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Issues Around Bioprospecting

Traditional Knowledge and Access and Benefit Sharing in international and national legislation

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Contents

Summary

Biodiversity was during the 1990s perceived as ‘green gold’. With the emergence of the biotechnology industry, biodiversity prospecting, or bioprospecting, was perceived to provide opportunities to gain benefits for several purposes. Benefits would attribute towards conservation, development of source countries, new medicines, profits for the industry and welfare to local providers of biogenetic resources and traditional knowledge. Biodiversity became the object of international legislation, the 1992 Convention on Biological Diversity (CBD).

The Biodiversity Convention introduced several new concepts, of which the most important one was national sovereignty over biological resources. Through this, access and obligation of conservation was put under the control of the source country. The reason for introducing sovereign ownership of resources that before had been the “common heritage of mankind” was to enable benefit sharing, i.e. ensuring that benefits arising from the use of biological resources were channelled back to the source. The Convention further afforded protection to traditional knowledge. The level of protection has however, in the light of several highly-publicized biopiracy cases involving traditional knowledge, been the subject of an intense ongoing debate. The discussion has come to involve another international instrument, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs).

The TRIPs Agreement establishes a system of minimum protection for intellectual property rights. Although a minimum system for developed countries, this was a substantial adjustment for several developing countries that did not afford patent protection to the extent of the minimum requirements in TRIPs. However, the promise of capacity-building technology transfer was the bargain that developing countries got in exchange for entering the Agreement.

The relationship between the CBD and the TRIPs Agreement is an ongoing issue. Bioprospecting is at the heart of the intersection. Traditional knowledge is a form of an intellectual property right that is not provided for in the conventional system. Closely related to this are questions on patents derived from biological resources and associated knowledge and the legal framework for the sharing of the benefits accrued. Should benefits be shared when the patent is based on biogenetic material which was accessed with the assistance of traditional knowledge, but where the compound has been isolated in the laboratory and used in a product to treat a completely different disease than the disease envisaged by the traditional knowledge? And how should they be shared?

This thesis poses two main questions. How is biological resources and associated traditional knowledge protected through international and national legislation when it is the subject of interest in bioprospecting activity, and does this stimulate bioprospecting projects or do current trends in legislation act as a deterrent? Through an overview of legislation and, to a

rudimentary extent, economic theory, it tries to provide with some suggestive answers.

The thesis begins with presenting key concepts to biodiversity and bioprospecting in the introductory chapter. Terms like biodiversity, biological resources traditional knowledge (TK), prior informed consent (PIC) and access and benefit sharing (ABS) are briefly explained.

Chapter 3 gives an overview of value theories of bioprospecting and access and benefit sharing. It shows that the value of biodiversity is elusive, and dependent on how it is used. As raw material the value is less than as a piece that is used to create an idea. The idea itself has more value than biodiversity (for example as timber) but less value than an invention. Further it presents a market based approach to ABS where it is argued that the regulatory approach in current national legislations is detrimental to future bioprospecting projects. Bioprospecting is also put forward as cost-saving for the government.

The second part of chapter 3 presents two projects that provide practical examples.

In chapter 4 the international framework for patent protection and biodiversity conservation and sustainable use presented. The relevant articles in TRIPs and the CBD are presented as well as voluntary guidelines and codes of conduct.

Chapter 5 elaborates on the relationship between the TRIPs Agreement and the CBD. It is established that while there is no direct relation between IPRs and conservation of biodiversity, IPRs nevertheless form part of the economic and social context in which conservation takes place. Intellectual property rights are relevant for the crafting of ABS arrangements relating to equity. Furthermore, the chapter gives an overview of the differing opinions of developing contra developed countries, reflected through discussions in the TRIPs Council. Mainly developing countries are pressing for a requirement of prior informed consent which would be mandatory in patent application. Developed countries, with the US on the front line, oppose such requirements stating that the intellectual property system is not the right forum to solve issues of biopiracy and ABS.

Chapter 6 is devoted to describing and comparing two national (the Philippines and Costa Rica) and two regional (the Andean Community and the Organization of African Unity (OAU)) ABS instruments. When looking closer at regional and national regimes no one model emerges, rather there are considerable variations. Different cultural and legal systems require adaptation to local conditions. It is also possible that the time at which the legislation was adopted plays a significant role. The Philippine who was the first to enact ABS legislation opted not to include provisions on intellectual property while the OAU has very explicit provisions on traditional knowledge, perhaps reflecting the discussion in the TRIPs Council.

Chapter 7 further analyzes the somewhat ambivalent view of the European Community on traditional knowledge and ABS. Given the importance of the biotechnology industry for the development of economic growth in Europe it is perhaps not strange that the EC is reluctant to introduce any constraints on intellectual property rights. Nevertheless, the EC has supported the Swiss

proposal to introduce a disclosure requirement in the Patent Cooperation Treaty which governs international patent applications.

Chapter 8, the analysis and the conclusion in chapter 9 suggests an appropriate trade-off between stimulating third generation biotechnology (genetic engineering techniques), on the more advanced level of research, and stricter application of the patentability criteria (i.e. novelty, inventive step and industrial application) to patent applications relating to "raw" material such as biological resources and associated TK. Otherwise the tightened IPR regime that is imposed on developing countries through the implementation of the TRIPs Agreement will aggravate biodiversity conservation and the maintenance of traditional knowledge relating to biodiversity. Further it is suggested that the biodiversity-rich countries (mainly the South) are trying to compensate for the non-stringency of the industrialized (North) countries' intellectual property rights legislation, thereby implementing restrictive rules that unintentionally hinders scientific research. This could be remedied through the fulfilment of the commitment of developed countries to provide for technology transfer to developing countries. In the creation of a viable technological platform for the developing countries to take advantage of the patent system under TRIPs, domestic traditional knowledge could receive adequate protection. In the end, bioprospecting is dependent on the achievement of good faith.

Abbreviations and Acronyms

ABS	Access and Benefit Sharing
APEC	the Asia-Pacific Economic Cooperation
ARA	Academic Research Agreement
CBD	the Convention on Biological Diversity
COP	the Conference of the Parties (to the CBD)
CRA	Commercial Research Agreement
DENR	Department of Environment and Natural Resources
EO	Executive Order
EPC	the European Patent Convention
EPO	the European Patent Office
FAO	the Food and Agriculture Organization of the United Nations
GRULAC	the Group of Countries of Latin America and the Caribbean
GSK	GlaxoSmithKline
ICBG	International Cooperative Biodiversity Groups
ICTSD	the International Centre for Trade and Sustainable Development
INBio	Instituto Nacional de Biodiversidad (National Biodiversity Institute, Costa Rica)
ISE	the International Society of Ethnobiology
IUCN	the International Union for the Conservation of Nature and Natural Resources (the World Conservation Union)
MOSAICC	the Micro-Organisms Sustainable Use and Access Regulation, International Code of Conduct
MTA	Material Transfer Agreement
NAFTA	the North America Free Trade Association
OAU	the Organization for African Unity
PhRMA	the Pharmaceutical Research and Manufacturers of America
PIC	prior informed consent
RAFI	the Rural Advancement Foundation International
TK	traditional knowledge
TRIPs	Agreement on Trade-related Aspects of Intellectual Property Rights
UNCTAD	the United Nations Conference on Trade and Development
UPOV	Union International pour la Protection des Obtentions Végétales (International Union for the Protection of New Varieties of Plants)
WIPO	the World Intellectual Property Organization
WTO	the World Trade Organization

1 Introduction

What is bioprospecting and why has it been the focus of so much attention over the last years?

Biodiversity prospecting was the title of a book published in 1993 by Walter Reid and co-authors. With that book the term *bioprospecting* was coined, and it was soon reciprocated by the responding term *biopiracy*. Simply put, *bioprospecting* is the search, collection and screening of biological material[1] and/or traditional knowledge (hereinafter TK) for commercial ends, with particular reference to the pharmaceutical, biotechnological and agricultural industries.[2] *Biopiracy* was coined by the Rural Advancement Foundation International (RAFI) as a response to the depicted win-win scenario championed in the book and implied by the term bioprospecting.[3] Instead of the promising picture of mutually beneficial contracts, *biopiracy* reflects the impossibility of such contracts due to the current socio-economic environment.[4]

Biopiracy is not a uniform concept *per se*. Rather; one can distinguish between two main "clusters" of biopiracy opponents. There are those who recognize a difference between the two terms; bioprospecting does not necessarily mean biopiracy. Instead, bioprospecting is seen as the search for commercially useful biological material and/or associated knowledge while biopiracy is the *appropriation* of such resources *without* prior consent and fair compensation. From this perspective bioprospecting is the primary step which may or may not be followed by the second illegal step of biopiracy.

Another more radical position equates bioprospecting with biopiracy, thereby entirely denouncing the concept of bioprospecting. In other words; there is no bioprospecting, only biopiracy.

The opinions on how important bioprospecting is for the advancement of new pharmaceuticals differ greatly. Plotkin, an ethnobotanist currently the president of Amazon Conservation Team, sees a great future for biological material as basis for new medicines. According to him:

> "*Synthetic drugs will continue to play a major role in the market place, but natural and semisynthetic medicines (based on chemicals that occur in nature that have been manipulated or duplicated in the lab) will increase in importance for the foreseeable future."*[5]

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[1] For the purpose of this thesis the term *biological resources/material* will be used as a comprehensive term, including genetic resources. See below, chapter 1.3.

[2] Dutfield, 'Bioprospecting: legitimate research or biopiracy?', revised version 2002, Science and Development Network, http://www.scidev.net/dossiers/index.cfm?fuseaction=printarticle&dossier=7&policy=40, 24/04/06.

[3] Mooney, 'Why we call it biopiracy', in Svarstad and Dhillion (eds), *Bioprospecting: From biodiversity in the South to medicines in the North*, 2000, p. 37.

[4] Ibid.

[5] Plotkin, *Medicine Quest: In search of Nature's Healing Secrets*, 2000, p. 22.

Another argument for the increasing value of natural compounds is the possibility, with the advancement of technology, to extract the potent compound and change it slightly to make it more or less toxic or to remove any unwanted side effects. In other words, chemists can use the molecule of interest and use it as a brick in order to construct something completely new. The chemical structure of the natural compound is often to complex to be thought of by a synthetic organic chemist. An example of this would be Taxol, an anti-cancer compound derived from the yew tree.[6]
As Plotkin has stated:

"*...the value of nature as a source of novel compounds with therapeutic applications increases (rather than diminishes) as technology advances*."[7]

Not only plants offer promises of new drugs. Different poisons, both toxins and venoms, form the basis for pharmaceutical research. The drug Capoten, used to treat hypertension, was developed based on research on the Brazilian viper venom.[8] Another example is Botox, a cosmetic substance used for anti-wrinkle treatments which consists of small amounts of the deadly botulism bacteria. When injected into the facial muscles, it causes temporary paralysis, resulting in a surgeyless face-lift.[9]

Biological material exploited as pharmaceutical remedies is perhaps what first comes to mind when envisaging the concept of bioprospecting. However, biological resources present more fields of use. There is an increasing interest in biological organisms that can function as cleaners of toxic waste, perform in high temperatures in industrial processes or as inspiration for the design of new tools. One example is the microorganism *Thermus aquaticus*, discovered in the thermal pools of Yellowstone National Park. This microorganism contains an enzyme which has revolutionized genetic research. It forms the basis of PCR (polymerase chain reaction) which gives the researchers the ability to, from a tiny DNA sample such as a hair, duplicate and copy large numbers of the DNA for the researchers to analyze.[10]

Why then, if bioprospecting has such great potential, has it come under so much negative attention? As inferred above, the issue has larger implications than it first may seem. It is not simply a question of legislating to solve issues of ownership and intellectual property rights (hereinafter IPRs) but it has highlighted the on-going conflict between the developed North and the developing South. The bioprospecting activity cannot be separated from the divisive issue of global economic disparities, characterizing the relationship between North and South. The Convention on Biological Diversity (hereinafter CBD), and the Agreement on Trade-related Aspects (hereinafter TRIPs), international agreements that will be surveyed in this thesis, are both the result of negotiations where this

[6] Plotkin, 2000, p. 28.
[7] Ibid, p. 29.
[8] Ibid, p. 7.
[9] Ibid, p. 8.
[10] Ibid, p. 34.

relationship had to be balanced. In the CBD the developing countries received sovereign rights over their biological resources that previously were considered "common heritage of mankind" and developed countries got facilitated access to those resources and recognition of IPRs.[11] In TRIPs, developing countries made the concession of providing for IP protection in exchange for the promise of transfer of technology.

Biodiversity exists everywhere however, it is generally said that the South is more biodiversity-rich than the North. 17-19 countries[12] are often referred to as megadiverse countries as they alone harbour 60 to 70 percent of the world's biodiversity. A few of those will be closer scrutinized here. Closely related to biodiversity and biological resources is the TK which can provide important leads when exploring biodiversity. Another important function is to cover the health need of an estimated one third of the world's population. On the African continent around 80 percent of the population relies on traditional remedies for their primary health need.[13] As such, TK has a value both as source of information for research and development (hereinafter R&D) but also as already developed knowledge used in daily life. Arguably, the issue of protection afforded to biological resources and traditional knowledge becomes important, especially as TK is a "strange bird" in the IPR system under TRIPs. The question therefore arises whether the IPR system is supporting and facilitating the procurement of the vital necessities for people or if it renders it more difficult.

This issue is not only a matter of legal concern, but it also reflects the conflicts between the "rich" North and the "poor" South, the clash of different belief systems and perspectives on life and society.

1.1 Purpose and Delimitations

The main question guiding me throughout this thesis is how biological resources and associated TK is protected through international and national legislation when it is the subject of interest in bioprospecting activity, and whether this stimulates bioprospecting projects or if current trends in legislation act as a deterrent. A related question is if the conflicts in this area would subside if the existing IPR system was to be applied correctly, meaning applying the patentability criteria more restrictively. Or is it, as many will argue, that our current western patenting system does not provide for this kind of material and knowledge?

As implied above, the question of protection of these resources cannot be separately analyzed from issues of access and benefit sharing (hereinafter ABS) or capacity building and technology transfer. Consequently, it has

[11] For an overview of the trade-offs between industrialized and developing countries, see McGraw, 'The Story of the Biodiversity Convention: From Negotiation to Implementation', in Le Prestre (ed), *Governing Global Biodiversity*, 2004, pp 29-32.
[12] They are: Bolivia, Brazil, China, Colombia, Costa Rica, Democratic Republic of Congo, Ecuador, India, Indonesia, Kenya, Madagascar, Malaysia, Mexico, Peru, Philippines, South Africa, and Venezuela. Australia and the USA are additionally included.
[13] WHO Fact sheet No 134, revised version 2003, http://www.who.int/mediacentre/factsheets/fs134/en/, 25/04/06.

been an equal purpose of the author to closer analyze the legal provisions governing these issues as well as to offer a rudimentary economic setting to biodiversity, TK and ABS.

This thesis deals with TK, which can lead to patents. The initiated reader knows that this is only a small part of what can be said to constitute TK. Other forms of IPRs, for example trademarks or copyrights, have been left outside the scope of the thesis.

Patents themselves have been subject to further limitation in scope. Although protection for plant varieties is highly relevant and related to the questions dealt with here, I have chosen to exclude it. This means that *sui generis* systems such as the regime under UPOV, is excluded. Consequently, I only discuss patents and trade secrets concerning the biological resources and the associated TK for pharmaceutical and, to some extent, natural remedy purposes.

The different concepts that international and national legal instruments (together with voluntary guidelines, of which some are presented in the thesis) orbit around are essential to the subject at hand. The presentation of these is however not exhaustive, there is enough material and subsequent debate concerning the full definitions of the terms and to what extent they are fully covered in the law. The scope of this thesis only allows a general overview.

