knowledge

[179] Working Group on Article 8(j) CBD, *Elements of a Sui Generis System*, above no.157, p.13
[180] ibid., p.13
[181] ibid., p.6

used for the product sought to be patented. If an examiner identifies such knowledge in a registry, he has to reject the application as unpatentable, based on lack of novelty provided that there is no sufficient differentness.[182]

The prerequisite for the knowledge's recognition as prior art, is that the examiner disposes of access to such registers. It has therefore been recommended to provide all national patent offices access to such registries to carry out prior art searches. On the one hand, the limitation of access to the register or database to patent offices goes hand in hand with the limitation of misappropriation. On the other side, a general public access would certainly render challenges of misappropriation more difficult.[183] This is why, if traditional knowledge is secret, adequate measures are to be taken to protect it.

It has been suggested to differentiate the role of registers at different levels of operation. In a two-tiered system of traditional knowledge registers, at the local level, community-based registers could be created containing all kinds of cultural information. These would, for instance, contain information about traditional knowledge beyond its strictly technical components, such as information on associated rituals or ceremonial information. This detailed registration would best promote the registers' function as preservation and maintenance of traditional knowledge inclusive of its cultural aspects. As far as desired, the confidentiality of this information has to be safeguarded by means of restricted access. At the national level, registers could be restricted to provide only information as to the technical components of traditional knowledge necessary for providing evidence of prior art with respect to patent applications.[184] The task of establishing and maintaining the national register could be undertaken by the competent authority[185] as has been described above.

Besides making it more difficult to misappropriate traditional knowledge, the establishment of registries would offer an opportunity to quantify its economic value, enabling the rewarding of the knowledge holder and the benefiting of the world through new and beneficial products.[186] The latter is based on the assumption that, for example, pharmaceutical or agricultural companies gaining acknowledgement of certain appliances of traditional knowledge might be encouraged to develop beneficial products and launch them on the international market. It goes without saying that the description of the respective knowledge and appliances being made public would have to be restricted in order to prevent malpractice. This issue will be addressed below.

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[182] Krumenacher, above no.135, p.144
[183] ibid., p.156
[184] Working Group on Article 8(j) CBD, *Elements of a Sui Generis System*, above no.157, p.7
[185] ibid., p.13
[186] Krumenacher, above no.135, p.156

B4.2) Cons

However, there are also critical voices on the notion of documenting and registering this information. Opponents to this view argue that traditional knowledge is constantly developing, as was mentioned above. Once it is documented in a registry its significance will diminish over the years unless its records are being constantly updated.[187] This argument can be opposed, firstly, through suggesting that recorded traditional knowledge, which is out of date, is better than it being lost forever if its development and/or application ends in future. A significant problem and challenge to indigenous and local communities is the reluctance of their younger generation to become familiar with the "old ways". The young members of such communities often reject traditions as modern lifestyles encroach on their lives. This often goes hand in hand with the decline and eventual loss of traditional knowledge. Especially precarious is the situation in communities where the knowledge is held only by a single person. If the latter does not find an appropriate successor, the death of the knowledge holder can bring about the demise of an entire tradition and knowledge system unless it has been documented.[188]

Secondly, its registration should not distract from the priority of protecting traditional knowledge *in situ*, see above. Both the registration and the *in situ* protection are not mutually exclusive. However, it has to be pointed out again that considering that traditional knowledge is also contemporary knowledge, it is not only desirable to document and preserve such knowledge created in the past but also to develop a system going beyond the simple registration of the knowledge and contributing to the promotion and dissemination of innovations based on a progressive use of tradition.[189]

Moreover, problems could arise in cases where the knowledge is only recorded in private databases, for example, those that are not made publicly available through publication. If, for instance, a pharmaceutical company gains privately registered knowledge about a healing plant from an indigenous community and then patents this knowledge, the successful challenge of the patent would depend on the respective patent legislation where the patent is held. Generally, as mentioned above, parties to the TRIPS shall provide for patents for "any inventions [...] provided that they are new, involve an inventive step and are capable of

[187] Dutfield, above no.134, 1.1.
[188] WIPO, *Intellectual property needs,* above no.26, p.214
[189] ibid., p.212

industrial application".[190] The crucial point with regard to the registries would constitute the interpretation of 'prior art' and 'public domain' in the respective legal jurisdiction.[191]
According to the US Patent Act (Title 35 U.S. Code, Section 102), prior art is interpreted amongst others as

> "unless [...] the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent ...".

That is, if for example an indigenous tribe in the US uses traditional knowledge to produce a medical product out of a plant, an application of a third party for patenting the same product using this traditional knowledge would not be granted. It would be regarded as being in the public domain. However, if the community applying the respective knowledge was situated in a foreign country, the application would be granted. Only if this specific knowledge has been patented or published in writing, no matter whether in the US or another country, the patent would be barred. If the concerned community, not having described the knowledge in a printed publication, would challenge the patent, it would fail. The impact of the approach the US have taken, which – as set out above – insists on the opinion that a conflict between the CBD and the TRIPS could be avoided by means of proper application of patentability criteria, becomes even clearer on the basis of the following theoretical example. If a country of the size of China, inhabited by indigenous people, uses traditional knowledge for centuries without having publicly documented it in written form, this knowledge would not be part of the public domain under the US Patent Act. If, however, a certain application of traditional knowledge is completely forgotten and only documented by means of a single copy of a book in a public library in South Greenland, the knowledge described in this copy would be in the public domain according to US law. Nevertheless, the US argue that the reason for the issuance of some bad patents is due to the inaccessibility of unpublished knowledge, in other words, the fault does not lie in the patent system.[192]
A diametrical approach is taken by the states party to the European Patent Convention. Its Art.54, Section 2 defines novelty, i.e. state of the art as

> "everything made available to the public by means of a written or oral description, **by use**, or in any other way, before the date of filing of the European patent application."
>
> [emphasis added]

[190] Art.27 (1) TRIPS
[191] Dutfield, above no.134, Appendix 1.3.
[192] WTO, *Review of Art. 27.3(b) TRIPS, US Communication*, above no. 113, p.4, 113

That is, even if the respective traditional knowledge was registered only in a private database, the granting of the patent would be barred as long as the community simply uses or even has used the traditional knowledge.

The only way to enable challenges and revocation of patents with knowledge documented in a private registry, without respect to its use, is to recognize prior art not disclosed to public, possible in a *sui generis* system.[193]

However, irrespective of their capacity to constitute prior art, serving as cultural libraries, private registries are most effective as a mechanism for preservation and maintenance of traditional knowledge.[194]

Eventually, one advantage of a public registry of traditional knowledge forms a disadvantage at the same time. As mentioned above, a public registry constitutes prior art. This basically prevents third parties from gaining patents on products based upon the knowledge. However, the same goes for indigenous communities which decide to apply for a patent on their own traditional knowledge after their respective knowledge has been registered. Even if the traditional knowledge were basically appropriate for being patented, the application would be rejected, not fulfilling the requirement of prior art, unless the respective IPR regime provides for a grace period as the U.S. Patent Act does.[195]

Another weakness inherent in a public registry is the disclosure of knowledge to others outside the community. Placing knowledge in the public domain, the former may lose its commercial value for the holder. Rather, the knowledge can be used by anyone in any way they wish without permission.[196] Moreover, each inventive development of published knowledge of indigenous communities through western laboratories could be patented,[197] unless required by national IPR regime, without the community's participation in the benefits. This is why, there is a need for advice, information and training for indigenous and local communities on considering IPR implications before the respective knowledge is published through documentation.[198] Being informed about the consequences of publication it is then up to the communities whether - provided that the current national IPR regime does not provide for it - they want to abandon their commercial participation on the one side but to hinder or at least to aggravate the acquisition of unauthorized IPRs to third parties on the other side. The

[193] Hansen, VanFleet, above no.155, p.26
[194] ibid., p.27
[195] Title 35 U.S. Code, S.102 (b)
[196] Hansen, VanFleet, above no.155, p.27
[197] Heineke, C., *Traditionelles Wissen auf dem Markt - Um die Regeln der Veräußerung streiten sich Staaten, Unternehmen und die TrägerInnen des Wissens selbst,* [Online], Available: http://www.ila-web.de/artikel/263traditionelles.htm, last accessed 12.05.2006
[198] WIPO, *Intellectual property needs,* above no.26, p.227

task of information, again, could be carried out by the respective national IPR offices or related agencies.

CHAPTER 3 - Bioprospecting and the protection of traditional knowledge – selected national approaches

I. The South African approach

1. The South African Biodiversity Act

A) Introduction

Although South Africa occupies only about 2% of the world's land area it is home to virtually 10% of the world's plants and 7% of the world's reptiles, birds and mammals.[199] In 2004, South Africa enacted the National Environmental Management: Biodiversity Act, Act 10 of 2004,[200] aiming generally speaking to ensure the management, conservation and sustainable use of its biological resources as well as the fair and equitable sharing of benefits arising from the use and application of genetic resources and materials. A further aim and merit is the establishment of the South African National Biodiversity Institute.[201]

Provisions that are of particular interest with regard to this current research are. Chapter 2 'South African National Biodiversity Institute', Chapter 6 'Bioprospecting, Access and Benefit-Sharing', Chapter 7 'Permits' as well as Chapter 9 'Offences and Penalties'. The Act establishes the Institute[202] with its head office in Pretoria, the latter will regulate and manage botanical gardens and act as an advisory and consultative body on biodiversity related matters to organs of state and other biodiversity stakeholders.[203] As such the state installs a national focal point following the Bonn Guidelines, see above. Furthermore, *inter alia*, the Institute must monitor the status of the Republic's biological diversity, as well as the conservation status of threatened or protected species and ecosystems.[204] It may also undertake and promote research on indigenous biodiversity and the sustainable use of indigenous biological resources.[205]

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[199] South African National Biodiversity Institute, *Biodiversity & SANBI Mandate*, [Online], Available: http://www.sanbi.org/aboutbiodiversity.htm, last accessed 18.05.2006
[200] hereinafter Act
[201] hereinafter Institute
[202] S.10 (1) National Environmental Management: Biodiversity Act [in footnotes hereinafter SA BdA]
[203] South African Ministry of Environmental Affairs and Tourism, 2003, *Parliamentary Media Briefing by the Minister of Environmental Affairs and Tourism Mohammed Vallimoosa: Human Resource Development and Employment Strategy Cluster*, [Online], Available:http://www.info.gov.za/speeches/2003/03021809461006.htm, last accessed 18.05.2006; S.11 (1)(c),(j) SA BdA
[204] S.11 (1)(a) SA BdA
[205] S.11 (1)(l) SA BdA

B) Bioprospecting, Access and Benefit-Sharing

The purpose of Chapter 6 of the Act is *inter alia* "to regulate bioprospecting involving indigenous biological resources" and "to provide for a fair and equitable sharing by stakeholders in benefits arising from bioprospecting involving indigenous biological resources".[206] Different from the common definition of bioprospecting, see above, the legislator defines the term as

> "in relation to **indigenous** biological resources, [...] any research on, or development or application of, indigenous biological resources for commercial or industrial exploitation"[207]
>
> including
>
> "the utilisation for purposes of such research or development of any information regarding any traditional uses of indigenous biological resources by indigenous communities"[208]
>
> [emphasis added]

So, firstly, the legislator includes the research in traditional knowledge in the concept of bioprospecting. Furthermore, indigenous biological resources are defined as including among others

> "any living or dead animal, plant or other organism of an indigenous species [...] any derivative of such animal, plant or other organism; or [...] any genetic material of such animal, plant or other organism".[209]

Genetic material of human origin is excluded from this list.[210] Indigenous species is defined as

> "a species that occurs, or has historically occurred, naturally in a free state in nature within the borders of the Republic, but excludes a species that has been introduced in the Republic as a result of human activity".[211]

So, secondly, the legislator limits the application of the provisions ruling bioprospecting, access and benefit sharing to indigenous genetic resources. This approach stands in contrast to the one taken by the CBD. We must recall that its provision in this context ranges basically to genetic resources in *in-situ* conditions, that is "where genetic resources exist within

[206] S.80 (1)(a),(c) SA BdA
[207] S.1 (1)(b) SA BdA
[208] S.1 (1)(b)(bb) SA BdA
[209] S.80 (2)(a)(i) referring to S.1 "indigenous biological resource" Para (b) SA BdA
[210] S.80 (2)(b)(i) SA BdA
[211] S.1 (1) "indigenous species" SA BdA

ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties".[212] This means that according to the CBD an alien species which exists within a member state's ecosystem would be embraced from the appliance of its respective bioprospecting provisions. The Act, however, excludes this species from its scope of applicability. The focus of the South African approach on indigenous plants becomes obvious if one considers the provision in Chapter 4 and 5, dealing with threatened or protected ecosystems and species, and species and organisms posing potential threats to biodiversity, respectively. The only way to let an alien species fall into the scope of the bioprospecting provisions of the Act is to alter it with "any genetic material or chemical compound found in any indigenous species" through the use of biotechnology.[213]

If someone seeks to "engage in bioprospecting involving any indigenous biological resources; or [...] export from the Republic any indigenous biological resources for the purpose of bioprospecting or any other kind of research" the person has to await the issuance of a permit according to the provisions in Chapter 7.[214] The issuing authority – a competent national authority in terms of the Bonn Guidelines, see above - can request the applicant to disclose "all information concerning the proposed bioprospecting and the indigenous biological resources to be used for such bioprospecting that is relevant for a proper consideration of the application".[215]

Before the authority issues the permit, it has to ensure that the interests of stakeholders are protected. Such stakeholders are either concerned as they provide access to the indigenous biological resource.[216] Or as an indigenous community "whose traditional uses of the indigenous biological resources to which the application relates have initiated or will contribute to or form part of the proposed bioprospecting; or [...] whose knowledge of or discoveries about the indigenous biological resources to which the application relates are to be used for the proposed bioprospecting".[217] Stakeholders are thus either landowners or people managing an estate, on the one hand, or communities whose traditional use of or knowledge about an indigenous biological resource caused or are used for the proposed bioprospecting on the other. Other stakeholders such as communities neighbouring the area to be prospected which are finally affected by the planned actions would, according to the

[212] Art.15 (3), Art.2 "Country of origin of genetic resources" and "In-situ conditions" CBD
[213] S.80 (2)(a)(iii) SA BdA
[214] S.81 (1)(a),(b), 87 (c),(d)SA BdA
[215] S.81 (2) SA BdA
[216] S.82 (1)(a) SA BdA
[217] S.82 (1)(b)(i),(ii) SA BdA

wording of S.82 be excluded. That is, their interests would not have to be taken into account before the permit is issued.