In the chapter on national ABS legislation I have chosen two national laws that are in force and two model legislations that reflects the aims of regional entities. As of now there are only three national legislations in force, the Philippine EO 247, the Costa Rica Biodiversity law and the Brazilian Provisional Measure No. 2-186-16 of August 23, 2001. Both the Philippine and Brazilian legislations are not enacted by the legislative assembly, possible to repeal with a Presidential Order. When presenting the national ABS laws I have chosen to refer to articles and parts of articles that I have deemed relevant to this essay. This means for instance that some of the mutually agreed terms conditioned in the Costa Rican Biodiversity Law have been omitted.

1.2 Method and Material

The traditional legal dogmatic approach has been used in this thesis together with a comparative method in the chapter on national and regional ABS legislation. The thesis addresses two international legal instruments, one dealing with intellectual property and technology transfer (the TRIPs Agreement) and the other with conservation and sustainable use of biodiversity (the CBD). Relevant articles in these instruments are explained and scrutinized. The second step has been to explore the relationship between the two and to closer analyze a number of regional and national legal instruments.

When selecting the regional and national legislation intended for further analysis, it was availability of English translations, chronological adoption of the legislation and ampleness of written information on the instruments that were the selective criteria. Thus, the Philippine ABS legislation was the

first to be adopted and the Costa Rican Biodiversity Law has received much attention as Costa Rica has extensive experience with bioprospecting contracts. The Andean Community was also quick to adopt a regional decision with several megadiverse countries as members while the Organization for African Unity (hereinafter the OAU) with its Model Law provides an example of a framework meant to cater for multi-cultural and national diversity. The GRAIN website has been the source of the English translations.

In order to obtain a conceptual overview I have had to go beyond the legal literature. Bioprospecting enlists legal experts, chemists, ethnobotanists, activists, economists; the list can be made long. The suggestive interdisciplinary analysis provided is, in the author's opinion, of particular value to this area of legal research.

1.2.1 Discourse analysis

As a part of the analysis I have had to strike a balance between the two different discourses mainly present in literature and articles. A useful theory to navigate by has been the discourse analysis. It focuses not directly on the phenomenon, in this case access to biological resources and TK itself, but on the claims concerning the phenomenon, the claims-makers and the claims-making process.[14] Different patterns of expressions used are identified.

Discourses contain a corpus of statements that are homogenous in expression. The homogeneity implies that the statements are based on common knowledge and perception of the issue in question. Metaphors are used to describe a complex situation in few or a single word.[15]

Almost all literature on the subject of bioprospecting can be divided into two camps:

- *the **bioprospecting proponent's** discourse*; or
- *the **biopiracy opponent's** discourse*.

The same event is often, depending on which of these two discourses the narrator belongs to, described very differently.

Simply put, the bioprospecting advocate sees bioprospecting as an activity that may contribute to the conservation and sustainable use of biodiversity and, in particular, the fair and equitable sharing of benefits from the use of biological resources.[16] New medicines are lying out there to be discovered and both patients, industry, local providers of resources such as TK and the provider country will profit.

The narratives within this discourse are fundamentally positive; bioprospecting is seen as one of the answers to loss of biodiversity and the

[14] Svarstad, 'Reciprocity, biopiracy, heroes, villains and victims', in Svarstad and Dhillion (eds), 2000, p. 19-20.
[15] For an analytical framework see e.g. Foucault, 'Politics and the Study of Discourse' in Burchell et al. (eds), *The Foucault Effect- Studies in Governmentality*, 1991.
[16] Svarstad, supra f.n.15, p. 21.

need for capacity building in biodiversity-rich poorer countries. Quite often the stories are presented by the involved actors themselves, such as Diversa Corporation, presented further below, Shaman Pharmaceuticals[17] (now in bankruptcy), or ICBG[18]. The term *bioprospector* is at the heart of the discourse, signalling an explorer, sent out to the wilderness to discover new medicines for the good of mankind.

Opposed to the bioprospecting concept stands the metaphor of *biopiracy*. Essentially, the biopiracy opponent sees the exploration of biodiversity for commercially valuable genetic and biochemical resources as biopiracy. The same activity is thus given a radically different association.

This discourse is represented by several NGOs, such as GRAIN or RAFI. Another famous opponent to bioprospecting is the Indian activist Vandana Shiva who in several publications has compared modern bioprospecting and western IPRs system to the brutal colonization and imperialism of old times.[19] In her book, *Biopiracy – The Plunder of Nature and Knowledge*, she writes:

> *At the heart of Columbus' 'discovery' was the treatment of piracy as a natural right of the colonizer…Biopiracy is the Columbian 'discovery' 500 years after Columbus.*[20]

The biopiracy discourse is often concentrated on selected cases that are seen as indicative of the phenomenon as such. Such cases would be the Neem tree[21], the Madagaskar rosy periwinkle[22] or the Hoodia[23] plant. Typically the cases relate to patents that are perceived as a tool of the rich North to exploit the poor South, with indigenous communities caught in the middle, stripped of their knowledge without fair compensation or the possibility to preserve their TK for future generations.

The criticism against IPRs is a central issue. IPRs are not perceived as incentives for innovation but rather it restricts knowledge sharing and

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[17] See e.g. King and Carlson et al., 'Issues in the commercialization of medicinal plants', in Svarstad and Dhillion (eds), 2000, or Clapp and Crook, *Drowning in the Magic Well: Shaman Pharmaceuticals and the Elusive Value of Traditional Knowledge*, Journal of Environment and Development, 2002*,* Vol. 11, No.1, pp. 79-102.

[18] International Cooperative Biodiversity Groups, see e.g. Berlin and Berlin, *NGOs and the process of prior informed consent in bioprospecting research: the Maya ICBG project in Chiapas, Mexico*, The International Social Science Journal, 2003, Vol. 55, Iss. 4, pp. 629-638.

[19] Moreover, she denies any need for patent protection as it does not stimulate scientific creativity and invention but rather is a tool for market control.

[20] Shiva, 1998, *Biopiracy – The Plunder of Nature and Knowledge*, p. 11.

[21] Used traditionally in India as a natural pesticide, medicine and fertilizer. Several patents were awarded to various Neem products. In 2000, one such patent was revoked by the EPO after being challenged by Indian scientists and several NGOs.

[22] In the 1950s and 60s, research scientists from Eli Lilly, enlisted by NCI, extracted two compounds, vincristine and vinblastine from the rosy periwinkle after being guided by traditional medicine using the plant to treat diabetes. The compounds turned out to be powerful anti-cancer drugs, earning Eli Lilly $100 million annually by 1985. No royalty has been paid to Madagaskar or the suppliers of the original knowledge.

[23] This cactus is traditionally used by the San people to suppress hunger and thirst. South Africa's Council for Scientific Research isolated the active agent and licensed it to the British company Phytopharm which licensed it further to Pfizer for $32 million. No royalties were paid to the San.

curtails freedom to (re)create. And above all, TK is not something that would fit into or should be adapted to that system, due to its nature *per se*. Both bioprospecting proponents and biopiracy opponents advocate values where the well-being of people and the importance of biodiversity conservation in developing countries are central. The discrepancy lies in how these values are perceived to best be reached and what means that are to be employed.

As perhaps already apparent when reading the title of this work, it is the author's view that bioprospecting is a possible concept. Biopiracy can be avoided, not only through complying with national legislation, but taking one step further and applying the broad concept of prior informed consent (explained further below). The author has continually throughout this work taken due care and attention when assessing available material, to uphold a satisfactory academic standard.

1.3 Key Concepts in Biodiversity and Bioprospecting

To facilitate understanding of the issue at hand it is helpful to get a general overview of the terms that are used in legislation and literature. Hence the key concepts that are discussed in the thesis are presented here.

1.3.1 Definitions under the CBD

Article 2 of the CBD encompasses the important definitions for the purpose of the Convention. Notwithstanding the limited scope of the definitions, they are useful when considering different aspects of bioprospecting as the different terms generally have a similar tenor when used elsewhere.

The Article defines "***Biological diversity***" as:

> *The variability among living organisms from all sources, 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.*

Further, for the interest of this thesis, the terms biological and genetic resources and material are also defined as well as biotechnology.

"***Biological resources***"[24]:

> *...includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential value for humanity.*

[24] For the purpose of this thesis, biological resources and biogenetic resources are used interchangeably.

"***Genetic material***":

…means any material of plant, animal, microbial or other origin containing functional units of heredity.

"***Genetic resources***":

...means genetic material of actual or potential value.

The CBD Article 2 additionally defines the term "***Biotechnology***" as:

> *...any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use*.

1.3.2 Traditional knowledge

Traditional knowledge (TK) is generally used as a generic term for traditional cultural expression, relevant for this presentation e.g. knowledge, innovation and practices. It comprises of both aesthetic and useful elements. Categories include, *inter alia*, expressions of folklore, for example cultural handicrafts, designs, music and dance; elements of language; agricultural knowledge and medicinal knowledge.[25]

A distinction is made between 'traditional knowledge' and 'indigenous knowledge'. Indigenous knowledge is a subset within the traditional knowledge category: indigenous knowledge is traditional knowledge held and used by communities, peoples and nations that are indigenous.[26] Although the individual may hold TK, the individual's right to it is collectively determined.[27]

1.3.3 Prior informed consent

There is relative consensus in the literature and in national legislation on ABS that prior informed consent (hereinafter PIC) can be defined as the consent to an activity that is given after receiving full disclosure regarding the reasons for the activity, the specific procedures the activity would entail, the potential risks involved, and the full implications that can realistically be

[25] van Overwalle, *Protecting and sharing biodiversity and traditional knowledge: Holder and user tools*, Ecological Economics, 2005, Vol. 53, pp. 585– 607, at p. 586.
[26] *Intellectual property needs and expectations of traditional knowledge holders* (WIPO Report on Fact-finding Missions on Intellectual Property and Traditional Knowledge—1998–1999), Geneva 2001, p. 25.
[27] Report of the UNCTAD-Commonwealth Secretariat Workshop on Elements of National *Sui Generis* Sytems for the Preservation, Protection and Promotion of Traditional Knowledge, Innovation and Practices and Options for an International Framework, Geneva 4-6 February, 2004, unedited version, p. 11.

foreseen. Prior informed consent implies the right to stop the activity from proceeding, and for it to be halted if it is already underway.[28]
The subsequent question of from whom the consent must be obtained and under which circumstances is slightly more complicated and will be further elaborated upon in chapter 4.

1.3.4 Access and benefit sharing (ABS)

Access and benefit sharing comprises of two separate but inextricably linked concepts. Access refers to the entry/bioprospecting/collection/removal of biological resources and/or TK.

Benefit sharing is usually the condition for access. It was introduced as a concept in the CBD and could be compared to the concept of technology transfer in Article 66.2 of the TRIPs Agreement[29]. Benefit sharing is fair and equitable sharing of the benefits arising from the utilization of biological resources, which is based on the idea of utilization and means much more than just ”payment” for access.[30] The benefits can be monetary and non-monetary, short-term, medium- and long-term. Non-monetary benefits can for example be the sharing of R&D results and participation in product development. Moreover, capacity-building, both institutional and in human resources to help strengthening the capacities for technology transfer, can form part of the ABS terms.[31]

1.3.5 Mutually agreed terms

According to Article 15 (4) CBD, access to biological resources, where granted, shall be on mutually agreed terms. The mutually agreed terms are pursued under national law. Normally, they entail a consultation process with the designated State Authority and, if national law requires, consultation with indigenous/local communities. This usually is accomplished through an application and the concluding of an ABS contract.

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[28] Darryl, A. Posey, Graham Dutfield, *Beyond Intellectual Property, Toward Traditional Resource Rights for Indigenous Peoples and Local Communities*, 1996, International Development Research Centre, Ottawa.
[29] Article 66.2 states that “*Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base*.” This was seen by many developing countries as “part of the bargain” in which they agreed to provide for IP protection.
[30] Medaglia, *A Comparative Analysis on The Legislation And Practices on Access to Genetic Resources and Benefit Sharing (ABS): Critical Aspects for Implementation and Interpretation*, p. 213. Available at:
http://www.iucn.org/themes/law/absdocuments/eng_critical_aspects.pdf, 27/04/06.
[31] The Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, COP Decision VI/24, presents a suggestive list on possible monetary and non-monetary benefits in Appendix II.

The Bonn Guidelines[32] provides an indicative list on mutually agreed terms in contracts. These include, *inter alia*;

- type and quantity of genetic resources and any limitations on the possible use of the material;
- capacity-building in various areas;
- a clause on whether the terms of the agreement in certain circumstances (e.g. change of use) can be renegotiated;
- whether the TK of indigenous and local communities have been respected, preserved and maintained, and whether the customary use of biological resources in accordance with traditional practices has been protected and encouraged;
- treatment of confidential information;
- provisions regarding the sharing of benefits arising from the commercial and other utilization of genetic resources and their derivatives and products.[33]

[32] The Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, COP Decision VI/24.
[33] The Bonn Guidelines, chapter IV, section D, para. 44.

2 The Value of Bioprospecting

The opinions on the importance of biological resources for health, food and agriculture and the related TK for the global economy differ greatly.

There are a number of studies trying to estimate the market value of those resources, particularly the pharmaceutical sector and its related botanical medicine industry.[34] One estimate is that between 1989 and 1995, 60 percent of new anti-cancer and anti-infective drugs were of natural origin. If, as Farnsworth's research suggests, 74 percent of the 119 plant-based compounds used in medicine worldwide has the same or related use as the traditional medicinal plants from which they derived, TK was likely used by the bioprospectors and the pharmaceutical companies in their product development.[35]

The question however remains. Despite the obvious earlier value of biological resources and TK, it is difficult to predict the future of that value. The case of Shaman Pharmaceuticals provides an argument for the questionable value of at least TK. However, this is only applicable in the field of conventional pharmaceuticals. The field of botanical medicine is growing in the developed world and it is well established in countries with a traditional health system such as India or China. Much of the developing world is in fact depending on medicinal plants and their related TK.[36]

2.1 Economic theory

To understand the complex issue of bioprospecting and to obtain a clearer understanding of the mechanisms that are affected by legislation, the economic nature of biodiversity in general and bioprospecting in particular should be assessed.

2.1.1 The economic nature of biodiversity in bioprospecting

Simply put, natural resources are 'common pool goods'. One user's consumption subtracts from the supply but, due to the nature of the resource it can be difficult to exclude users. In economic terms this is referred to as public goods. Biological material is part of a value chain that can produce

[34] See for example ten Kate and Laird, *The commercial use of biodiversity*…, 2002, Principe, *Economics and Medicinal Plants*, 1998, Cragg et al, *Natural Products in Drug Discovery and Development*, 1997 and Farnsworth, *Screening plants for New Medicines*, 1988.

[35] Dutfield, *Intellectual Property, Biogenetic Resources and Traditional Knowledge*, 2004, pp. 18-19.

[36] WHO Fact sheet No 134, revised version 2003, http://www.who.int/mediacentre/factsheets/fs134/en/, 27/04/06.

what is referred to as 'other'[37] goods and services however, until the biological material is used as input into the production of 'other' goods and services, biodiversity constitutes common pool goods.[38]
Bioprospecting activities differ from other harvesting activities. Polski identifies in her article three types of bioprospectors, the knowledge creator, the entrepreneur and the collector. They all have distinct but often overlapping objectives as the table below shows.

Table 1
Bioprospectors and their purposes

Purpose	Knowledge Creator	Entrepreneur	Collector	Activity
Advance knowledge	Yes	Yes	No	Dynamic
Solve problems	Maybe	Yes	No	Dynamic
Create new products, processes, applications	Maybe	Yes	No	Dynamic
Develop profitable products	Maybe	Yes	No	Dynamic
Expand collection	Maybe	Maybe	Yes	Static
Sell specimen to others	No	Maybe	Yes	Static

Knowledge creators, such as shamans or scientists bioprospect to create or advance knew knowledge. In that process they may come up with new products or applications and add to collections but the primary objective harvesting from biodiversity for the advancement of knowledge and to solve problems which in economic terms is quite different from simply harvesting a commodity from nature. The entrepreneur is primarily interested in building business and to develop profitable products. The collector on the other hand utilizes biological resources for immediate consumption, to add to a collection or to sell to others. The added economic value is thus not large and rather static in comparison to the knowledge creator's or entrepreneur's bioprospecting activities that are multidimensional in purpose and involve both static and dynamic economic activities.[39]

In contrast to biological resources as common pool goods, the new or added knowledge are private goods *per se*. It remains so until the holder chooses to share it. Products stemming from that knowledge are also private goods until the inventor relinquishes control over production.

In connection to this, one must recognize the relative value of biodiversity and in extension TK. Biological resources may have one value as a static commodity, or the potential input into creative processes, and

[37] For instance pharmaceuticals, furniture, energy, religious practice, recreation, soil stabilization, food, et cetera.
[38] Polski, *The institutional economics of biodiversity, biological materials and bioprospecting*, Ecological Economics, 2005, Vol. 53, p. 546.
[39] Ibid, p. 547. *Static* activity is, like Table 1 suggests, one-dimensional, intended for immediate consumption, adding little economic value to that which is consumed. *Dynamic* activity on the other hand is value-adding, creating new knowledge and new products. It arguably follows that static activity is easier to calculate the value of.

another value when put in the hands of an experienced knowledge creator or entrepreneur. That is also the case with the idea contra an invention. The idea could have many possible applications but is not as specific as an invention. To estimate the value of an idea is therefore more difficult, until it is disseminated into inventions or products. The value of the invention can be estimated but cannot be fully known until it too is fully disseminated.[40]

The process of knowledge creation is defined as a high risk inter-temporal asset transformation process. The extraction of economic value is heavily dependent on the possibility of assigning property rights to the products of the process. The economic value of knowledge is however not static but it changes as it develops and is transformed into inventions. Three different kind of economic goods can be distinguished: the biological resource; the idea; and the invention.

The obvious example of this process would be the drug discovery process. Typically, only one in every five thousand component researched reaches the market. It takes on average ten years at the cost of 800 million US$.[41] Fewer than fifteen percent of the marketed drugs generate enough revenue to recover the R&D costs.[42]

The answer to the question on how to best form incentives and how to govern bioprospecting activity is founded on the economic nature of biodiversity, biological resources and bioprospecting. Polski suggests that a relational contracting basis adapted for the individual case and involving key stakeholders, who have an interest in the resource system where the bioprospecting activity occurs, is the best way to ensure success and the objectives of the different stakeholders. Nevertheless, much uncertainty remains as the empirical project examples are quite few and have yet to bring forth any commercialized product.[43] Accrued benefits are often characterized as 'spillovers' from the R&D process, such as transfer of equipment and know-how and local capacity building.[44]

2.1.2 A market-based approach to ABS

Presently, the international community are in debate on whether access to biological resources and benefit-sharing regimes should be implemented with a regulatory approach with strict rules to guarantee that benefits are distributed fairly. This approach is however not shared by everyone. A study from the Australian APEC[45] Study Centre, sponsored by PhRMA[46], advocates a market-oriented approach, based on a clear delineation of property rights and developed in an international non-binding regime.

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[40] Polski, 2005, p. 548.
[41] Information from PhRMA website: http://www.phrma.org/innovation/, 11/04/06.
[42] Standard and Poor's Corporation, 2003, Industry Survey on Healthcare: Pharmaceuticals, June 26, New York.
[43] However, see the example of Diversa Corporation below.
[44] Polski, 2005, p. 554.
[45] The Asia-Pacific Economic Cooperation.
[46] The Pharmaceutical Research and Manufacturers of America.

The main argument against the highly regulatory approach is that concerns regarding biopiracy have been exaggerated. The assumption that biological resources from biodiversity-rich countries would constitute 'green gold' is misguided and to limit access will inhibit the already failing bioprospecting activity and ultimately any benefits to share. Involvement by the private sector supporting research provides benefits for the country, North or South, in helping to discover and document biodiversity. Research collaborations between research institutions and the private sector in bioprospecting projects mean reduced costs for the government.[47]

Biotech-industry is regarded as the future solution to problems of development and conservation. It holds the promise of future pharmaceuticals and improvements to agriculture. The need for facilitated access to genetic resources is vital for this industry and any discouraging measures would work to a disadvantage for the country itself.[48]

'Good practice' in regulation is ensuring that costs of compliance are not greater than the benefits deriving from the activity being regulated. Generally it can be said that compulsory compliance of government regulation is the most onerous form while voluntary compliance of guidelines is the least onerous form.[49] It is argued that if a regulatory approach is undertaken in the bioprospecting area; due to low activity and an industry in the early stages of development, the full costs will never be known as regulation effectively will stop the activity almost entirely. Overlapping rules, e.g. requiring different permits from different government agencies for the same project, also constitutes an onerous aspect of the regulatory approach.[50]

The market-based approach is strongly opposed to introducing additional conditions for patent applications. IPRs (in this thesis mainly patents) are fundamental for the existence of any bioprospecting activity. Any additional conditions would diminish the value of patents which would be detrimental to researched-based companies. Extending the patent process with subsequent rise in costs would, according to research by Wolfe and Zycher, lead to the estimated loss of 150-200 drugs over the next twenty years.[51] Excessive bureaucracy is stated as the main contributory cause for loss of new drugs.

The study recognizes the difficulty of comparing a regulatory and market-based model. As the market-based model has not been widely adopted, it is a complicated task to compare the supposedly suppressed demand under a regulatory model with any conclusions of potential market demand in a

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[47] Bowen, *Developing an effective international regime for access and benefit sharing for genetic resources; Using market-based instruments*, the Australian APEC Study Centre, Monash University, Melbourne, December 2005. pp. 17-18.
[48] Ibid, p. 10.
[49] Ibid, p. 13.
[50] Ibid, p. 15.
[51] See Wolfe and Zycher, 2005, *Biotechnological And Pharmaceutical Research And Development Investment Under a Patent-Based Access And Benefit-Sharing Regime*, Pacific Research Institute for Public Policy, May 2005, where a patent-based regime is seen as an equivalent to a long-run tax on biotechnological and pharmaceutical research, thus having the effect of reducing investment into such research. 27 countries were subject to the study that was circulated in connection to a WIPO meeting in Geneva 6-10 June, 2005.

market-based model. The potential size of the bioprospecting market is not fully known.[52]

What standing indigenous communities have under the regulatory model contra the market-based model is also addressed. It is claimed that a regulatory regime makes the indigenous communities and their TK entirely dependent on government decisions. A market-based model could correct that situation through allocating assets, in the form of property rights to the indigenous communities. The advantage of transparency is also put forward.[53]

2.2 Biotechnology generations

For the purpose of a more diversified understanding of the ABS issue and possible technology transfer in accordance with the TRIPs, an overview of the fundamental structure of the biotech industry and biotechnology is helpful.

Biotechnologies are often divided into three different generations. The *first* generation is not a novel craft but includes traditional technologies such as beer brewing and bread baking, technologies that have been utilized for thousands of years.[54] The *second* generation begins with Louis Pasteur developing the process of fermentation of the antibiotics. It also includes tissue culture and modern plant and animal breeding.[55] The "new biotechnologies" constitutes the *third* generation and is what one normally would define as biotechnology, i.e. genetic engineering techniques which transfer DNA from one life-form to another, creating transgenic organisms with new and useful properties.[56] The PCR process, mentioned above,[57] is included in the third generation of biotechnology.

Commercially attractive is the health area in which pharmaceutical companies provide the classic example with high returns and R&D intensive activity. Development is not only of new drugs but also diagnostics and enhancement of the efficiency of the drug discovery process.[58]

The biotechnology "revolution", i.e. mainly the third generation of biotechnologies has created new business opportunities and lead to the development of four types of business:

- Technology providers who produce DNA sequencing machinery and other equipment;
- Information providers who collect and organize sequencing information;
- Research based companies, that are dedicated biotechnology firms, and generally do the upstream (i.e. initial or basic) research, but lack the

[52] Bowen, APEC Study, supra f.n. 47, p. 21.
[53] Bowen, APEC-study, supra f.n. 47, p. 24.
[54] Dutfield, 2004, p.14.
[55] Ibid.
[56] Ibid.
[57] See page 5.
[58] Dutfield 2004, p.15.

resources or the intention to do downstream (i.e. final, close to the market) research, including product development and marketing;
- Health, industrial and agricultural biotechnology firms. These are typically pharmaceutical, chemical and life science companies that are longer established businesses, but also larger dedicated biotechnology firms that are vertically integrated (performing on both upstream and downstream scale).[59]

The process from basic research to a finished product is particularly long and costly within the pharmaceutical industry. Furthermore, one company may not be the best equipped to see through the whole process. This can also be an obstacle to bioprospecting and the regime of ABS.

Extensive patent portfolios are an important tool to attract investors which is crucial in research-based industry. Companies have a strong incentive to acquire patent with a broad scope and with claims that are drawn in a way that anticipates future scientific development. For developing countries, securing third generation IPRs to generate more wealth, the question remains on how to keep the value of basic biogenetic resources and to encourage technology transfer in line with the provisions in TRIPs.

2.3 Bioprospecting economics in practice

Companies, especially trans-national, operate on a global market. The financial risks that a company must bear in developing a new product are substantial and must be considered in the discussions around bioprospecting and ABS. IP protection over products and processes is the only way to recoup those investments. Under these circumstances, the value attributed to the raw biological resource and/or TK is dubious.[60]

2.3.1 Successful(?) bioprospecting projects

It is often said that the commercial use of bioprospecting is overrated and that there have yet to be any commercial products on the market emanating from such activities. The Merck-INBio agreement presented below which has been renewed a number of times has yet to bring forth any product.

However, there are examples of ethical bioprospecting, compliant to the CBD and with an ethical code that has been successful, generating royalties to the source providers. Such an example is Diversa Corporation (San Diego, California).

It can be difficult to evaluate the projects as they are presented and discussed in articles influenced by the different discourses presented above. How bioprospecting is approached in practice is nevertheless enlightening.

[59] Dutfield, 2004, pp. 15-16.
[60] ten Kate and Laird, *The commercial use of biodiversity: Access to genetic resources and benefit sharing*, 2002, pp. 6-7.

2.3.1.1 The Merck-INBio Agreement

A classic example often used is the agreement between Merck, a pharmaceutical company, and the National Biodiversity Institute (hereinafter INBio). INBio is a non-profit, non-governmental, scientific organization, created in 1989 on the recommendation of a presidential commission. It carries out bioprospecting activities through a formal agreement with the Ministry of Environment and Energy which is given ten percent of the research budget to cover costs of conservation. They also share the potential royalties on products deriving from Costa Rica, negotiated by INBio.[61]

The first agreement between INBio and Merck was signed in 1991. Under the terms of the agreement, INBio would provide 10,000 samples of plants, animals, and soil to Merck. Merck would have the exclusive rights to study these samples for two years, and retain the patents to any drugs developed using the samples. In return, Merck paid INBio $1 million up front, and supplied the institute an additional $130,000 worth of laboratory equipment.

Interestingly, the deal included stipulations on royalties for any drugs developed from the biological samples provided. These royalties would be paid on all sales and not just sales in the United States or Costa Rica. As a part of the deal, half of these royalties will go to the Costa Rican Ministry of Environment and Energy, which would use the proceeds for conservation of biodiversity.[62] The precise percentage amount of the royalties remained undisclosed for some time but was later disclosed to be 5 percent.[63] The agreement has faced criticism, mainly due to the fact that it neither contains any provisions on indigenous knowledge, nor includes indigenous communities in the negotiations. It is the government and INBio that are beneficiaries to the Merck agreement, indigenous communities are not covered as INBio has stated no interest in TK.[64] The agreements has furthermore been criticized for reducing INBio to 'lab technicians', however it is generally seen as a functional example of a bioprospecting agreement.

2.3.1.2 Diversa Corporation

This company has developed a model for ethical bioprospecting in which participating countries, institutions and corporate stakeholders benefit, all with minimal conflict and disagreement.[65]

Diversa Corporation is a biotech company concentrating on the discovery, evolution and production of commercially valuable enzymes and molecules with pharmaceutical, agricultural, chemical and industrial applications. Through its patented technologies it can rapidly target and

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[61] See INBio website: http://www.inbio.ac.cr/en/default.html, 12/04/06.
[62] Coughlin Jr, M. D, *Using the Merck-INBio agreement to clarify the Convention on Biological Diversity*, Columbia Journal of Transnational Law, 1993, Vol. 31 Iss. 2, pp. 337-375.
[63] See http://www.grain.org/seedling/?id=372, 12/04/06.
[64] Dutfield, *Between a rock and a hard place: Indigenous peoples, nationstates and the multinationals*, 1998, in FAO document *Medicinal plants for conservation and health care*.
[65] Christoffersen and Mathur, *Bioprospecting ethics & benefits; A model for effective benefit-sharing*, Industrial Biotechnology, 2005, vol. 1, No. 4, p. 255.

identify substances from small environmental samples to discover novel gene products. It has entered into agreements in places such as Alaska, Antarctica, and Costa Rica, Ghana, Kenya, Russia and more.

The company has formed alliances and joint ventures with several larger companies such as GSK[66] plc, Dow Chemical Company and affiliates with Syngenta AG.[67]

Diversa has developed a set of principles for selecting partners and for creating agreements ensuring long-term relationships based on the principles of CBD, i.e. the sustainable use of genetic resources. The first step is to assess the country in question in terms of legal framework, political will, potential partners and the presence of unique habitats. When the country of interest and the institutional candidate have been identified, Diversa employs a bioprospecting framework, developed by the company, to help the structuring of the collaboration agreement.[68]

Partners to Diversa have been receiving financial payment, third party grants and training of scientists. Infrastructural and scientific capacities improvements have also been made.

The model does not incorporate TK first-hand as the company focuses on micro-organisms as opposed to plant extracts. However, the potential conflict between traditional land tenure and property rights to genetic resources and moreover, ownership of the results from use of genetic resources is considered on a case-by-case basis in the access agreement and in the choice of benefit-sharing mechanisms employed.[69]

There are three main criteria that Diversa considers central for successful bioprospecting programs. These are:

- Efficient and reasonable permit systems (requiring no more than three months to secure a permit and oblige the permit holder to reasonable reporting criteria);
- Efficient and reasonable benefit-sharing negotiations; and
- A goal of creating fair and trusting relationships that result in expanded, long-term cooperation

The company is of the opinion that "biodiversity collaborators" (often the source country) that are more flexible in terms of monetary benefit-sharing mechanisms are more able to capture the most value of biodiversity. As the market potential for an end-product usually is non-obvious, there is a possibility of using graduated royalties, depending on e.g. sales volumes of the end-product.[70]

[66] GlaxoSmithKline.
[67] See corporate website: www.diversa.com, 06/04/06.
[68] Mathur et al., *An overview of bioprospecting and the Diversa Model*, IP Strategy Today, 2004, No. 11, p. 2.
[69] Ibid, p. 7.
[70] Ibid, p. 15.

3 Bioprospecting and Intellectual Property Rights

In this and the following chapter, the legislative provisions related to intellectual property, biological resources, traditional knowledge and access and benefit sharing are explored. It provides in no way an exhaustive overview of the international legal instruments in focus, rather, it isaimed to serve as a background to the issues around bioprospecting dealt with here and to provide a framework for comparison with the national and regional legislation scrutinized in chapter 5.

3.1 Patent protection for inventions

Before penetrating the issues surrounding patent protection on biological material with an indicated pharmaceutical use there are standard criteria that need to be fulfilled in order for the material/invention to receive patent protection. The patent itself is further defined in different structures so as to provide sufficient clarity. This is briefly explained below.

3.1.1 Patentability criteria for patents

There are three criteria to be fulfilled in order for an invention to be available for patent protection. These are novelty, inventive step and industrial application.[71] TK in particular could have an impact for the assessment of at least two, i.e. novelty and inventive step.