If there is a stakeholder, as set out in Subsection (l)(a), for example, a landowner or the like, the issuance may only be carried out "if the applicant has disclosed all material information relating to the relevant bioprospecting to the stakeholder and on the basis of that disclosure has obtained the prior consent of the stakeholder for the provision of or access to such resources".[218] Moreover, in this case the provision requires that the applicant and the stakeholder have entered into a material transfer agreement regulating the provision of or access to the resources as well as a benefit-sharing agreement providing for "sharing by the stakeholder in any future benefits that may be derived from the relevant bioprospecting".[219] The MTA must specify, amongst others, particulars of the parties to the agreement, the type, concerned location and quantity of indigenous biological resources to which access is sought, the purpose for which the resources are to be exported and an indication of their present potential use, as well as the conditions under which the party seeking for access may provide them to a third party.[220] Thus the party providing access must be elucidated as to which resources are prospected, the intensity and intended utilization that they will be subject to.

The benefit-sharing agreement must firstly provide some of the particulars already included in the MTA such as specification of the resource, its source, quantity and potential utilization.[221] Furthermore, it has to specify any traditional uses of the resources by an indigenous community.[222] Crucially, the specification of the aspired manner and extent to which the resources are to be utilized or exploited for the purpose of bioprospecting, as well as the manner and extent to which the respective stakeholder will participate in any benefits arising from such bioprospecting must also be declared.[223] This information provides the foundation for the respective stakeholder to assess whether the grant of access is remunerative. Since, as mentioned above, it is not always possible to foresee the precise respective kind of utilization, the section provides for a "regular review of the agreement by the parties as the bioprospecting progresses".[224] Particularly in respect of monetary benefits due to stakeholders, all moneys must be paid into a Bioprospecting Trust Fund, "from which all payments to, or for the benefit of, stakeholders must be made".[225]

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[218] S.82 (2)(a) SA BdA
[219] S.82 (2)(b)(i),(ii) SA BdA
[220] S.84 (1)(b)(i)-(vii), SA BdA
[221] S.83 (1)(b)(i),(ii),(iii),(v) SA BdA
[222] S.83 (1)(b) (iv) SA BdA
[223] S.83 (1)(d),(e) SA BdA
[224] S.83 (1)(f) SA BdA
[225] S.85 (1) SA BdA

However, the MTA and the benefit-sharing agreement are not sufficient to issue the permit. Rather, the Minister has to approve such agreements and their amendments. Without this approval the respective agreement does not take effect[226] and the issuance of the permit has to be refused.[227]

The provisions regarding the use of traditional indigenous biological resources related knowledge are set out analogically. Again the disclosure of relevant information to the stakeholder, the latter's prior informed consent on the basis of these information,[228] as well as the agreement on benefit-sharing are all required.[229] Again, the issuance depends on the Minister's approval of the agreement.[230]

In order to bring the agreement/s on the right track, the issuing authority may engage the parties to the agreement/s on the terms and conditions[231] ensuring that the benefit-sharing agreement is fair and equitable.[232] Doing so, the authority may ensure that the negotiations "are conducted on an equal footing".[233] This approach corresponds to the provisions in the Bonn Guidelines calling on the parties to enhance the capacity of indigenous and local communities to represent their interests fully at negotiations against the background of different bargaining powers, see above.

If the issuing authority is not sure about the consequences and impact of the sought act of bioprospecting it may "in writing require the applicant to furnish it, at the applicant's expense, with such independent risk assessment or expert evidence as the issuing authority may determine".[234] If all conditions are met, the issuing authority grants the permit. Thereby the latter must specify amongst others "the purpose for which it is issued; [...] the period for which it will remain valid" as well as conditions on which the permit is issued.[235]

Once the authority has issued the permit it may cancel the latter *inter alia* if the documents on which the grant of the permit was based were misleading or false or the permit holder has "contravened or failed to comply with [...] any condition of the permit".[236]

If an applicant or permit holder feels unfairly treated by the imposition of conditions, the rejection of the application, or whose permit has been cancelled, they can "lodge with the Minister an appeal against the decision within 30 days after having been informed of the

[226] S.83 (2)(b) SA BdA
[227] S.82 (2)(c), 83 (2), 84 (2) SA BdA
[228] S.82 (3)(a) SA BdA
[229] S.82 (3)(b) SA BdA
[230] S.82 (3)(c), 83 (2) SA BdA
[231] S.82 (4)(a) SA BdA
[232] S.82 (4)(c) SA BdA
[233] S.82 (4)(b) SA BdA
[234] S.89 SA BdA
[235] S.90 (1)(a)(i),(ii),(b) SA BdA
[236] S.93 (a),(b)(i) SA BdA

decision."[237] The appeal itself is non-suspensive.[238] The minister has to either decide the appeal, hand over this task to the responsible MEC for Environmental Affairs or to designate a panel for the decision.[239] A further remedy against this appeal decision is not provided by the Act.

If someone engages in bioprospecting involving any indigenous biological resources or exports those from the territory of the Republic for bioprospecting or research without permit, he or she is guilty of an offence.[240] Just as if a bioprospector already holding a permit disobeys any condition attached to the issuance of the permit or allows any other person to do so.[241] The same goes for persons who fraudulently alter any permit, create, use, pass or alter any document purporting to be a permit as well as the making of false statements to obtain a permit.[242] A person convicted of such a defence is liable to a fine in terms of the Adjustment of Fines Act, 1991 (Act No.101 of 1991) or up to five years imprisonment.[243]

2. The South African Patents Act

South Africa has a currently valid national patents act at its disposal dating back to 1978. The first version of the South African Patents Act, 1978,[244] even after getting several amendments, did not authorize the registrar of patents to refuse, invalidate or revoke a patent application which did not disclose at all or disclosed wrongfully the origin of the biological material forming the base of the invention.[245] It was not before 2005 that this empowerment of the patent examiner became established in the South African patent legislation through the Patents Amendment Act, 2005.