The criteria of *novelty* (or new) is defined as that which is not part of the state of the art (often referred to as prior art). Prior art is in turn defined differently in the US[72] than in Europe. In Europe it is defined in an unlimited sense, without territorial boundaries. Article 54(2) of the European Patent Convention (EPC) defines it as "everything made available to the public by means of a written or oral description, by use, or in any other way".

The patent claim must contain at least one indispensable technical feature not found in the prior art. This is not necessarily linked to one specific document but if that document refers explicitly to another document (e.g. a document providing more details), the latter can be regarded as incorporated into the primary document.[73]

Inventive step, or non-obviousness, means that, with regard to prior art, it is not "obvious" to a person skilled in the art. This provision is commonly considered to be the most difficult criteria to apply in patent law, and it is equally difficult to analyse.[74] This is particularly so within the

[71] Article 27 TRIPs.
[72] Only written descriptions are accepted. See 35 U.S.C. § 102 (a)-(b).
[73] Domeij, *Pharmaceutical Patents in Europe*, 2000, p. 130.
[74] Ibid, p. 199.

pharmaceutical industry, due to the unpredictability of biological reactions. The term "obvious" is interpreted as not going beyond the normal progress of technology, but merely plainly or logically following from the prior art.[75]

The *industrial applicability* (usefulness) criteria is to make sure that patents are only permitted where the applicant has demonstrated that he can develop the commercial products that fall within the granted protection.[76] A patent's function is not to enable claims to what others may develop in the future.[77] This could be relevant for bioprospecting when biological material is the subject of a patent application in the early stages of the research. Does the supposed area of utility, often indicated by the TK, fulfil the standards of industrial applicability?

3.1.2 Patents on biological material

Compounds with a therapeutic effect can be defined in three different ways or with a combination of these three different ways in order to provide sufficient clarity: structural formula, product-by-process claims and parameters relating to the compound.[78]

The *Structural formula* is the most precise way of defining a chemical compound and ought to be used if feasible. This normally is a delineated generalised structural formula, which forms the independent and broadest claim as the scope depends on which compounds may be created by combining the different alternatives mentioned for the different positions in the formula. Usually, dependent claims with a narrower scope are also applied for as a "safety measure". In these dependent claims the commercially most interesting individual compounds are singled out, which prevents competitors to make selection inventions within the scope of the broader claim.[79]

If the compound cannot be defined by any other means, the *product-by-process claim* can be used. It is a definition of the compound by describing how it is manufactured. This type of claim is common where compounds are particularly susceptible to structural variations such as naturally occurring chemical compounds, catalysts (enzymes), macromolecules and products of microbiological process. The compounds are difficult to define unambiguously by their structure.[80]

However, the product-by-process claims are definitions of new compounds and the compound in itself must fulfil all patentability requirements. The manufacturing process itself can only serve as a

[75] EPO Guidelines for examiners, Part C, Chapter IV, para. 9.4. The EPO has adopted the "problem and solution approach" for determining the inventive step criteria, which is to ensure an objective assessment and avoid an *ex post facto* analysis of the prior art. See EPO Guidelines, art C, Chapter IV, para. 9.8 and forward.
[76] Domeij, 2000, p. 28.
[77] Ibid.
[78] EPO Guidelines for examiners, Part C, Chapter III, para. 4.7a.
[79] Domeij, 2000, p. 68.
[80] Ibid.

definition, it cannot, however novel it might be, actually constitute the invention.[81]

Parameters relating to the claims; meaning characteristic aspects of a product, relating to characteristic features of the compound are sometimes used together with product-by-process claims. This is to get the most unambiguous scope of protection when a structural formula is not available. From the inventor's standing, the scope of the claim should be as broad as possible, as there is a direct correlation between the breadth and the economic value of the patent.[82]

Despite the spirit of patent laws requiring novelty, inventive step, and industrial application, biogenetic resources today may be considered closer to human "inventions" than to natural "discoveries" in legal terms. Thus, bioprospectors are able to reap profits from living organisms (or products derived therefrom) that would have been considered "common goods" only a century ago. The legislative response is, of course, attuned to the higher stakes in the current biogenetic resources market, but it might overlook the fact that these resources did not entirely originate in the laboratory.[83]

3.2 The TRIPs Agreement

As a result of the Uruguay Round in 1995 of trade negotiation, a new intergovernmental organization was established. This was the World Trade Organization (WTO). Together with Japan and the EC, the US pressed for the inclusion of IPRs. The outcome was TRIPs, the Agreement on Trade-related Aspects of Industrial Property Rights. The developed countries, spurred by strong industry lobbying, sought to establish a standardized IPR system with minimum standards that more closely reflected the IPR systems of the developed world. The existence of a dispute settlement mechanism within WTO (lacking from WIPO) also made it an attractive arena for an IPR agreement.

3.2.1 Objectives and general principles

Article 7 in TRIPs acknowledges the public policies of the agreement. It can be seen as part of the deal the developing countries got for accepting the TRIPs Agreement. It provides:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and

[81] Ibid, p. 69.
[82] Domeij, 2000, p. 63.
[83] Environmental Policy Studies Workshop, School of International and Public Affairs, Columbia University, *Access to Genetic Resources: An Evaluation of the Development and Implementation of Recent Regulation and Access Agreements*, 1999, p. 6.

users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

However, the main object with WTO and subsequently the TRIPs Agreement can be found in the preamble of the Agreement, namely:

Members,
Desiring to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade.

It also explicitly recognizes that Intellectual Property Rights are *private* rights.

In Article 3 one of the core principles of the Agreement is enshrined, namely that of *national treatment*. Simply put the principle purports that member states must award the same level of IP protection to nationals of other member states as they award their own nationals. This together with the next core principle in Article 4 and the standardization of IPR legislation can be said to constitute the heart of the Agreement.

Article 4 requires *most-favoured-nation* treatment of the member states. The concept means that any privileges, favours, advantages or immunities granted to one member state, immediately shall be accorded to the other member states of the Agreement.

The Agreement required all member states to have implemented these articles within on year of the entry into force of the WTO Agreement.

3.2.2 The relevant articles

Section 5 of the TRIPs Agreement deals with patents. Article 27, the first paragraph of the section is controversial, providing an indirect link to the CBD.

The relevant parts of the article state:

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application…

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability…

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

3.2.2.1 Article 27.1

This is a significant Article for several reasons. Firstly it defines patentable subject-matter. The conditional criteria are novelty, inventive step and industrial application.

In case a Member chooses to protect living organisms through patents, only such organisms having undergone a certain technical modification are not pre-existent in nature and may thus be considered as new. Since the determination of the precise meaning of novelty (like the other patentability criteria) is left to the WTO Members' discretion, the degree of technical intervention required to satisfy the novelty criterion varies widely among domestic patent laws.[84]

Secondly, it stipulates non-discrimination in three different areas. In the first area it requires that patents be available and patent rights enjoyable without discrimination as to the *place of invention.* This had significant consequences for the USA who had to change its patent law. The US has the, now unique, system of first-to-invent as opposed to first-to-file which operates everywhere else in the world. Up until the TRIPs Agreement, US courts were barred from accepting foreign[85] evidence of dates of the invention in cases where priority of invention was to be established.[86]

The second area of non-discrimination relates to *all fields of technology*. Several countries at that time did not provide patent production for pharmaceutical products and/or processes and the introduction this amounted to an important advancement for the pharmaceutical industry.[87]

The third and last area of non-discrimination refers to the words *whether products are imported or locally produced*. Another common requirement was that patented products had to be manufactured locally in order to enjoy IP protection. Now a product can be imported and put on the market without loosing national IP protection.[88]

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[84] UNCTAD-ICTSD, 2005, *Resource Book on TRIPS and Development*, pp. 389-390.
[85] Section 104 of the US Patent Act stated that 'in proceedings in the Patent and Trademark Office, in the courts, and before any other competent authority, an applicant for a patent, or a patentee, may not establish a date of invention by reference to knowledge or use thereof, or any other activity with respect thereto, in a foreign country…'. This was subsequently changed in 1994 and the phrase 'other than a NAFTA country or a WTO member country' was added.
[86] Dinwoodie et al, *International Intellectual Property and Policy*, 2001, p. 389.
[87] Dutfield, *Intellectual Property, Biogenetic Resources and Traditional Knowledge*, 2004, p. 27.
[88] Ibid.

3.2.2.2 Article 27.2

Article 27.2 may at first seem to provide for exceptions common in international law, namely *ordre public* and morality.

The term *ordre public*, derived from French law, is not an easy term to translate into English. The English term public order is more narrowly construed, making the French concept more akin to the term public policy. In short it relates to matters that threaten the structure of civil society as such.[89] Protection of human, animal or plant life, health or serious prejudice to the environment is stated as legitimate reasons. The Article does put such possibilities under one important condition; it may only be invoked if the commercial exploitation needs to be prevented to protect the interests above. It precludes commercial exploitation as such and cannot be used when there is an interest in e.g. public health for the diffusion of the invention. In other words, invoking *ordre public* or morality means no commercialization at all.[90] However, prohibition on exploitation of the invention is not a reason to refuse patentability.

How large is the countries' discretional scope in this matter? It has been argued that the exclusions provided in 27.2 should be narrowly applied, on a case-by-case basis in order for member countries to comply with TRIPs. If the TRIPs Agreement intended for broad clauses of patents (e.g. life-forms) to be allowed to be excluded, it would have been explicitly indicated.[91] Nevertheless, some countries have included such an exception, e.g. the French Patent Law, as amended 1994. It reads as follows:

> *...The human body, its elements and products as well as the knowledge of the whole or part of a human gene cannot as such be subject to patents...*[92]

The European Patent Office (EPO) has on the other hand routinely granted patents on human genes or cell lines and the Opposition Division of the EPO has not found the patenting of human genes as inherently unethical.[93]

3.2.2.3 Article 27.3 (b)

Often called the biotechnology-clause, Article 27.3(b) is the only article in the Agreement to be explicitly subject to an early review. The debate surrounding it has revealed different, seemingly irreconcilable, viewpoints (see further below), starting with the dispute over the term review.

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[89] UNCTAD-ICTSD, 2005, *Resource Book on TRIPS and Development*, p. 375.
[90] Ibid, p. 376.
[91] Moufang, *The Concept of 'ordre public' and Morality in Patent Law*, 1998, pp. 65-77.
[92] Book VI, Title I, Chapter 1, Section 3, Art. L. 611-17 (a), Code De La Propriete Intellectuelle.
[93] See e.g. http://www.european-patent-office.org/news/pressrel/2005_10_27_e.htm, 03/04/06 or http://www.ladas.com/BULLETINS/1995/1195Bulletin/EPO_PatentsHumanGenes.html, 03/04/06.

Developed countries, e.g. the US and Australia[94], held that the Article called for a review of implementation while for developing countries, "review" should enable the revising of the Article itself.[95] With the Doha-declaration in 2001, a discussion on review, the relationship with the CBD and protection of TK was initiated.

The Article allows for plants and animals other than micro-organisms, and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes, to be excluded from patentability. Plant variety protection is introduced as a compulsory requirement.[96] A key area of uncertainty is how the term micro-organism should be defined. In the US the concept of 'new' does not mean pre-existing, but novel in relation to prior art. Hence, a purified or isolated natural product would be patentable. The EU has adopted a similar approach with the Directive on Biotechnological Inventions[97] (hereinafter Biotechnology Directive). The EPO Guidelines for examiners provide some clarity to how the term is to be interpreted:

> *The term "micro-organism" includes bacteria and other generally unicellular organisms with dimensions beneath the limits of vision which can be propagated and manipulated in a laboratory,… including plasmids and viruses and unicellular fungi (including yeasts)*[98]

The term *microbiological process* is defined as well for the purposes of determining what an essentially biological process is. The Guidelines explain it as 'any process involving or performed upon or resulting in microbiological material.' It covers not only processes performed upon microbiological material or resulting in such (e.g. by genetic engineering), but processes including both microbiological and non-microbiological steps can be claimed.[99]

The product of a microbiological process may also be patentable through product claim. For the purposes of Article 53(b)[100], the dissemination of the micro-organism itself is to be construed as a microbiological process. Consequently, as a product obtained by a microbiological process, the micro-organism can be protected *per se*.[101]

The key to interpreting the difference between a mere discovery and an actual invention (the line can with microbiological inventions be rather blurred), is the *technical effect*. An example would be a substance occurring in nature which is found to have an antibiotic effect. Additionally, a micro-organism that is discovered to exist in nature and to produce an antibiotic,

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[94] See e.g. U.S. communication IP/C/W/209; Australia communication IP/C/W/310 ("the coverage of this agenda item is relatively narrow, that is, the item is concerned with a review of the effectiveness of the operation of an optional exclusion to patentability . . . ").
[95] UNCTAD-ICTSD, 2005, supra f.n. 91, p. 395.
[96] E.g. the UPOV-regime.
[97] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions. [OJ 2/1999, 101].
[98] EPO Guidelines for examiners, Part C, Chapter IV, para. 3.5.1.
[99] See also Article 2.2 Biotechnology Directive.
[100] Article 53(b) of the EPC on which Article 27.3(b) is modelled.
[101] EPO Guidelines for examiners, Part C, Chapter IV, para. 3.5.1.

the micro-organism as such may be patentable as an aspect of the invention.[102] Technical effect or process is also used as the defining criteria in the preamble to the Biotechnology Directive.[103] Thus, the ambit between essentially biological processes contra non-biological and microbiological processes appears to offer considerable room for interpretation.

3.2.3 Protection of undisclosed information

Article **39** provides for the protection of undisclosed information, more generally referred to as "trade-secrets" or "know-how". Although not usually considered an IPR, it was proposed by the US, the EU, and Switzerland as a necessary measure for the fulfilment of the obligation under the Paris Convention to suppress unfair competition.[104] The obligation under Article **39.1** is consequently limited to the protection against *unfair* competition, not of exploitation *per se*.

Unlike other IPRs the protection does not afford "exclusive right". Falling under a category of intellectual property (TRIPs Article 1.2), it does not imply any existence of "property rights" in the undisclosed information. Instead there is recognition of the "possession" or *de facto* "control" over the said information.

Undisclosed information encompasses any secret information of commercial value such as;

- technical know-how, such as design, process, formula and other technological knowledge often resulting from experience and intellectual ability;
- data of commercial value, such as marketing plans, customers lists and other business-related information that provides an advantage over competitors;
- test and other data submitted for the approval of pharmaceutical and chemical products for agriculture.[105]

Protection is to be provided against the disclosure, acquisition or utilization without consent in "*a manner contrary to honest commercial practices*" as long as the information a) is secret, i.e. not generally known or readily accessible to persons that normally deal with the kind of information in question; b) has commercial value because of its secrecy and c) has been subject to reasonable steps to be kept secret.[106] The commercial value must have *actual* value under the Agreement but it is possible for member countries to extend the protection for *potential* value as well.[107]

For the purpose of this provision, "*a manner contrary to honest commercial practices*" stands for, at least, practices such as breach of

[102] Ibid, para. 2.3.1.
[103] Biotechnology Directive, preamble para. 20-21.
[104] Paris Convention for the Protection of Industrial Property, 20 March 1883, Article 10bis.
[105] UNCTAD-ICTSD, 2005, *Resource Book on TRIPS and Development*, p. 521.
[106] TRIPs, Article 39.2 (a)-(c).
[107] UNCTAD-ICTSD, 2005, p. 529.

contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition.[108]

[108] TRIPs, footnote to Article 39.