According to the Act a patent may "be granted for any new invention which involves an inventive step and which is capable of being used or applied in trade or industry or agriculture".[246] In terms of the Act an invention is new "if it does not form part of the state of the art immediately before the priority date of that invention".[247] Different from the above mentioned US-American approach

> "[t]he state of the art shall comprise all matter (whether a product, a process, information about either, or anything else) which has been made available to the

[237] S.94 (1) SA BdA
[238] S.94 (3) SA BdA
[239] S.94 (2)(a),(b),(c) SA BdA
[240] S.101 (1)(a) SA BdA
[241] S.101 (2)(b),(c) SA BdA
[242] S.101 (3)(a)-(d) SA BdA
[243] S.102 (1),(2)(a) SA BdA
[244] hereinafter Act
[245] Memorandum, 1.1 Patents Act [in footnotes hereinafter SA PA]
[246] S.25 (1) SA PA, see exeptions in Subsections (2) to (4)
[247] S.25 (5) SA PA

> public **(whether in the Republic or elsewhere)** by written or oral description, *by use* or in any other way".[248]
>
> [emphasis added]

That is if a certain utilization of a plant for medical purposes is already practiced in a foreign country, the "invention" would not deem to be new in terms of the Act. New are the requirements for patent applications set out in S.30 (3A), (3B) Act. They read as follows:

> ''(3A) (a) Every applicant who lodges an application for a patent accompanied by a complete specification shall lodge with the registrar a statement in the prescribed form, stating whether or not the invention is -
> (i) directly derived from an indigenous biological resource or a genetic resource; and
> (ii) based on or derived from traditional knowledge or traditional use.
>
> [...]
>
> (3B) The registrar may call upon the applicant to furnish proof in the prescribed manner as to his or her title or authority to make use of the indigenous biological resource or genetic resource or of the traditional knowledge or traditional use if an applicant lodges a statement that acknowledges that the invention is directly derived from an indigenous biological resource or a genetic resource, or that the invention is based on or derived from traditional knowledge or traditional use''.

One could assume that the registrar could require the applicant to furnish a permit issued in terms of Chapter 7 'National Environmental Management: Biodiversity Act'[249] if the invention is at least based on an act of bioprospecting in South Africa. This, however, would not be sufficient. In such cases the Patent Regulations Pursuant to the Patents Amendment Act, 2005 come into play. They additionally require the applicant, on the one hand, to furnish if applicable a proof of prior consent as contemplated in S.82 (2)(a) or S.82 (3)(a) Biodiversity Act. On the other hand, the applicant has to submit if applicable a proof of both a material transfer agreement in terms of S.82 (2)(b)(i) and a benefit-sharing agreement as contemplated in S.82 (2)(b)(ii) or 82 (3)(b) Biodiversity Act.
If an applicant cannot provide for the necessary proof the registrar "may refuse to accept the application or require the application [...] to be amended in such manner as may be

[248] S.25 (6) SA PA
[249] hereinafter Biodiversity Act

necessary".[250] In the former instance the applicant shall be given the opportunity of being heard.[251]

Despite this one has to bear in mind that both the Act and the Biodiversity Act as far as they refer to indigenous biological resources or traditional knowledge only refer to South African indigenous biological resources or knowledge of indigenous communities. With regard to the Biodiversity Act this was developed above. The same applies to the Act, which becomes recognizable on the basis of S.30 (3A)(a)(i),(ii) in connection with the S.2 Definition of 'indigenous biological resource or genetic resource', 'traditional knowledge' and 'traditional use' Act. That is the Act does not prevent the granting of a patent for an invention based on e.g. a Peruvian indigenous plant and traditional knowledge of an indigenous community settled in Peru without meeting any prerequisites of prior informed consent, MTA or an agreement on benefit-sharing as far as the further requirements according to the Act are met.

II. The Indian approach

1. The Indian Biological Diversity Act

A) Introduction

Being one of the twelve mega-biodiversity countries of the world, India embraces only 2.4 per cent of the world's land area but according to estimates in 2000 already accounts for 7 to 8 % of the recorded species of the world. Based on a survey of 65 to 70 % of the total geographical area of the country over 47,000 species of plants and 81,000 species of animals have been recorded. However, some of the remaining areas like the Himalayan region may be far richer in biodiversity than most of the areas already surveyed. In other words, the share in the world's recorded species is supposed to be even higher. Furthermore, India is at disposal of rich traditional knowledge, both coded and informal.[252]

Already in 2000 India responded to its obligation arising from the CBD, enacting the Biological Diversity Act, 2000.[253] Similar to the South African approach the Act aims "to provide for conservation of Biological Diversity, sustainable use of its components and equitable sharing of the benefits arising out of the use of biological resources and for matters

[250] S.34, 35 (1) SA PA
[251] S.16 (1) SA PA
[252] WTO Committee on Trade and Environment Council for Trade-Related Aspects of Intellectual Property Rights, 2000, *Protection of Biodiversity and traditional knowledge – The Indian Experience*, p.1, [Online], Available: http://docsonline.wto.org/DDFDocuments/t/IP/C/W198.doc, [hereinafter WTO, *Indian Experience*], last accessed 13.05.2006
[253] hereinafter Act

connected therewith or incidental thereto".[254] As with South Africa, India establishes a National Biodiversity Authority with a head office based at Chennai.[255]

B) Bioprospecting, Access and Benefit-Sharing

At first the Act determines that certain persons shall not

> "without previous approval of the National Biodiversity Authority [256] obtain **any** biological resource occurring in India or knowledge associated thereto for research or for commercial utilisation or for bio-survey and bio-utilisation".[257]
>
> [emphasis added]

Those persons are essentially non-citizens of India and body corporates, associations or organisations not incorporated or registered in India or which share capital or management has a non-Indian participation.[258] Furthermore, no person shall without previous approval of the Authority, "transfer the results of any research relating to any biological resources occurring or obtained from India for monetary consideration or otherwise to any person" as essentially described above. However, transfer in this regard "does not include publication of research papers or dissemination of knowledge in any seminar or workshop" being in accordance with certain central governmental guidelines.[259] In case of contravention, attempt to contravention or abet to the latter, the offender "shall be punishable with imprisonment for a term which may extend to five years, or with fine which may extend to ten lakh rupees, or with both".[260]

Merely certain collaborative research projects with a foreign relation that conform to those guidelines and need to be approved by the Central Government are not affected by S.3 and 4 Act.[261]

Just as certain collaborative research projects "based on agreements concluded before the commencement of [...] [the] Act and [being] in force", provided that they are consistent with the provisions of the Act or the just mentioned guidelines.[262]

On receipt of an application for one of the above mentioned intended activities, the Authority may, after making fit enquiries and "if necessary after consulting an expert committee

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[254] Preamble Biological Diversity Act [in footnotes hereinafter I BDA]
[255] S.8(3) I BDA
[256] hereinafter Authority
[257] S.3(1) I BDA
[258] S.3(2)(a),(c)(i),(ii) I BDA
[259] S.4 I BDA
[260] S.53 (1) I BDA
[261] S.5 (1),(3)(a),(b) I BDA
[262] S.5 (2),(3)(a) I BDA

constituted for this purpose" grant approval. The latter may be subject to any regulations, terms and conditions as the Authority may deem fit. If the latter rejects the application, it has to give the applicant the opportunity of being heard prior to the decision.[263]

However, as soon as a person has obtained an approval according to the provisions set out above, he or she is not free to do what he or she pleases with the biological resource or the related knowledge. Rather, if the successful applicant intends to transfer any biological resource or associated knowledge being subject of such an approval, the applicant has to obtain a further permission of the Authority.[264] The means to make this decision are the same as for the original permission, as set out above.[265]

While granting the above mentioned approvals, the Authority shall ensure that an equitable sharing of benefits arising out of the utilization of the accessed biological resources, as well as associated knowledge in accordance with mutual terms between the applicant, local bodies concerned – as set out in S.2 (d) Act - and conservers of biological resources and knowledge holders respectively is secured.[266] Subject to any regulations made on this matter the Authority shall determine the benefit sharing, taking into account aspects such as the grant of joint IPR ownership to the just mentioned benefit claimers, the transfer of technology, location of production to raise the standard of living in the concerned areas, as well as payment of monetary compensation.[267] In the latter case, the Authority may order the money to be deposited in the National Biodiversity Fund, established under S.27 Act. If the accessed biological resource or associated knowledge was obtained from a specific individual or group or organisation, the Authority may direct the amount to be paid directly to such providers according to terms of any agreement and as it deems fit.[268] In so far the Indian provisions differ from the South African. The latter provides that such payments must firstly be paid to the Bioprospecting Trust Fund in any event, see above.

A contravention of these provisions "shall be punished with a fine which may extend to one lakh rupees and in case of a second or subsequent offence, with fine which may extend to two lakh rupees and in the case of continuous contravention with additional fine which may extend to two lakh rupees everyday during which the default continues".[269]

Howsoever, neither Indian citizens nor domestic body corporates, associations or organisations are exempted from any kind of authorization prior to their act of bioprospecting

[263] S.19 (3) I BDA
[264] S.20 (1) I BDA
[265] S.20 (3) I BDA
[266] S.21 (1) I BDA
[267] S.21 (2)(a),(b),(c),(e) I BDA
[268] S.21 (3) I BDA
[269] S.54 I BDA

for commercial utilisation, bio-survey or bio-utilisation. Rather they have to intimate their intentions to the respective so called State Biodiversity Board,[270] which has to be established according to S.22 (1) Act. The only exceptions are local people and communities of the area practising indigenous medicine.[271] The Board can, similar to the Authority, consult the concerned local bodies, make fit enquiries and finally prohibit or restrict any such activity planned if it holds the view that the latter contradicts the objectives of conservation and sustainable use of biological diversity or the equitable sharing of benefits deriving from such activity.[272] Interesting in this regard, however, is the differing phraseology of the respective provisions regarding the Board on the one hand and the Authority on the other. The Board is authorized to prohibit or restrict an intimated act of bioprospecting but of course also to grant approval. Different from the competences of the Authority, according to the wording the Board is not empowered to impose its own conditions, for instance, in respect of benefit-sharing while granting approval. Either the Board grants approval or it restricts or prohibits a planned activity. The activity, however, is the act of bioprospecting and has to be distinguished from aspects of benefit-sharing. In the end, however, the competences lead to the same. If the Board takes exception to a benefit sharing agreement, it can prohibit the access until it is pleased by new proposals of benefit sharing arrangements. Again, a decision prohibiting or restricting access shall only be made after giving the affected person an opportunity of being heard.[273]

Contravention of these provisions shall be punishable, even though these offences carry a less heavy penalty. The contravention, attempt to or abet to contravention, shall be punished "with imprisonment for a term which may extend to three years, or with fine which may extend to five lakh rupees, or with both".[274]

After the Authority has been reserved the right to approve the obtaining of biological resources or associated knowledge thereto by the above mentioned group of people for the set out purposes, the Authority is also involved in the application for IPR. Accordingly, no person, that is with no reference to nationality, shall apply for any IPR – except for plant variety rights[275] - "in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval" of the Authority. Provided that a person applies for a patent, the permission may be obtained after its

[270] hereinafter Board
[271] S.7 I BDA
[272] S.24 (2) I BDA
[273] S.24 (2) I BDA
[274] S.53 (2) I BDA
[275] S.6 (3) I BDA

acceptance but prior to its sealing.[276] While granting the approval the Authority 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".[277] In cases in which an IPR is granted in a foreign country on any biological resource obtained from India or associated knowledge, the Authority is empowered to take any measure necessary to oppose the grant.[278] As such it could embrace measures in the run-up to the granting of a certain IPR as well as an application for its revocation once it has been granted. Again, the contravention, attempt to contravention or abet to the latter shall be punishable with imprisonment up to five years, or with fine which extending up to ten lakh rupees, or with both.[279] Moreover, for this case but also for the above mentioned offences under the Act the following is applicable: where the offence "has been committed by a company, every person who at the time the offence or contravention was committed was in charge of, and was responsible to the company for the conduct of the business of the company, as well as the company, shall be deemed to be guilty of the offence or contravention and shall be liable to be proceeded against and punished accordingly". However the respective person is free prove "that the offence or contravention was committed without his knowledge or that he had exercised all due diligence to prevent the commission of such offence or contravention".[280] The same applies to directors, managers, secretaries or other officers of the company if the offence has been committed with their consent or connivance or is due to their neglect.[281]

Thus, through comparison it becomes clear that the Indian approach to bioprospecting differs in a significant aspect from the South African. The South African provisions concerned only relate to South African indigenous biological resources. The Indian regulations however do not provide for such a restriction, they even go beyond the scope set out in Art. 15 (3) CBD, since they do not restrict the scope of the bioprospecting provisions to biological resources in *in-situ* conditions, see above. Moreover the South African provisions do not treat nationals and foreign nationals differently. Both Indians and 'foreigners' have to apply for acts of bioprospecting at different authorities and, if both offend against the rules, the respective provisions, the sentences will differ: the foreigner will receive a heavier penalty.

Lastly, with regard to the above mentioned protection of traditional knowledge by means of registries, it has to be pointed out that "the preparation of village-wise community

[276] S.6 (1) I BDA
[277] S.6 (2) I BDA
[278] S.18 (4) I BDA
[279] S.53 (1) I BDA
[280] S.55 (1) I BDA
[281] S.55 (2) I BDA

biodiversity registers [...] for documenting all knowledge, innovations and practices has been undertaken in a few [Indian] States".[282]

Moreover India initiated the preparation of an easily navigable computerized database of documented traditional knowledge relating to use of medicinal and other plants, which is already in the public domain. The latter database is known as the Traditional Knowledge Digital Library and shall provide patent offices access to search for prior art, worldwide.[283]

2. The Indian Patents Act

India's currently valid Patents Act[284] dates back to 1970. Even though provisions on benefit-sharing in cases of application for any IPR in and outside India were already enacted in S.6 Biological Diversity Act, see above, the legislator amended the Act with regard to the subject of bioprospecting and the protection of traditional knowledge by way of the Patents (Amendment) Act 2002 as well as 2005.