4 The Convention on Biological Diversity

The main international legal instruments concerning biodiversity in general and the issues of ABS and TK in conjunction with bioprospecting in particular, is the Convention on Biodiversity.
The CBD was the result of the Earth Summit in Rio de Janeiro, Brazil, in 1992. It entered into force on 29 December 1993.[109] Presently 188 countries are parties to the Convention. All the Member States of the European Union are parties however the USA most notably, is not.[110]

4.1 General overview

The CBD is a comprehensive legal instrument but as an United Nations effort, it also suffers from the disadvantages of international agreements, namely lack of enforcement mechanisms and dependence on national implementation. It creates a body of rules on *in situ* and *ex situ*[111] conservation and establishes procedural requirements such as the elaboration of national biodiversity strategies.[112] It also constitutes an institutional framework for the continual work on legal, policy and scientific initiatives on biological diversity.[113] The Parties to the Convention are obliged to take a number of measures including monitoring and identification of biodiversity, environmental impact assessments, developing national strategies and to integrate the biodiversity policy into the relevant sectoral and and cross-sectoral plans, policies and programmes.[114]

4.1.1 Who is bound by the Convention

The CBD, as an international Treaty establishes rights and obligations of its Contacting Parties, the sovereign states. Private individuals do not have to adhere to the Convention. There are however, institutions which are governmental bodies of the Contracting Parties that arguably could be

[109] Bernstein et al, Earth Negotiations Bulletin, 1993, available at: http://www.iisd.ca/vol09/0918001e.html, 26-01-2006.
[110] http://www.biodiv.org/world/parties.asp, 26-01-2006.
[111] *in situ*: Genetic resources existing within ecosystems and natural habitats. *ex situ*: components of biological diversity outside their natural habitats, CBD definitions. It encompasses conservation in botanical gardens, zoos and aquaria, genebanks and other collections.
[112] Tarasofsky, R, *The Relationship Between the TRIPs Agreement and the Convention on Biological Diversity: Towards a Pragmatic Approach*, RECIEL, 1997, Vol. 6, Iss. 2, p. 149.
[113] ten Kate and Laird, 2002, p. 13.
[114] Ibid, p.14.

bound by the CBD provisions. Further, public institutions, e.g. universities, genebanks or botanic gardens may also be bound, depending on the provisions and to what extent they rely on public funding and grants that obligate adherence to public law. The obligation to comply with the CBD would then not be dependent on national implementation.

4.2 Objectives and general principles

The objectives of the Convention on Biological Diversity are enshrined in the Preamble and Article 1. The intrinsic value of and the importance of the conservation of biological diversity is affirmed. The close relationship and dependence of many indigenous and local communities embodying traditional lifestyles on biological resources is also recognized. In Article 1 the objectives are stated as the conservation of biodiversity[115], the sustainable us of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources. The objectives are in other words three, conservation, sustainable use and fair and equitable sharing of the benefits accrued.

The most important general principle is enshrined in Article 3. The principle of ***national sovereignty*** over their biological resources replaced the earlier notion that biological resources were

> "*common heritage of mankind to be preserved and freely available for use, for the benefit of present and future generations*".[116]

That ideology was challenged in the 1980s due to a perceived imbalance between free access to genetic resources on the one hand and the development of patents on biotechnological inventions on the other. A strong environmental movement pushing to convince the public on issues such as the perceived value of biodiversity, especially to the pharmaceutical industry and the emerging life-science industry, and the more classical North-South political relationship.[117]

4.3 Relevant articles of the Convention

The most significant Article with reference to TK is **Article 8 (j)**. It states:

> *Each Contracting Party shall, as far as possible and as appropriate:*

[115] Biological diversity and biodiversity are interchangeably used in this thesis.
[116] FAO Conference of November 1983 when adopting the International Undertaking (IU) on plant genetic resources.
[117] Le Buanec, *Plant genetic resources and freedom to operate,* Euphytica, 2005, Vol. 146, Iss. 1, p. 2.

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 language of the article is somewhat vague and possible obligations arising from it are weakened by being preceded by term such as "as far as possible and as appropriate" and "subject to national legislation. In 2000 the Conference of the Parties to the Convention on Biological Diversity (COP) adopted a decision to clarify matters saying that access to TK should be subject to PIC of such holders of TK. Although a laudable effort the question is to what extent this serves to facilitate access to biological resources as it raises difficult practical and cultural issues.[118]

Article 16 deals with access to and transfer of technology. Transfer of technology, including biotechnology is essential for the objectives of the Convention and access shall be facilitated through legislative, administrative or policy measures. The transfer is to be made under mutually agreed terms and IPRs shall be adequately protected.[119] State measures to facilitate private sector participation, e.g. joint R&D or transfer of technology, are also to be undertaken.

In **Article 16(5)** the CBD's relationship with patents and other intellectual property rights is articulated:

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 and do not run counter to its objectives.

This can be interpreted as a subtle hint that the objectives of the CBD are superior to intellectual property law and if there is inconsistency, an adjustment of IPR rules would be possible.

Article 19 specifically deals with the handling of biotechnology and the distribution of its benefits. It obligates the Contracting Parties to take legislative, administrative or policy measures to make available an effective participation in biotechnological research, especially by developing countries that provide the biological resources for such research. Measures shall be taken to promote and advance access to the results and benefits

[118] Greene, 2002, 'Intellectual Property, Resources or Territory? Reframing the Debate over Indigenous Rights, Traditional Knowledge, and Pharmaceutical Bioprospection', in Bradley, M. P, and Petro, P (eds) *Truth Claims: Representation and Human Rights*, pp. 229-249.

[119] Article 16(2). The term adequate and effective protection is specifically there to establish a link with the, then draft, TRIPs Agreement. It is however also stated in the last sentence that the application of this paragraph shall be consistent with paragraphs 3, 4 and 5, i.e. Article 16(5).

arising from such research. Access shall be on a fair and equitable basis and on mutually agreed terms.

4.3.1 Article 15, access to genetic resources

In this article, several of the fundamental provisions are laid down. Article **15 (1)** expresses the right of the sovereign States to determine access to their natural and genetic resources through national legislation, a reflection of the general sovereignty principle in Article 3. According to Article 15 (4), access when granted, shall be on mutually agreed terms. Any subsequent benefit-sharing shall comply with articles 16 and 19 and as well be mutually agreed upon (Article 15(7)). Parties must nevertheless in consistence with Article 15 (2) endeavour to facilitate access, i.e. striking a balance between controlling access in order to ensure that mutually agreed terms are reached, but make sure that procedures and requirements do not block access.[120]

The crucial concept of *prior informed consent* is enshrined in Article **15 (5)**. It is not defined any closer in the Convention but there is substantial literature on the subject. The last phrase of article 15(5): "*unless otherwise determined by that Party*" means that imposing the requirement of prior informed consent is an option rather than an obligation, with the consequence that a user is only required to submit to PIC if the providing Party has taken steps to establish the necessary procedure in its legal system.[121]

4.3.1.1 Whose consent is required?

Identifying which *governmental* authority from whom to obtain permission from can prove to be difficult. In countries where legal and administrative steps have been taken, the legislation often identifies the appropriate organ. However, many countries have not yet enacted such legislation making access to biological resources subject to a patchwork of different laws, e.g. access to protected areas, export, the CITES[122], biosafety, laws on private property etcetera, and an equally diverse group of organizations such as ministries, local and regional governments, institutions and individuals.[123]

The question of whose consent that is required is further complicated. The CBD only provisions PIC at the national level, on the condition that national legislation stipulating PIC is enacted. Moreover it is necessary for the countries to enact laws with provisions of mandatory PIC of indigenous/local communities. This has been done in various ways as can be seen in the national examples below.

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[120] ten Kate and Laird, 2002, p. 27.
[121] Hendrickx, F, Koester, V, Prip, C, *The Convention on Biological Diversity – Access to Genetic Resources: A legal Analyses*, Environmental Policy and Law, 1993, Vol. 23, Iss. 6, p. 250.
[122] Convention on International Trade in Endangered Species of Wild Fauna and Flora.
[123] ten Kate and Laird, 2002, pp. 27-28.

PIC at local level involves the same disclosure requirements as above but in a form more suitable for the context. Posey and Dutfield have written about it as a process in which:

- the person seeking access must obtain consent from every affected community in the traditionally recognized manner;
- before seeking consent, the person seeking access should distribute and hold community discussions regarding all relevant information to the community in a culturally appropriate manner;
- consent should be part of an ongoing process in which the community may choose to give or not to give consent; and
- community leaders may revoke consent for legitimate reasons.[124]

As noted above it does create uncertainty. How much must stakeholders understand in order to be able to give a truly informed consent? On what level do they need to be informed on issues such as patent laws, conservation biology, and biotechnology? It is nevertheless clear that PIC cannot be given in a single unitary moment of time at the beginning of the bioprospecting project, but it must be an ongoing process of interactive character that gradually expands to cover issues of a broader interest.[125]

4.3.2 The Bonn Guidelines

The Bonn Guidelines were adopted at the 6th Conference of the Parties to the Convention (COP) in the Hague in April 2002. Although the Guidelines are voluntary[126] they were adopted unanimously by 180 countries which give an undisputable authority.[127] It was adopted to assist in adopting effective measures and strategies implementing the CBD.

The Guidelines identify the steps, with particular reference to Articles 8(j), 10(c)[128], 15, 16 and 19, in the access and benefit-sharing process, with an emphasis on the obligation for users to seek the prior informed consent of providers. They also provide the basic requirements for mutually agreed terms and define the main roles and responsibilities of users and providers as well as stress the importance of the involvement of all stakeholders. Finally, they enumerate suggested elements to be included in material transfer agreements and provide an indicative list of both monetary and non-monetary benefits.[129]

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[124] Posey and Dutfield, 1996.
[125] Berlin and Berlin, 2003, pp.630-631.
[126] CBD, Article 7.
[127] 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.
[128] Article 10(c) reads as follows: *Each Contracting Party shall, as far as possible and as appropriate: Protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements.*
[129] Ibid.

4.4 The Relationship between the TRIPs Agreement and the CBD

The direct relationship between TRIPs and the CBD is an issue of debate. While two instruments with different objectives, there is no doubt that they intersect when dealing with the activities and results of bioprospecting, namely patenting of biological resources and associated TK, issues of technology transfer and the controversial issue of the patenting of life, and with the Doha Declaration from 2001, the relationship was brought into WTO discussions.

Although, the connection between the two international documents is frequently made, the exact nature of this connection is still a topic of considerable rhetoric and political controversy.[130] The TRIPs Agreement has the focus on establishing harmonized global IPR regime and technology transfer and the CBD concerns the conservation and sustainable use of biodiversity. The philosophical point of departure in TRIPs is the fundamental belief in the need for adequate (strong) private property rights within the framework of a market economy. Typically it is the developed countries that are better placed to carry out R&D leading to innovation in need of IP protection and thus enjoying the benefits of IPRs.

The Biodiversity Convention sets out from a different starting-point. Although recognizing the potential influence of IPRs on the implementation of the Convention such rights, they must not run counter to its objectives.[131]

There is no direct relation between IPRs and conservation of biodiversity, nevertheless, IPRs form part of the economic and social context in which conservation takes place. Intellectual property rights are relevant for the crafting of ABS arrangements relating to equity. They can enhance or hinder the equitable economic benefit sharing to the custodians of biodiversity arising from the conservation and sustainable use of biological resources.

A relevant question to be asked is to what extent they facilitate access to and transfer of environmentally-sound technology. Another general issue is the much-debated question of whether life forms should be patentable to the extent of falling under the CBD requirement to regulate processes and activities harmful to biological diversity.[132]

The relationship between TRIPs Article 27.3(b), CBD and TK has also been explored within the WTO. Discussions on the relationship have been taking place in the TRIPs Council since 1999.

Article 27.3(b) allows exclusions from patentability but does not provide for any clear definitions of the key terms (see above). Some countries have requested that the TRIPs Council should closer examine and clarify those terms in order to make the scope of the exclusion possibility more clear. It has not been a suggestion free of opposition.

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[130] Tarasofsky, R, *The Relationship Between the TRIPs Agreement and the Convention on Biological Diversity: Towards a Pragmatic Approach*, RECIEL, 1997, Vol. 6, Iss. 2, p. 148.

[131] Article 16 (5) CBD.

[132] Tarasofsky, 1997, p. 149.

As the current IPR system stems from the continuing process to encourage trade and technological development, it has gradually expanded, recognizing new rights and new patentable subject-matters. Now it is the legitimacy of the whole system that is in dispute while questions on compulsory disclosure of origin still remain controversial.[133] There have been a number of submissions to the TRIPs Council where mainly four different views can be delineated:

- there is no conflict between the Agreements and governments can implement the two in a mutually supportive way through national measures;
- there is no conflict between the Agreements and while governments can implement the two in a mutually supportive way through national measures, further study is required to determine whether any international action in relation to the patent system is called for;
- there is no inherent conflict between the two Agreements but there is a case for international action in relation to the patent system in order to ensure or enhance, in their implementation, the mutual supportiveness of both Agreements. There are differences of view on the exact nature of the international action needed, including on whether or not an amendment is needed to the TRIPS Agreement, to promote the objectives of the CBD;
- there is inherent conflict between the two instruments, and the TRIPS Agreement needs to be amended to remove such conflict.[134]

4.4.1 Developed v. developing states

Despite the fact that it is often held that indigenous groups wish to keep their TK outside the conventional patent system on the grounds that a system based on time-limited individual exclusive rights is inherently incompatible with the nature of TK, many developing countries are expressing a different view in the discussions of the TRIPs Council. Developing countries maintain that the issue of misappropriation of biological resources and associated TK together with ABS must be recognized within the current IPR system in the form of disclosure requirements in patent applications. As mentioned above, clearer definitions of key terms such as microbiological processes, to give a more precise scope of TRIPs Article 27.3 (b) has been requested by several developing countries

The EC does not find the TRIPs Council to be an appropriate forum but would rather refer the issue of closer definition of key terms to WIPO, which has the competence to deal with complex technicalities such as this one. furthermore, the EC argues that closer definitions of the terms would limit the flexibility that the member states now enjoy.[135] An amendment to

[133] Communication from Peru, IP/C/W/441/Rev.1, 19 May 2005, p.2.
[134] Note by the Secretariat, IP/C/W/368/Rev.1, 8 February 2006, p. 4.
[135] Communication from the EC, IP/C/W/383, 17 October 2002, p. 6.

Article 27.3 (b) would, to use a metaphor, open up a can of worms and could lead to demands for broader protection of biotechnological inventions. Therefore, the EC is of the opinion that the current balance struck is apt and should not be amended. In the WTO Communication from the EC it is also reminded that IPRs for biotech inventions are key factors for the domestic development of skills in that sector.[136]
Developed countries, the USA and Japan in particular has fiercely opposed adding disclosure of origin as a compulsory requirement for patent applications, stating that the matter is better pursued through the work in WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). Switzerland has acknowledged that such issues should be addressed under the patent system and has proposed an amendment to the WIPO Patent Cooperation Treaty (PCT) where, in appropriate cases, disclosure of origin of the genetic material would be a voluntary requirement.[137] The EC on the other hand has approved of the idea of a system to keep track of all patent applications concerning genetic resources but has clarified that the legal consequences for non-respect of disclosure of origin should lie outside the scope of patent law.[138]

The United States has consistently held the opinion that patent law is not designed to regulate general misconduct or misappropriation of biogenetic resources, but that the establishment of searchable organized databases, the disclosure of information material to patentability and the post-grant opposition and possible re-examination procedure, directly achieves this goal.[139] The US regards new patent disclosure requirements within the TRIPs as an inappropriate solution,[140] and recalls that the CBD contains no obligation or mentioning of patent disclosure requirement.[141] The US states that such a requirement would only provide a useless "hint", with little or no effect of protecting the intellectual contribution in question.[142] Instead, a contract-based system is proposed as it is seen as the best way to maintain control of the biological resource and its associated TK. Contracts could contain regular reporting requirements, choice of law clauses and provisions on PIC and source of origin for patent applications.[143]

4.4.2 Digital libraries as protection for TK

When discussing traditional knowledge it is useful to work around three operational objectives. These are: to *preserve* TK; to *protect* TK; and to *promote* TK. These objectives are interlinked and need to be considered together. If one only looked at an issue from one perspective it can be

[136] Communication from the EC, IP/C/W/383, 17 October 2002, p, 7.
[137] IP/C/W/400; reiterated in IP/C/W/423.
[138] See EC Communication from 17 October 2002, IP/C/W/383.
[139] Communication of the United States, IP/C/W/469, 13 March 2006, p. 2.
[140] Ibid, p. 3.
[141] Communication of the United States, IP/C/W/449, 10 June 2005, p. 2.
[142] IP/C/W/469, 13 March 2006, e.g. pp. 6 and 7.
[143] IP/C/W/469, 13 March 2006, para. 36 and IP/C/W/434,26 November, 2004, para. 20.

counterproductive from another. An example is TK documentation, which often is put forward as a mean for Patent Offices around the world to establish prior art, can also facilitate unauthorized commercialization if not the objective of protection also is considered.[144]
Another issue is the deeply personal character of TK. It cannot be separated from the communities and their customs. TK is a living body of knowledge that really only can be preserved and protected if the communities' economic and cultural integrity is protected. TK stored in a database does not provide information to the full extent, as would a traditional holder of TK.[145] As an integral part of the life of the community it is linked to questions such as territorial rights, rights over and to resources and human rights.