Firstly, similar to other national patent legislations, the applicant can apply for the grant of patent for an invention. The latter is defined as "a new product or process involving an inventive step and capable of industrial application".[285]

> "[A]n invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components"

is not deemed to be an invention within in the meaning of the Act.[286]

Secondly, an applicant has to provide his application to grant a patent with a provisional or complete specification.[287] If the specification includes particulars on biological material which is not available to the public, firstly, such material shall be deposited to an authorised depository institution. Secondly, the application shall "disclose the source and geographical origin of the biological material in the specification, when used in an invention".[288] This obligation is not restricted to biological resources obtained in India. However, even if the resource is of Indian origin, the Act does not explicitly require the applicant to attach a copy of the approval of the National Biodiversity Authority for the use of the genetic material, as set out above.

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[282] WTO, *Indian Experience*, above no.252, S.18
[283] ibid., S.22
[284] hereinafter Act
[285] S.2 (1)(j) Patents Act [in footnotes hereinafter I PA]
[286] S.3 (p) I PA
[287] S.7 (4) I PA
[288] S.10 (4)(d)(ii)(D) I PA

If the application and the specification are complete, both are referred to an examiner. The latter has to examine whether both the application and the specifications are in accordance with the requirements of the Act, as well as whether there are any objections to other aspects which may be prescribed.[289] The latter aspect might eventually serve as the gateway for the provisions of prior informed consent and benefit sharing set out in S.6 Biological Diversity Act, see above. Finally, the application may be refused if "the application or any specification or any other document filed in pursuance thereof does not comply with the requirements of [the] Act" or the applicant may be required to amend the application, specification or the other documents, as the case may be.[290]

Once the application for a patent has been published but the patent has not yet been granted, any person may oppose the granting of the patent on the ground, amongst others, "that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention" or that the claimed invention anticipates traditional knowledge "available within any local or indigenous community in India or elsewhere".[291] The same goes for a granted patent, however, only before "the expiry of a period of one year from the date of publication of grant of a patent".[292]

If it turns out that "the subject of any claim of the complete specification is not an invention within the meaning of [the] Act", that is e.g. that it just reproduces traditional knowledge, the patent may be revoked.[293] The same goes for a patent which was granted "on a false suggestion or representation", in other words, for instance if the source and geographical origin of biological material used in an invention is not disclosed".[294]

Recapitulatory, it can be established, that the Indian patent provisions governing the subject of bioprospecting and traditional knowledge are less explicitl than the South African legislation. There are no concrete requirements involved in the Act with regard to prior informed consent and the sharing of benefits arising out of the utilization of Indian genetic resources and associated traditional knowledge. Those matters can only become established by means of the above mentioned blanket clause. Eventually both patent laws, in respect of the Indian approach taking the Biological Diversity Act into account, rule nearly the same. One significant difference, however, is the disregarding of national but non-indigenous

[289] S.12 (1)(a),(d) I PA
[290] S.15 I PA
[291] S.25 (1)(j),(k) I PA
[292] S.25 (2)(j),(k) I PA
[293] S.64 (1)(d) I PA
[294] S.64 (1)(j) I PA

biological resources in the South African law, whilst the Indian regulations do not know such limitations in this regard.

III. The Bolivian approach

1. The Bolivian Supreme Decree No. 24676

A) Introduction

Containing about 18,000 species of plants and more than 2,500 known species of vertebrates with a high index of endemism, Bolivia is the world's eighth-biodiversity-richest country in the world.[295] The Country is member of the Andean Community. In 1996, i.e. only four years after the adoption of the CBD, this community enacted the Andean Community Decision 391: Common Regime on Access to Genetic Resources. One year later, in 1997, Bolivia implemented this decision by means of the Supreme Decree No. 24676, Regulation of Decision 391 on the Common Regime for Access to Genetic Resources[296].

The main objective of the Decree is the establishment of the obligation for parties seeking access to genetic resources to sign a Contract of Access[297] with the Bolivian State to acquire genetic resources.[298]

Bolivia determines the National Secretariat of Natural Resources and the Environment as the Competent National Authority[299].[300] Its function is, amongst many more, "to permit or to deny the access to [...] genetic resources".[301]

B) Bioprospecting, Access and Benefit-Sharing

Covered by the Decree are "genetic resources of which Bolivia is the country of origin, their derivatives, their associated intangible components and to genetic resources of migratory species that by natural causes are in the national territory".[302] 'Country of origin' is defined as a "country that possesses genetic resources in *in situ* conditions, including those which,

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[295] The World Bank, 2006, *Strengthening Conservation in Bolivia*, [Online], Available: http://web.worldbank.org/WBSITE/EXTERNAL/COUNTRIES/LACEXT/BOLIVIAEXTN/0,,contentMDK:20020154~menuPK:322301~pagePK:141137~piPK:141127~theSitePK:322279,00.html, last accessed 29.04.2006; The World Bank, 1992, *Bolivia Biodiversity Conservation*, p.7, [Online], Available: http://www-wds.worldbank.org/external/default/WDSContentServer/IW3P/IB/1999/04/28/000009265_3980420170516/Rendered/PDF/multi_page.pdf, last accessed 30.04.2006

[296] hereinafter Decree

[297] hereinafter Contract

[298] Art.1 Decree

[299] hereinafter Authority

[300] Art.4 Decree

[301] Art. 5 (h) Decree

[302] Art.2 Decree

having been in *in situ* conditions, are now in *ex situ* conditions".[303] '*In situ* conditions' are "those in which the genetic resources are found in their ecosystems and natural environments; in the case of domesticated or cultivated species or those having escaped domestication, in the environments where they developed their specific properties".[304] At this point the scope of the Decree in respect of genetic resources is not only broader than the South African Biodiversity Act but also than the one provided by the CBD. The latter excludes genetic resources in *ex-situ* conditions regardless of whether their have been in *in situ* conditions, see above.

As mentioned above, the Decree establishes the obligation to conclude a Contract between the bioprospector and the State. An exception is only made for indigenous towns and communities exchanging genetic resources and "farmers for their own consumption and in accordance with customary practices".[305] In this point the Bolivian approach differs from the one taken by South Africa and India. As described above, South Africa does not treat nationals and non-nationals differently at all. India only provides for another authority responsible for applications or rather intimations submitted by Indian citizen or domestic body corporates, associations or organisations. Excluded from the obligation to apply for or intimate bioprospecting, respectively, are only local people and communities practising indigenous medicine, see above.

Apart from the final grant of access to the genetic resources, the Contract is aimed to enhance the capacity of Bolivian nationals and institutions in research in genetic resources. To pursue this object, the Contract must provide for "the participation of personnel of the National Institution of Support in the work of investigation and/or experimentation,"[306] if possible within Bolivia, as well as "mechanisms for the transfer of know-how and technology".[307] With regard to the obligatory involvement of Bolivian personnel, Bolivia goes beyond what both South Africa and India require in their benefit sharing provisions, see above.

Moreover the Contract shall provide amongst others for

> "[t]he just and equitable **participation of the Bolivian State** in any economic, technological or other benefit [...] that derive from the access to the genetic resources."[308]
>
> [emphasis added]

[303] Art.1 "Country of Origin of the Genetic Resource" Andean Community Decision 391- Common Regime on Access to Genetic Resources, 1996, [hereinafter Decision 391]
[304] Art.1 "In situ conditions" Decision 391
[305] Art.3 Decree
[306] Art.15 (1), 42 (b) Decree
[307] Art.17 (b),(c) Decision 391
[308] Art.15 (2) Decree

Ultimately, this participation will pursue the objectives of Decision 391, since the benefits gained "will be distributed for conservation, the sustainable use and development of genetic resources in the national territory."[309]

However, this aspect of the State's participation contrasts with the approaches that South Africa and India adopted. The latter approaches do not provide for benefit sharing between the party seeking access to genetic resources and the State.

Further, the representative organisations of indigenous communities, if those communities are involved as providers of associated intangible components of genetic resources to which access is sought, may also be participants.[310] Such components are constituted out of "all know-how, innovation or individual or collective practice, with a real or potential value, that is associated with the genetic resource, its by-products or the biological resource that contains them"[311], thus traditional knowledge. The participation of indigenous communities providing traditional knowledge may consist of a representative's involvement in the applicant's work of investigation and experimentation, as well as the obtaining of payments from the applicant.[312]

The requests for access to genetic resources must be submitted to the Authority if the applicant is a natural person or legal foreigner. Otherwise, for example, if a natural person or legal national seeks access, the application basically needs to be presented before the responsible Departmental Authority, which sends it to the Authority, when bioprospecting is intended in the jurisdiction of a single Department. If there is more than one Department concerned, the right addressee is again the Authority.[313]

Taking into account a technical opinion of the Technical Advisory Body,[314] the Authority will "accept or reject the origin of the request and will notify the applicant" to negotiate and process the above mentioned Contract. The negative decision can be opposed in the form provided for by Bolivian legislation.[315]

"[W]henever the genetic resource to which access is requested is located" in a protected area, occupied by some regional indigenous population, the applicant has to sign an Accessory Contract with both the director of the protected area and "the representative organization of the community or involved communities".[316] Something similar applies in the case of genetic

[309] Art.40 Decree; Art.2 (c) Decision 391
[310] Art.15 (2), 42 (b) Decree
[311] Art.1 "Intangible component" Decree
[312] 42 (b), 43 (1) Decree
[313] Art.17, 20 Decree
[314] in terms of Art.7 Decree
[315] Art.26 Decree
[316] Art.32, 30 Decree

resources *ex situ* conservation centres, that is, an Accessory Contract has to be concluded with the director of the centre.[317] Moreover, an Accessory Contract is necessary between the bioprospector and "the owner, possessor or administrator of the property on which the biological resource that contains the genetic resource is found".[318]

If the indigenous community does not act as a provider of genetic resources, but of indigenous knowledge, the party seeking for the latter and the community have to sign an Annex Contract objecting the participation in the benefits derived from the genetic resource and the knowledge. Moreover the parties to the Annex become members of the Contract.[319]

Finally, the Authority, represented by a lower authority, "will sign with the applicant the terms of the Contract of Access taking into account: the benefits that derive from the access, the form and opportunity of its distribution, the conditions for the determination of the owner/holder of the intellectual property rights and the conditions for the commercialization of the results".[320] Furthermore, amongst others, aspects like the "[s]tipulation of the duration, use and extension of time of the Contract" as well as its "modification, suspension, rescission, and resolution" have to be included.[321] Once the applicant obtained the genetic resources its transference to a third party has to be preceded by an authorization of the Authority.[322]

Contraventions of the provisions established in the Decision 391 and the above mentioned obligations committed by applicants, governmental officials or third parties constitute administrative infractions and will give rise to sanctions.[323] According to the nature and gravity of infringement the sanctions to be imposed may consist, amongst others, of a written reprimand, fines, suspension of the activities of access, revocation of authorization as well as the resolution of the Contract.[324] Remarkably, with regard to fines is the fact that those "will be deposited in a special account [...] and destined for the compensation of environmental damages and/or to programs for conservation and development of the genetic resources".[325] That is, the fines are not just used to balance a budget deficit but to promote the aims of both the Decree and the CBD.

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[317] Art.35 Decree
[318] Art.50 (b) Decree
[319] Art.44, 47 Decree
[320] Art.36 Decree
[321] Art.37 (g),(h) Decree
[322] Art.60 (e)(2) Decree
[323] Art.57 et seq. Decree
[324] Art.59 (a),(g), 60 (a),(c),(d),(e) Decree
[325] Art.62 Decree

2. Decision 486

Bolivia's steps to modernize both its legislation and its enforcement capabilities regarding IPR protection are only halting. During 2000-2001, the Ministry of Justice completed a draft IPR reform law, which the congress has not yet approved. However, being a member of the Andean Community, Bolivia is obligated to comply with decisions of the Andean Community.[326] In 2000 the latter adopted the Andean Community Decision 486 - Common Intellectual Property Regime.[327] Even without national implementation, the Decision is applicable as of the date of its entry into force,[328] i.e. from December 1, 2000.

The member countries are obliged to ensure that IPR protection "shall be accorded while safeguarding and respecting their biological and genetic heritage, together with the traditional knowledge of their indigenous, African American, or local communities". It follows from this that the granting of patents on inventions based on that heritage or knowledge shall be bound to the acquisition of that material or knowledge in accordance with international, Andean Community, as well as national law.[329]

Likewise with the South African and Indian approaches, "the member countries shall grant patents for inventions [...] that are new, involve an inventive step, and are industrially applicable".[330]

An invention may be deemed new when it is not included in the state of the art. According to the South African Patents Act, the state of the art "comprises everything that has been made available to the public by written or oral description, use, marketing, or any other means".[331]

With respect to the patent application it is to be emphasized that the applicant is required to submit

> "a copy of the contract for access, if the products or processes for which a patent application is being filed were obtained or developed from genetic resources or byproducts originating in one of the Member Countries".[332]

Furthermore,

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[326] US Embassy La Paz, 2002, *Bolivia Country Commercial Guide FY 2003: Invest Climate*, [Online], Available: http://strategis.ic.gc.ca/epic/internet/inimr-ri.nsf/en/gr108614e.html, last accessed 11.05.206

[327] hereinafter Decision 486

[328] Transitional Provisions First. Decision 486

[329] Art.3 Decision 486

[330] Art.14 Decision 486

[331] Art.16 Decision 486

[332] Art.26 (h) Decision 486

> "if applicable, a copy of the document that certifies the license or authorization to use the traditional knowledge of indigenous, African American, or local communities in the Member Countries where the products or processes whose protection is being requested was obtained or developed on the basis of the knowledge originating in any one of the Member Countries",

pursuant to Decision 391.[333] Thus it becomes clear that the decision aims at ensuring the protection of genetic resources and related traditional knowledge not only in the respective member country where the application is submitted but in all the five member countries. Of no importance, however, is the question, whether the genetic resources or related traditional knowledge was obtained in non-member states according to their respective access and benefit sharing rules. As mentioned above, South Africa's corresponding provisions only aim at the protection of South African indigenous biological resources and related traditional knowledge. Furthermore, the South African provisions only authorize the patent registrar to call for proof of authorization to make use of the resources or the knowledge, however, this call for proof is not compelling, see above. India, however, simply requires the disclosure of sources and geographical origin of biological material when used in an invention with no limitation to Indian resources.