The establishing of TK Digital Libraries constitutes a defensive cause of action for protecting TK. Defensive tactics is mainly to prevent the misappropriation or misuse of TK, i.e. the granting of "bad patents", patents based on TK to unauthorized third parties.

Further defensive action is to make the Digital Libraries available to patent examiners across the world and, perhaps most important, the legal requirement to disclose the source of origin of the biological resource and the related TK. However, none of the developed countries, the US, EU and Japan incorporate any conditions for disclosure for granting patents.

4.5 Non-legislative documents

Several guidelines have been adopted through various collaborations. These are normally voluntary and serve to provide a framework for 'best practice' and to ensure good faith between parties in bioprospecting activities. Three different examples are presented below.

4.5.1 The FAO International Code of Conduct

The FAO[146] International Code of Conduct for Plant Germplasm Collecting and Transfer was adopted as early as 1993. The 1990s was furthermore the time when the "biopiracy" debate intensified. It should be seen as a balancing act and a promoter of rational collection and sustainable use of genetic resources. The Code aspires to prevent genetic erosion and to protect the interests of both donors and collectors of germplasm. The Code is

[144] Report of the UNCTAD-Commonwealth Secretariat Workshop on Elements of National *Sui Generis* Systems for the Preservation, Protection, and Promotion of Traditional Knowledge, Innovations and Practices and Options for an International Framework Geneva February 4-6 2004, Unedited Version, p. 3.
[145] Supra f.n.145, p. 7.
[146] The Food and Agriculture Organization of the United Nations is one of the largest specialized agencies within the UN system. FAO was founded in 1945 with the mandate to raise levels of nutrition and standards of living, to improve agricultural productivity and to improve the condition of rural populations. There are 183 Member States and one member organization, the EU.

voluntary and primarily directed to governments however; it also provides guidelines for collectors.[147] Chapter IV and V establishes the responsibilities of the collectors (bioprospectors), sponsors, curators and users. The responsibilities entail, *inter alia*, to upon arrival in the host country acquaint themselves with relevant research results[148], respect local customs and demonstrate a sense of gratitude towards local communities, especially if TK is being used on the characteristics and value of the resource[149], and to inform the host country on impending threats to plant population.[150]

Sponsors should make sure that the Code is observed and curators should as far as possible respond to enquiries from local communities and the host-country. They should also upon request supply samples of the germplasm.[151]

4.5.2 MOSAICC

The Micro-Organisms Sustainable Use and Access Regulation, International Code of Conduct, was adopted in 2000. MOSAICC is the result of a consensus obtained between a balanced group of representatives from North and South, including representatives from the public (government, culture collections, academics, NGOs) and the private sector (pharmaceutical, chemical and food industry).[152] It is a voluntary document, aimed at assisting microbiologists who want to access biological material and countries who wish to establish mechanisms for PIC and to monitor transfer of material through *material transfer agreements* (MTAs).

PIC is narrowly and literally interpreted as the prior informed consent of the country (or designated national competent authority) providing the biological resource. It refers to Article 15 of the CBD which confirms countries sovereign rights to their biological resources (see above). MOSAICC recommends that permission should be obtained from the landowner where necessary; it does however not refer to TK or PIC from indigenous/local communities. It is for national legislation to create mechanisms for PIC other than the narrow CBD concept.

The Code of Conduct nevertheless recommends that indigenous communities are included as partners to an agreement in so far as the community is the owner/usufructuary of the area where the biological resource is collected; is well represented by an officially recognized representative and; willing to preserve and maintain knowledge, innovations and practices relevant for the conservation and sustainable use of the resource.[153]

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[147] International Code Of Conduct For Plant Germplasm Collecting And Transfer, FAO Conference, 27th session, November 1993, Preamble and Articles 3.1 and 3.3.
[148] Ibid, Article 9.1.
[149] Ibid, Article 10.1.
[150] Ibid, Article 11.1 (e).
[151] Ibid, Articles 12.1 and 13.2.
[152] MOSAICC, p. 4, footnote 2.
[153] MOSAICC, Section I.6, p. 14.

MTAs are defined as a generic term which can cover everything from very short documents such as shipment documents, delivery notice, invoices containing standard requirements or more detailed contracts including *mutually agreed terms*. The Code of Conduct sets minimum requirements for a document to be defined as a MTA. These are:

- *information about the in-situ origin;*
- *information about provider and recipient;*
- *mutually agreed terms for the access to and the transfer of microbial genetic resources (MGRs), the access to and the transfer of technology, the fair and equitable sharing of the benefits as well as for technical and scientific cooperation.*

The main advantage of the MOSAICC is the MTA checklist. This is to be used when a more custom made contract is needed and provides guidelines for any negotiations. It divides the possible use of biological material into three different categories where the MTA content consequently will differ. The checklist is:

• ***Basic*** *terms*

- Description of MGRs (country of origin, place and date of isolation, strain reference number, identification data, name of the individual that has isolated the strain from *in situ* conditions or, if individual's name is not available, the name of the institution (legal entity) that employed the individual at the time of the isolation of the strain);
- *Bona fide* and sustainable use, following the CBD-principles;
- Clause governing the payment of the costs of handling;
- Type of transfer: transfer where distribution to 3rd parties is **either** excluded **or** possible (The choice between these two options is subordinate to the kind of recipients.).
- Information about provider and recipient: names, addresses.

• ***Use-specific*** *terms*

Category 1: Use for test, reference, bioassay, control and training purposes. No commercial use. No IPRs on MGRs, derived technology and information. The recipient has to follow the protocols of standard test and reference procedures.
Category 2: Use for research purposes. No commercial use. No IPRs on MGRs, derived technology and information.
Category 3: Commercial use. Need for more precise MTA provisions on IPRs, information feedback, patent application and benefit-sharing (see additional terms).

• *Accompanying terms*

Mention of the country of origin, reference to the original PIC; previous MTA-terms if any.

• *Additional terms*

- IPR related to MGRs and derived technology,
- Terms on training, technical and scientific co-operation, access to and transfer of technology, exchange of information and publication policy. Terms providing possibilities for capacity building in, among others, taxonomy and general microbiology for the provider of

microbial genetic resources should be emphasised and prioritised to compensations such as financial arrangements.
- Conservation of MGRs.
- Partnerships involving other stakeholders than provider and recipient of MGRs, including indigenous and local communities
- Monetary terms: Initial, up-front payment; milestones payment and royalties payment.

The Code of Conduct stresses the importance of non-ambiguous definitions and clear descriptions of use, as the term commercial use necessitates a more precise agreement beforehand.

Section I.6 deals with ABS, technology transfer and joint research. It reads that terms with regards to benefit sharing can be chosen to be negotiated on at the time of any commercial utilization of the biological material, but that preliminary benefit-sharing terms can be included when concluding the MTA. This is also the recommended cause of action. Likewise, it is recommended that the issue on IPRs to the MGR or associated technology is agreed upon *before* investments are made into research and development that could result in commercial use of the MGR or related technology.[154]

4.5.3 The ISE Code of Ethics

The International Society of Ethnobiology's Code of Ethics has its origins in the Declaration of Belém (Brazil) agreed upon in 1988 at the Founding of the International Society of Ethnobiology. At the First International Congress of Ethnobiology, indigenous peoples from various parts of the world met with scientists and environmentalists to discuss a common strategy to stop the rapid decrease in the planet's biological and cultural diversity. The result was the Declaration of Belém, explicitly outlining the responsibilities of scientists and environmentalists in addressing the needs of local communities and acknowledging the central role of indigenous peoples in all aspects of utilization of biological resources. In 1998 the Code of Ethics was adopted. The ISE wishes to work in a genuine partnership and collaboration with indigenous/local communities in order to avoid past injustices. The objective is to build towards developing positive, mutually beneficial, and harmonious relationships in the field of ethnobiology.[155]

The ISE recognizes the fundamental need for collaboration in order to optimize the outcome and to reduce adverse effects of R&D. It also acknowledges and supports the rights of indigenous peoples to the preservation, control and continued development of their heritage knowledge. For this purpose the Code consists of a set of principles, including the recognizing of indigenous peoples' rights to self-determination, to confidentiality, to give or veto PIC and to equitable compensation and sharing.[156]

[154] MOSAICC, section I.6, p. 12.
[155] See http://ise.arts.ubc.ca/ethics.html, 05/04/06.
[156] See http://ise.arts.ubc.ca/ethics.html, 05/04/06.

The Code of Ethics is further elaborated on in the complementing ISE Guidelines for Research, Collection, Databases and Publications.[157] They define the concept of full disclosure and emphasizes that PIC and agreements for ABS are to be granted *before* undertaking any research, collection or publication. All activities are to be carried out with respect, understanding and good faith. Noteworthy is the commitment *not* to undertake any research, collection et cetera deriving or obtained from information/biological resources from any community that has requested a moratorium on research, collection or publication. This means that the information/biological resource accessed continues to be in the sphere of control of the communities, even after such information has left their *de facto* control.

[157] See http://ise.arts.ubc.ca/research.html, 06/04/06.

5 National and Regional ABS legislation

There are a number of countries that have adopted ABS rules concerning access to biological material. They are still on different stages of implementation. For example, the Philippines and India have implemented national legislation while a number of South American countries (the Andean Community) and African countries have adopted model legislation that have yet to be implemented on a national level.

The approach towards issues such as access to biological material, PIC, technology transfer, IPR in general and TK in particular, varies somewhat. However, where legislation has been implemented nationally, the practical examples seem to be scarce. This could be due to an extensively bureaucratic procedure.

5.1 Philippines Executive Order 247 and its Implementing Rules and Regulations

The Philippines pioneered the enactment of legislation in order to incorporate the objectives of the CBD into national legislation. Any reference to intellectual property was consciously avoided.[158]

The Executive Order No. 247 entered into force in 1995 and was the result of a consultative process involving a wide range of different stakeholders.[159] The initiative and the first draft came from a network of natural product chemists. [160]Consultations were subsequently held with academics and university scientists, government officials and at a later stage, with different government departments, NGOs, organizations representing indigenous communities and the (mainly Philippine) private sector.[161]

After the Executive Order was signed by President Ramos in May 1995, work began on the Implementing Rules and Regulations. This was a process where drafts were circulated for comments to the different participants mentioned above. The final version was signed in June 1995.[162]

Although the legislation has been in force roughly for a decade, only two research permits have been issued, which could indicate that the procedure has taken a form too complex.[163]

[158] Dutfield, 2004, p. 138.
[159] Ibid.
[160] Medaglia, supra f.n. 31, p. 186.
[161] Dutfield, 2004, pp. 138-139.
[162] Ibid.
[163] Ibid, p. 142.

5.1.1 Mutually agreed terms

All bioprospecting depend on permission in the form of a research agreement between the bioprospector and the government. A research proposal must first be submitted to the government and a copy to any community affected. The EO distinguishes between an Academic Research Agreement (ARA) and a Commercial Research Agreement (CRA). There are minimum terms that apply to all agreements and a number that apply specifically to each agreement.
The terms include, for the interest of this thesis;

- *Periodic reports on the collections made;*
- *Availability of commercial products derived from Philippine resources to the national government and local communities concerned;*
- *Equitable sharing of immediate, medium- and long-term benefits resulting from the bioprospecting among the stakeholders concerned;*
- *The requirement that all the bioprospecting research, including subsequent technological development of a product be conducted in cooperation or collaboration with Philippine scientists from domestic institutions;*
- *That any technologies developed be made available royalty-free for commercial and local use to the national government;*
- *In case of a commercial product or technology is developed, an equity or remittance, the amount to be mutually agreed upon, shall be equitably shared between the Philippine government, protected areas fund (if the material or resources came from such an area) or the concerned indigenous/local community who gave the PIC, and with the individual who modified such material or resource that came from private property.*
- *The requirement that a separate agreement be made for the transfer of royalties, benefits and technologies.* [164]

5.1.2 Prior informed consent

Under the Philippine legislation, prior informed consent must be obtained by the applicant from the concerned: local community; indigenous people; protected area management board or the private land owner. PIC presupposes full disclosure of the intent and the scope of the bioprospecting activity in a language and process understandable to the community. This must take place before any bioprospecting activity is undertaken.[165] There is also a mandatory public notification requirement[166] and followed by a two-week waiting period, a detailed description of the activities proposed is to be presented by a legitimately convened assembly of the local communities

[164] Columbia University, 1999, supra f.n. 84.
[165] Section 2 of the Implementing Rules and Regulations.
[166] Section 7.1.1, Implementing Rules and Regulations.

involved.[167] Further a "categorical statement" that "such activity to be conducted will not in any way affect their traditional use of their resources is stipulated in Section 7.1.2.

PIC is not formally required from the state itself; rather a PIC certificate issued by the different stakeholders mentioned above must follow any application. However, considering the detailed terms necessary for any research agreements to be granted a *de facto* PIC requirement can be said to exist.[168]

5.1.3 Benefit sharing, technology transfer, joint R&D

The Implementing Rules and Regulations refer to benefit sharing as the sharing of the results of bioprospecting activity and the benefits arising from the commercialization and/or use of the biological/genetic resources, fairly and equitably with the stakeholders concerned (e.g. indigenous community or private land owner) by the Principal or Collector. Result and Benefits can be e.g. royalties, technology, training and joint research or capacity building.[169]

5.1.4 Protection of TK

The legislation refers to the CBD which recognizes the close relationship between indigenous communities' lifestyles and TK and the conservation of biological diversity. This ties the interests of the indigenous and local communities in the existing resources in their domain, to benefit sharing and the PIC procedure. Explicit rules however, only stipulate that ownership to resources accessed remains with the Republic of Philippines. Another stipulation can be found in ARAs where IP rights cannot be sought without prior consultation with the designated national agency.[170] It does not, strengthen indigenous rights over their TK or solve the question on how to handle the transfer of TK to bioprospectors (other than through the PIC procedure) and the issues of intellectual property rights of commercial products deriving from TK.

[167] Section 7.1.2, Implementing Rules and Regulations.
[168] Ibid.
[169] Ibid, p. 141.
[170] Medaglia, supra f.n. 31.