Whenever the relevant national office ascertains that the application fails to comply with any of the requirements for a patent grant, it shall notify the applicant accordingly. If the applicant does not respond to that notification within sixty days as from the notification, the period may be extended once only for thirty additional days. If the applicant fails to duly satisfy the required request, the patent office shall deny the patent.[334]

If the patent was already granted and it turns out later, that the invention is based on genetic resources originating in one of the member countries or traditional knowledge belonging to the above mentioned communities in the member countries, the patent office may revoke the patent if the applicant failed to submit the required authorization documents.[335]

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[333] Art.26 (i) Decision 486
[334] Art.45 Decision 486
[335] Art.75 (g),(h) Decision 486

CHAPTER 4 – Conclusions and Recommendations

A foundation stone for strong national regimes ruling the access to genetic resources while ensuring the equitable share in the benefits arising out of their utilization and the protection of traditional knowledge is laid by means of the CBD and the Bonn Guidelines. Now it is up to the member countries to implement these provisions. Some, but by far not all, countries have met their commitments to do so, therefore the implementation is still in development.

With regard to biodiversity-rich countries, this fact is surprising when it is considered that an ABS and traditional knowledge protection regime would benefit indigenous and local communities and, as the Bolivian approach shows, possibly even the state itself. Commercialising products deriving from biological resources and related traditional knowledge can lead to huge financial benefits for pharmaceutical or agricultural companies. Since indigenous communities usually lack resources to launch those products on the international market, it is a great opportunity to make use of the help of such companies, not least in order to comply with the CBD's objective of promoting the wider application of such knowledge. Of course, this has to go hand in hand with financial but also non financial participation in the benefits. As long as there are several indigenous communities holding the same traditional knowledge, for instance, with regard to the application of a certain herb, the problem has to be solved as to who might be deemed to be the recipient of benefits. One could consider the contractual partner as the appropriate recipient. To avoid a mutual undercut of the respective communities if a company approaches them one could install a national fund into which the monetary benefits could be paid and afterwards distributed to the communities holding the knowledge in a fair manner.

The South African and Bolivian approaches are indicative of the fact that national legislatures are sometimes far removed from effectively tackiling the subject, particularly in terms of an approach that exceeds national borders and interests. South African legislation requires patent applicants only to state whether a South African, indigenous biological resource or related knowledge was used and, if that is the case, to submit the respective proof of authorization. Similarly the legal situation in Bolivia only extends the obligation to declare the source of genetic material or related knowledge if it is originating in one of the member states of the Andean Community. That is, even mega-biodiversity countries, those countries that are in particular targets of bioprospectors and sometimes even biopirates do not care about how a biological resource or related knowledge was obtained, as long as it is not originating from their own territory or territory of a community they belong to. Therefore it is not surprising that biodiversity-poor countries are reluctant or at least not especially endeavoured to

implement patent legislation that protects the interests of countries providing biological resources and traditional knowledge. Nevertheless, it is desirable to include provisions requiring the giving of source and proof of authorization to use and market the resource and related knowledge. An appropriate means to achieve this aim would be the insertion of corresponding provisions into the TRIPS, although it is unlikely that such an agreement be concluded due to strong resistance from a large section of parties to the agreement. Critics advance that requiring such statements and proofs would render the patent grant procedure involved and complicated. This point is incomprehensible when it is considered that the simple copy of the respective authorization would suffice to meet the demands. The patent examiner could examine the respective foreign ABS rules by means of a simple table sketching them. Such a list could be drawn up by the TRIPS Council and be submitted as a standardized checklist to the parties to the agreement.

Be this as it may, if reasons for non-implementation of the concerned CBD provisions are due to financial or human capacity shortcomings, the international community has to take steps to grant help to such countries to meet their commitments. For all that it has to be considered that only to adopt national ABS regimes and to adjust the patent provisions does not suffice to fight biopiracy effectively. If the respective indigenous community does not know about the applicability of the provisions and are approached by bioprospectors, it is unlikely that the community, if at all, concludes an appropriate ABS agreement. So, it is of decisive significance, firstly, to familiarize those communities with the national ABS regime, and secondly, to strengthen their position in negotiating the conditions of the agreement by means of information and training. Moreover, it is not only important to make efforts to prevent biopiracy but also to warrant the prosecution if the latter takes place. That is why national laws have to be established ensuring an effective prosecution. To prosecute infringements of ABS rules in the CBD member states, cooperation on the international level has to be promoted. An especially effective national regime, in this regard, would be one that makes infringements of foreign ABS rules punishable under domestic law.

However, as has been elaborated in this minithesis, the legal protection of traditional knowledge, be it defensive or positive, is only one aspect in this regard. In addition, the substantial component has to be protected. That is indigenous communities and especially the youth, being vulnerable to being seduced by Western education and lifestyles, have to be supported and encouraged to follow their ancestors' traditions and to apply traditional knowledge.

However, the conservation of the habitats surrounding these communities is essential to protect this substantive element. Perhaps this component is even more important than the legal one. If the substance of traditional knowledge crumbles, at the end of this process there is no knowledge to protect in legal respect, as it would have disappeared. As shown, the establishment of traditional knowledge registers and databases could play a prominent role in the conservation of such knowledge. Knowledge holders could choose between both private and public registers. The advantage of public registers is that patent examiners could check the novelty criterion of certain applications on the basis of these. The prerequisite for this is of course that the examiner disposes of access to the register. In other words, if the knowledge holder chooses to make the knowledge he holds public, he, if necessary with the help of the state or NGO, has to ensure, if possible, worldwide access. To warrant this, a working relationship between the community and the national patent office, which could serve as a distributor, has to be established. If the other option is chosen, that of private registers, nevertheless national patent offices should be informed about those and be granted access to avoid the granting of bad patents. Of course, this is only of significance if the respective national patent office has to apply a patent legislation considering 'use' of traditional knowledge in a foreign country as part of the public domain. The US, which excludes foreign use from the public domain, states that the reason for the issuance of some bad patents is due to the inaccessibility of unpublished knowledge. So the fault lies not in the patent system. What is difficult to comprehend in this is how one can consider the publication of knowledge, which another person or group holds, as a matter of course. That is, why are indigenous communities compelled to publish their knowledge to avoid the grant of patents to companies without the community's participation? Of course the inclusion of 'foreign use' in the public domain cannot entirely prevent the erroneous granting of patents. However, at least it could warrant the revocation of such patents. For this reason it is desirable to include 'use' and especially 'foreign use' in the definition of 'novelty' in national patent legislation.

After all, it has to be stated, that if the respective objectives with regard to ABS are properly implemented into national legislation and national patent systems are adjusted, a positive protection of traditional knowledge in terms of conferring IPR would be unnecessary.

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