5.2 The Andean Community Decision 391

The Decision 391, establishing a common system on access to genetic resources, was adopted by the Andean Community[171] member states in 1996. It was the result of a two-year process where the participation of indigenous communities and NGOs was intended to be a vital part through workshops and comments. Unfortunately in 1994 at a workshop, attended by NGOs and a large number of indigenous peoples' organizations, the second draft report was misinterpreted by some groups as being draft law and they sought to have it rescinded. The result of the misunderstanding was that civil society involvement in the process became more limited.[172]

The scope of the decision is set out in Article 3. It applies to:

- *Genetic resources for which the member countries are countries of origin;*
- *Their derivatives and intangible components; and*
- *The genetic resources of migratory species found for natural reasons in the territory of the member countries.*

Article 2 establishes the objectives of the Decision which generally are to regulate access to genetic resources and their derivatives in order to:

- *Establish the conditions for fair and equitable sharing of the benefits arising from such access;*
- *Establish a basis for the recognition and appreciation of genetic resources, their derivatives and related intangible components, especially when involving indigenous, Afro-American and local communities;*
- *Encourage the conservation of biodiversity and sustainable use of biological resources containing genetic resources;*
- *Promote the consolidation and development of scientific, technological and technical capacities at local, national and subregional level; and*
- *Strengthen the negotiating capacity of the member countries.*

The Decision echoes the CBD in affirming the countries' sovereign rights over their biological resources; however, it has by establishing rights over the *derivatives* of such resources, gone further than the CBD.

Derivatives should be differentiated from a synthesized product which is a product obtained through an artificial process, using genetic information. An example of a derivative would be an herbal formulation while a synthesized product would be a pharmaceutical compound *modelled* on a natural compound.[173]

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[171] Formally known as the Cartagena Accord and also previously commonly referred to as the Andean Pact. The Andean Community countries are: Bolivia, Colombia, Ecuador, Peru and Venezuela.
[172] Dutfield, 2004, p. 143.
[173] Ibid, p. 144.

Intangible component refers to any knowledge, innovation or practice of actual or potential value associated with the genetic resource or its derivative. It does not have to be protected by intellectual property systems.[174]

The Andean Pact has been criticized for assigning tenure of biological resources to communities but reserving exclusive property rights for the state, thus limiting the distribution of benefits through a state-owned property regime while obligating communities to preserve the resources.[175]

5.2.1 Mutually agreed terms

Access is conditioned by an application (including a project proposal) and a contract. The party other than the applicant is the State concerned, represented by the competent national authority. The contract will stipulate a variety of conditions including;

- *Strengthening of mechanisms for technology and knowledge transfer (including biotechnologies), which are culturally, socially and environmentally safe and healthy;*
- *Development and strengthening of the capacities of indigenous, Afro-American and local communities relating to the intangible components associated with genetic resources and their derivatives;*
- *An obligation to inform the competent national authority of the results of the research carried out.*
- *Terms of transfer of accessed materials to any third party.*[176]

If access is sought to a genetic resource with an intangible component, an annex must be included in the contract with a scheme on fair and equitable sharing of any possible benefits arising from that component. The annex must be signed by the supplier of the intangible component however, there is no clear stipulation that the signer has to be a representative of the indigenous, Afro-American or local community.[177]

5.2.2 Prior informed consent

There is no explicit reference to PIC in the decision although applicants are required to provide all available information of the genetic resource including the actual and potential use of the resource, its derivatives and associated intangible components. It is not necessary to provide this information to any other stakeholder group.[178]

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[174] Dutfield, 2004, p. 144.
[175] Environmental Policy Studies Workshop, School of International and Public Affairs, Columbia University, 1999, *Access to Genetic Resources: An Evaluation of the Development and Implementation of Recent Regulation and Access Agreements*, p. 11.
[176] Decision 391, Title V, Chapter I, Article 17.
[177] Columbia University, 1999, supra f.n. 176, 11.
[178] Decision 391, Title V, Chapter I, Article 22.

5.2.3 Benefit sharing, technology transfer, joint R&D

The Decision incorporates technology transfer into the access contracts. Joint research is referred to in Article 10 but only in the context of subregional cooperation and is not specifically a requirement linked to access procedure.

5.2.4 Protection of TK

Traditional communities are not directly referred to as potential parties to ABS contracts. They are recognized only as suppliers of TK, or as potential landowners. Thus they become dependent on prior recognition of their land rights or intellectual right to their TK, something which is not necessarily always the case.

Another issue is the Decision affirmation of sovereign rights over derivatives of genetic resources and the potential conflict with Article 8 (j) CBD. This could include plant extracts which traditional remedies often consist of. The Decision further excludes from its jurisdiction the exchange of genetic resources, and its derivatives and related intangible components among traditional communities for their own use, thereby complicating the issue.[179]

IPRs obtained from genetic resources, derivatives, synthesized products or intangible components through violating the terms of access will not be recognized in any of the Andean Community member states. If national IPR offices encounter an application for protection of a product or technology where there is evidence that the genetic resource[180] originates from a member state, they must require the applicant to submit a copy of their access contract as a precondition of the concession of any IPR.[181]

5.3 The Costa Rica Biodiversity law

In April 1998 the *Ley de Biodiversidad* was passed. Although Costa Rica is a small country it is estimated to hold nearly 4 percent of the world's biodiversity.[182] At that time six individual contracts with transnational companies had been signed.[183]

The Costa Rica Biodiversity Law was as well created through an extensive consultation process involving indigenous people, small farmer groups,

[179] Dutfield, 2004, pp. 146-147.
[180] and/or its derivatives and intangible components.
[181] Decision 391, Complementary Provisions, Second and Third.
[182] http://www.inbio.ac.cr/en/biod/bio_biodiver.htm, 14/03/2006.
[183] One of these is the now famous contract between INBio and Merck, a pharmaceutical company.

legal experts, scientists, civil servants and representatives of the private sector. The first draft was published in 1996 and became the subject of a wide and conflicting range of views which delayed the process.[184]

Coming into force as Law No. 7788 in May 1998 it is an elaborate national law implementing the CBD and it covers all issues contained in the CBD, including, for the interest of this thesis, PIC, scientific and traditional biodiversity-related knowledge protected through IPRs and/or *sui generis* systems, and technology transfer. The Biodiversity Law has 10 chapters where two deal with ABS. Chapter V deals with access to genetic components, biochemicals and protection of associated knowledge. The chapter includes section III which contains protection of intellectual and industrial property rights. Article 83-85 set out a framework for developing a *sui generis* system for intellectual community rights which are recognized in the law. Chapter VI deals with education and public awareness, research and technology transfer, where Article 88 specifically deals with research and technology transfer (including biotechnology) related to biodiversity.

5.3.1 Mutually agreed terms

The definition of PIC states that it is the

> *"Procedure through which the State, private owners or the local or indigenous communities, as the case may be, properly supplied with all the required information, allow access to their biological resources or to intangible components associated to them, under mutually agreed conditions."*[185]

Article 63 links mutually agreed terms to terms of benefit sharing such as technology transfer and the equitable sharing of any potential benefit stemming from the resource. Additionally, it preconditions that the type of protection demanded from suppliers of TK is identified and complied with. Another condition is domestic legal representation for natural or legal persons not residing in Costa Rica.

5.3.2 Prior informed consent

The procedure to obtain PIC is not elaborated upon in the Biodiversity Law. However, the application for access to biogenetic resources is preconditioned by an attached PIC from the appropriate stakeholder group.[186]

[184] Dutfield, 2004, pp. 148-149.
[185] Article 7.9.
[186] Article 63.1.

5.3.3 Benefit sharing, technology transfer, joint R&D

An immediate remuneration is required in Article 76, which states that 10 % of the research budget is to be deposited in favour of the party that provides access to the resource. The party could be e.g. an indigenous community providing TK or access to their land, or a private land owner. Other forms of technology transfer can also form part of the access procedure but they are not explicitly mentioned in the Biodiversity Law. Long-term benefit sharing such as payment or potential IPRs obtained from the commercialization of a product or technology, stemming from accessed resources is further not mentioned in the Biodiversity Law.

5.3.4 Protection of TK

Article 77 of the Law acknowledges the need for protection of innovation and knowledge through intellectual property rights. The State goes on to specify what kind of protection it offers, such as patents, copyrights, farmers' rights, trade secrets etc. Further, the *sui generis* right of community intellectual rights is recognized. Article 82 states:

The State expressly recognises and protects, under the common denomination of sui generis community intellectual rights, the knowledge, practices and innovations of indigenous peoples and local communities related to the use of components of biodiversity and associated knowledge. This right exists and is legally recognised by the mere existence of the cultural practice or knowledge related to genetic resources and biochemicals; it does not require prior declaration, explicit recognition nor official registration; therefore it can include practices which in the future acquire such status.
This recognition implies that no form of intellectual or industrial property rights protection regulated in this chapter, in special laws and in international law shall affect such historic practices.

The community intellectual right is somewhat similar to copyrights in the sense that it does not require any formal registration in order to be recognized. Perhaps one could also compare it further to the length of the copyright, life of the creator plus seventy years.[187] As the community right is not held by an individual or group of individuals as such but to a community whose lifespan is longer than any of the individuals forming that community, the intellectual property right is protected for as long as the community exists. However, copyright protection is not available as it is as part of the intellectual property system an individual right by nature.

[187] According to the Berne Convention for the Protection of Literary and Artistic Works, of September 9, 1886.

5.4 The African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources

The African Model Legislation seeks to cover both ABS issues and provide an IPR instrument adjusted to the African continent context. It was adopted in 2000 and is, as the title suggests, model legislation, not intended for immediate national implementation. Instead it provides a framework, in compliance with both the CBD and TRIPs for the member states of the OAU[188] to craft specific national legislation adjusted to their own needs.[189] There are several underlying core elements of the Model Law all reflecting the particular African context, such as food sovereignty and security, community rights and responsibilities, and fair and equitable benefit sharing. The position of the OAU member states in negotiating in the WTO and with the industrialized world is also a matter of focus.[190] The need for capacity building in the form of participation in research and development rather than financial benefits is emphasized as well as the current trend towards Africa's biological resources becoming another trade commodity between North and South.[191]

5.4.1 Mutually agreed terms

Biological resources can be accessed under varying contracts. The access permits can be academic research permits, commercial research permits and commercial exploitation permits.[192] Different permits may not be used at the same time on the same resource unless granted so in written form.[193] The material accessed cannot be transferred from the country in question without a Material Transfer Agreement. Regular status reports must be submitted to the National Competent Authority on the progress of the research and development on the resource and if large quantities are collected, on the ecological state of the area.

[188] The Organization for African Unity, now the AU, African Union with 53 member states.
[189] Ekpere, J. A, 2000, *The OAU's Model Law, The Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources, An Explanatory Booklet*, p. 3.
[190] Ibid, pp. 10-15.
[191] Ibid, p. 28.
[192] OAU Model Law, Article 13.
[193] Article 13 (2).

5.4.2 Prior informed consent

To obtain an access permit it is necessary to first get PIC from both the State and the local/indigenous community concerned. The PIC must be enlightened, meaning that the information provided by the applicant must be fully understandable to the ones giving the PIC.[194] It must be ensured that women also are involved in the decision making.[195] PIC is a precondition for the granting of any access and if the requirement is not met the permit can be unilaterally withdrawn by the National Competent Authority. The Model Law further recognizes the Community Intellectual Rights and other Community Rights and provides the right to refuse consent and access.[196]

5.4.3 Benefit sharing, technology transfer, joint R&D

The definition of benefit sharing in the OAU Model Law is:

> "*The sharing of whatever accrues from the utilization of biological resources, community knowledge, technologies, innovation and practices."*[197]

The practical mechanisms are however not further elaborated on. The possible forms of benefit sharing are not very detailed; Article 12 speaks of the monetary share of the earnings arising from the biological resource and/or TK. The earnings can be directly or indirectly stemming from the access. At least fifty per cent of those benefits are to be channelled back to the concerned community. The explanatory booklet to the Model Law emphasizes the need for non-financial benefit sharing in terms of enabling the development of the OAU countries.

5.4.4 Protection of TK

The OAU provides an ambitious framework for protecting TK. Two terms are adopted, community rights (including community intellectual rights) and farmers' rights. The rights are recognized by the State as enshrined under the norms, practices and customary law of the concerned local/indigenous community.[198]

Patent protection for life-forms and biological processes are banned in Article 9 and consequently a collector cannot apply for such a patent in connection with accessed biological resources. IPR protection on product or

[194] Ekpere, The OAU's Model Law, p 27.
[195] OAU Model Law, Article 5 (1)(ii).
[196] Articles 16, 19 and 23.
[197] OAU Model Law Article 1.
[198] Part IV and V of the Model Law, Articles 16-27.

technology associated with the biological resource will not be granted without the PIC of the original providers.[199]

5.5 Comparing the different ABS legislations

A relevant question is whether it is suitable to combine IPR rules with ABS legislation. There is no doubt that the issues are closely related, however, to introduce provisions such as the ban on the patenting on life-forms as in the OAU Model Legislation into ABS legal instruments can give the appearance that the problem with IPR protection of rights that do not fall under the conventional IPR system is solved.

With the exception of the Philippine and the Costa Rican law the rest have yet to be implemented. This presents a problem in that it is difficult to evaluate the advantages and disadvantages of the different solutions. The Philippine law does not mention IPRs while the Andean Community and the OAU have created *sui generis* terms for TK. The Costa Rican Biodiversity Law expressly recognizes in Article 82 what is called the *sui generis* community intellectual rights. However, although the existence and the obligation to protect such rights are acknowledged, the nature and scope of the rights remain to be identified.

Mutually agreed terms:
All national ABS regimes are more or less implementing the CBD convention which created the states' sovereign rights to their resources.[200] Access must thus be granted by the state through the designated National Competent Authority. This takes place through a contract which character varies depending on whether it is a research or commercial contract, provided for in the Philippine EO and OAU Model Law. It seems reasonable to be less demanding of academic research than of commercial research but, as Dutfield points out; it can be difficult to distinguish between such researches.[201] However, as not all of the legislations are constructed as the Costa Rican Law which applies different fees for domestic and foreign applicants, too onerous terms can be detrimental to the national interest.[202]

The terms includes terms of benefit sharing, obligation to inform of research results and, in the case of the Philippine legislation, obligation to include Philippine scientists from domestic institutions in the bioprospecting research or development of the biological resource.

Prior informed consent:
As to who is to give PIC different options have been chosen. The Philippine and Costa Rican laws require PIC to be obtained from the concerned local/indigenous community, protected area management or the private land

[199] Dutfield, 2004, p. 159.
[200] Article 3, CBD.
[201] Dutfield, 2004, p. 160.
[202] Ibid.

owner, not from the State itself. The Andean Community Decision 391 only requires PIC from the State. The OAU Model Law has opted to require PIC from both the indigenous/local community concerned and from the State.

The definition of what is required for a PIC to be properly informed is most elaborated upon in the African Model Law Article 4 (1). The Costa Rican legislation mentions PIC as the approval after being properly supplied with information and the Philippine EO states that the consent is to be obtained in accordance with the customary law of the concerned community.[203] The implementing Rules and Regulations of the EO 247 require the full disclosure of the intent and scope of the bioprospecting activity in a language and process comprehensible to the community before any bioprospecting activity is initiated.[204]

Equally important as the requirement to obtain PIC is the right for indigenous/local communities to *refuse* or to *withdraw* PIC. The Philippine EO only provides for the rescission of an agreement in cases where the PIC has been obtained through fraud, stealth, false promises and/or intimidation.[205] The Costa Rican Law 7788 on the other hand recognizes the right to "cultural objection", be it for cultural, spiritual, social, economic or other motives.[206] The African Model Law provides for the withdrawal or restriction of PIC when the access activities are likely to be detrimental to the concerned community's socio-economic life, or its natural or cultural heritage.[207] However, the Model Law accepts those grounds of objection regardless of whether they are prior to or after the access has been granted.

Regarding the PIC's status in applications for IP protection again, different solutions are devised. The Costa Rican Biodiversity law preconditions the granting of IP protection to consultations between the Patent Office and the Technical Office for the confirmation that the applicant obtained PIC. Justified opposition from the Technical Office will result in the refusal of the IP application.[208] The Decision 391 also provides a copy of the access contract, when there is certainty or reasonable indication that the product or process emanates from biological resources originating from any of the member states. If the product/process has been obtained through non-compliance with the decision, protection shall be refused.[209] The OAU Model Law prohibits in Article 8 (v) the collector to apply for IP protection but it does not provide for a procedure in case of such an application. The Philippine legislation has, as mentioned above, not provided for any IPR rules.

Benefit sharing, technology transfer, joint R&D:

The different ABS legal instruments are strategically important for the countries capacity building. One example is India which has built a

[203] Executive Order 247, section 2.
[204] DENR, Administrative Order, No 96-20, June 21 1996, Implementing Rules and Regulations on the Prospecting of Biological and Genetic Resources, section 2. Available at: http://www.psdn.org.ph/chmbio/dao20-96.html, 15/03/06.
[205] Section 9, Article 9.1.
[206] Costa Rica Biodiversity Law, Article 66.
[207] OAU Model Law, Article 20.
[208] Costa Rica Biodiversity Law, Article 80.
[209] Andean Community Decision 391, Complementary Provisions, second and third.

biotechnology industry which is competitive on the international arena.[210] The long-term benefits should not only be directed towards technologies appropriate for conservation purposes but also contribute to the advancement of the country as such, to increase wealth, education and to improve the health of the population.

Decision 391 is quite detailed in this respect. Article 35 states that an annex stipulating fair and equitable distribution of the profits arising from the access to genetic resources with associated "intangible components", and the use thereof. Other typical access conditions are the participation of regional nationals in the research (also stipulated in the EO 247), strengthening of the transfer of technology (including biotechnology) and know-how, supply of information regarding science related to the genetic resource, all with the explicit aim to promote the consolidation and development of scientific and technological capacities at local, national and regional level.[211] The African Model Legislation only briefly mentions monetary remuneration.[212] The Costa Rican Law stipulates both a deposit of up to 10 percent of the research budget and the transfer of technologies relevant for the sustainable maintenance of biodiversity.[213] The Implementing Rules and Regulations of the EO stipulate as a minimum term for access to be granted that all discoveries of commercial products should be made available both to the State and the concerned local community, that all bioprospecting research should be made in cooperation/collaboration with Philippine scientists and that if any technology is developed it should be made available to the Philippine government royalty-free.[214] However, the legislation provides for the possibility of negotiating agreements with other terms, if appropriate.

Protection of TK:

Although all of the different legal instruments acknowledge the fundamental importance of preserving and maintaining TK, a developed system for this is lacking. The different legislations require benefits to be shared with the holders of the TK[215] provided. *Sui generis* systems of community intellectual rights are created but not very elaborated on in two of the instruments, the OAU Model Law and the Costa Rican Biodiversity Law. It is however clearly stated in Article 79 of the Costa Rican Biodiversity Law that any decisions made within separate conventional intellectual property system related to biodiversity *must* be in congruence with the Biodiversity Law's objectives, thus putting the objectives of the CBD and its Article 8 (j) first.

The Philippines, the first country to enact ABS legislation has chosen to separate IPR legislation from the rules of access to biological resources. Draft legislation concerning the protection of community intellectual rights protection (CIRPA) has been developed and presented by Philippine Senator

[210] Dutfield, 2004, p. 174 and forward.
[211] Articles 2 (d) and 17.
[212] OAU Model Law, Article 13.
[213] Costa Rican Biodiversity Law, Articles 76 and 88.
[214] DAO Implementing Rules and Regulations, Articles 8.1 (9), 8.1 (12) and (13).
[215] Such as the EO 247.

Flavier in 2001 but has yet to be adopted.[216] However, the draft law establishes community rights ownership through registration, while still being distinct and separate from patent law.[217] In the case of inventions, industrial designs and utility models the register would be managed by the Bureau of Patents, Trademarks and Technology Transfer (BPTTT), thus enabling for easy access when any application is to be appraised.[218] With the registries, the Philippines can award community claims over TK and establish a working *sui generis* system without involving the conventional, cumbersome patent system.[219]

The Andean Community Decision takes on a different approach. State sovereignty is emphasized while indigenous people's right and authority over their TK is recognized and valued.[220] The Decision also stipulates that access contracts shall bear in mind the rights and interests of the suppliers of genetic resources and their by-products with associated intangible components and it goes on to require equitable and fair sharing of the benefits.[221] The Complementary Provisions of the Decision requires national offices of intellectual property to request the serial number of the access contract when there are indications that the genetic resource for which IP protection is sought originates in one of the member states of the Andean Community. A system for exchanging information about access contracts and IP protection awarded is also to be set up.

So how is the TK protected in the Decision? The different ABS instruments have in common that indigenous/local community knowledge enjoys protection; the question is only of what kind. National sovereignty is emphasized over the absolute right of indigenous people to their knowledge, innovations and practices. There seems to be other factors at play.

There is no doubt that the States' need to conform to TRIPs has an impact on the different solutions chosen. It is reflected in the OAU Model Law's ban on patents on life and in the Philippines EO 247 concentration on access and benefit sharing, excluding all IPR. Costa Rica has taken the most pragmatic stand and is in the process of developing sui generic protection for TK in a consultative process, something that undoubtedly take time.

The Andean Community is politically marked by marginalization and oppression of indigenous communities, a legacy of colonialism. Many communities are in active opposition with their States in issues regarding land rights and more generally their position as citizens of their country.

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[216] Community Intellectual Rights Protection Act, 2001, S. No. 101.
[217] Ibid, Section 2 (b).
[218] Ibid, Section 6 (c).
[219] Blanco, J.L.B, 2000, *Harnessing Traditional Knowledge for Development and Trade: the Bicol (Phils.) Experience*, report prepared for UNCTAD Expert Meeting on Systems and National Experiences for Protecting Traditional Knowledge, Innovations and Practices, Geneva 30 Oct–1 Nov 2000.
[220] Andean Community Decision 391, Article 7.
[221] Andean Community Decision 391, articles 34 and 35.

5.6 EC View on TK and Access and Benefit Sharing

Dealing with biogenetic resources and TK does not wholly come under EC competence. EC measures concerning ABS, such as aspects of IPRs, relate to the internal market while other aspects, such as bi/multilateral negotiations, trade, international development co-operation et cetera, lies within the sovereign control of the Member States.[222]

Nevertheless, access and benefit sharing and related questions of TK are a source of discussion within the EC. The European Parliament has, in preparation for the COP meeting in Brazil, March 2006, called for the establishment of a legally binding ABS instrument and for the EC Commission and Member States to ensure that the CBD work programme is implemented with the full participation of indigenous/local communities.[223]

In a Communication from the European Commission to the European Parliament the EC policy is further explored.[224]

Europe is historically an important user of biogenetic resources in both research and product development. Europe is further a provider of such resources home to a rich biodiversity, including the Mediterranean "hotspot" (biodiversity rich areas), as well as harbouring a large number of *ex situ* collections such as botanic gardens and microbial culture collections. Some of these institutions have developed policies to facilitate the access and exchange of material in line with CBD and applicable national laws, on an individual basis and as members of broader networks.[225]

The level of demand for biogenetic resources within the EU and across different industrial sectors is difficult to estimate and shifts with time, e.g. in line with technological innovations. Nevertheless, the EU possesses substantial commercial R&D capacity and European life sciences industry constitutes an important sector of the European economy.

The Commission and the Member States were active participants in the negotiations leading to the adoption of the Bonn Guidelines and it is stated that implementation of the voluntary document is an issue of equity and fairness. It is also seen as an enhancement of the credibility of the EC.[226] The EC has yet to introduce comprehensive legislation governing ABS or to facilitate the protection of TK. Although the recital (55) in the EC Biotechnology Directive[227] contains an obligation for Member States to fully take into account Article 8(j) CBD, and related provisions in the

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[222] Second Report of the European Community to the Convention on Biological Diversity: Thematic Report on Access and Benefit-Sharing, October 2002, p.1.
[223] European Parliament resolution on preparations for the COP-MOP meetings on biological diversity and biosafety in Curitiba, Brazil, 16/03/06, P6_TA(2006)0098.
[224] Communication From The Commission to The European Parliament and The Council, 'The implementation by the EC of the "Bonn Guidelines" on access to genetic resources and benefit-sharing under the Convention on Biological Diversity', COM(2003) 821 final, p. 6.
[225] Supra f.n. 223, p. 4.
[226] Supra f.n. 225, p. 7.
[227] Directive 98/44/EC (6 July 1998) on the legal protection of biotechnological innovations.

adoption of national laws, regulations and administrative provisions, the EC position on, for example, a disclosure of origin requirement in patent law is ambivalent (see above chapter 5.1). The encouragement in recital (27)[228] of the same Directive cannot be said to constitute any pressing legal obligation for the patent applicant. The matter is further complicated by Article 1.2 of the Directive which states:

This Directive shall be without prejudice to the obligations of the Member States pursuant to international agreements, and in particular the TRIPs Agreement and the Convention on Biological Diversity.

This does not mean that there has not been any further activity in this area of law. Various institutions, networks and companies within the EC have been involved in the development of voluntary codes of conduct in order to provide a framework for ABS arrangements. These efforts have been supported by the EC, e.g. the Micro-organisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC) between 1997-1999.[229]

The EC recognizes in the Commission Communication the fact that the intellectual property system "plays a practical role in promoting the sharing of the benefits from access to genetic resources and associated TK".[230] It is argued that requirements that can entail the disclosure of origin of genetic resources and TK already exist under EC law and European intellectual property law. In line with established patent principles, three cases are provided for: the so-called enabling disclosure; the relevant prior art; and the identification of the true inventor(s).

Traditional knowledge, innovations and practices (TK) should be protected, both as an indispensable tool in the conservation and sustainable use of biodiversity, and to ensure the fair and equitable sharing of the benefits arising from the use of such knowledge, with the involvement and approval of its holders. The full involvement of indigenous and local communities in the negotiations of an international regime on ABS is encouraged. The continued cooperation between the CBD and WIPO is desirable.[231]

The EC has actively put forward its opinion on the issue of TK and a proposed disclosure requirement in the TRIPs Council. As mentioned above (chapter 5.1) the EC is positive towards examining ad discussing the

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[228] It states: Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents…

[229] Second report of European Community to the Conference of the Parties of the Convention on Biological Diversity, General Overview, p.10.

[230] WIPO Draft technical study on disclosure requirements related to genetic resources and traditional knowledge, document prepared by the secretariat for the 5th session of the Inter-governmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, WIPO/GRTKF/IC/5/10, Annex I, 8.

[231] Report of the Third Meeting of the Ad Hoc Open-Ended Inter-Sessional Working Group on Article 8(j) and related provisions of the convention on biological diversity, UNEP/CBD/COP/7/7, 12 December 2003.

possible introduction of a TK tracking system. This would enable Members and their authorities to monitor all patent applications relating to biogenetic resources at a global level. It is seen as a good solution that would ensure transparency and be helpful towards checking whether contractual arrangements are being respected. Nevertheless, the EC is of the firm opinion that such disclosure requirement should in no way affect the balance of rights and obligations laid down in the TRIPs Agreement. It should not disturb the rights of WTO Members to create a favourable environment for R&D activities in the field of biotechnology. The patent system should continue to be a highly effective tool for stimulating innovation, technological progress and economic development.[232]

The EC has further proposed 'an indispensable measure that could make the disclosure requirement an effective incentive to comply with access and benefit-sharing rules'. This is to introduce a simple notification procedure to be followed by patent offices. The patent office, which received a declaration of the country of origin or source of the genetic resources and/or associated TK, should notify this information to a centralized body. The Clearing House Mechanism[233] of the CBD would be an adequate central body to which the patent office should send the information.[234]

[232] Council for Trade-Related Aspects of Intellectual Property Rights, Minutes of Meeting, on 25-26 and 28 October, 29 November and 6 December 2005, 31 January 2006, IP/C/M/49, para. 122.
[233] Body within the CBD, coordinated by the Executive Secretary. The meaning of the term clearing-house is today extended to include any agency that brings together seekers and providers of goods, services or information, matching demand with supply.
[234] Supra f.n. 233, para. 126.

6 Analysis

This thesis has aspired to give an overview of the issues surrounding bioprospecting. As the reader has acquainted itself with the material it should have become apparent that the relationship between IPRs, TK and ABS is complex, although intrinsically linked.

The link between conservation of biodiversity and TK is normally taken for granted as a "common knowledge" basis when discussing IPRs, biological resources and TK. The correlation deserves nevertheless to be explicitly discussed. TK has normally developed over an extended period of time, within a defined group of people, and adapted to a distinct sphere of biodiversity in which that group of people has lived. Biodiversity conservation is dependent of sustainable use of the open-access biological resources, more easily upheld when there is a defined community using them. The knowledge is not only comprised of medicinal properties of biological material but also relates to harvesting techniques. Sustainable use and biodiversity conservation may not be directly impacted by bioprospecting for pharmaceutical or biotechnological (especially third generation biotechnology). It becomes more of a pressing issue in natural remedy medicine or within the cosmetic industry where over-harvesting can pose an imminent threat to biodiversity. Regrettably this area has been outside the scope of the thesis.

Let us glance back to an initial question posed at the beginning of the thesis. Is the patent system applied correctly or can the problems envisaged by many developing countries and NGOs be remedied by a more narrow application of the patentability criteria, novelty, inventive step and industrial application? Generally, broad patents granted on information products in fundamental research will foster fundamental research. Likewise, narrow patents imply higher diffusion of research that has developed beyond fundamental research. It has been argued that it will be followed by relatively more applications and small improvements.[235] The obvious answer would be an appropriate trade-off between stimulating third generation biotechnology, on the more advanced level of research, and to apply the patentability criteria in a stricter manner to patent applications relating to "raw" material such as biological resources and associated TK. Otherwise the tightened IPR regime that is imposed on developing countries through the implementation of the TRIPs Agreement will aggravate or strengthen biodiversity conservation.[236]

[235] Janssen, J*, Property rights on genetic resources: economic issues*, Global Environmental Change, 1999, Vol. 9, iss.4, p.319.
[236] Ibid, pp. 313-321.

6.1 Protection of TK

It cannot be emphasized enough that in order to make ABS instruments and protection of TK work, the industrialized countries need to take their responsibility. Although legal frameworks are developed by the countries rich in biodiversity and associated TK, they are limited in their scope and jurisdiction. The fact that IPR protection can be denied in the region where the biological resource was accessed is made redundant when the applicant can get patent protection in the EC or the US. In terms of capacity-building and development of a global market where local communities are to compete on strong markets such as the American one, the US patent awarded may prove to be detrimental. The free trade is, in this case, only flowing in one direction.

From the perspective of the legitimacy of the intellectual property system as such, the recognition and inclusion of PIC in the conventional IP system is essential. In intellectual property law, equitable principles require the refusal to grant or to enforce intellectual property rights when they would be or have been procured by fraud or deception.[237] The contrary would allow the intellectual property system to assist and reward the conduct contrary to honest commercial practice. From this aspect, the requirement to disclose evidence of PIC in patent applications is critical to advancing a more equitable and balanced international intellectual property system.

The protection afforded to undisclosed information in TRIPs Article 39 is widely considered to be essential for encouraging technology transfer. It is however uncertain whether such protection would be suitable for TK.

In documents prepared by GRULAC[238], for the WIPO Committee on the Relationship between Intellectual Property, Genetic Resources and Traditional Knowledge in 2000, it is stated that such protection would make it possible for monitoring access, exploitation and communication of TK to third parties. It is seen as an opportunity to control the means of dissemination of TK and to benefit from its exploitation.[239]

There have also been efforts made towards the forming of cartels. Such a project was carried out in Ecuador under the name of "*The Transformation of Traditional Knowledge into Trade Secrets*". The project attempts to achieve a cartelization of traditional knowledge within Ecuador and then expand the organizational structure to neighbouring countries. The knowledge from different ethnic groups wishing to participate in the project is being catalogued and deposited in a restricted access database, in which each community or group has its own file. Checks are made to verify whether different groups or communities have the same knowledge; if so, (future) benefits will be shared among all those groups sharing the same knowledge. Checks are also made to see whether each item of knowledge is

[237] Perrault, and Oliva, ICTSD/CIEL/IDDRI/IUCN/QUNO 'Dialogue on Disclosure Requirements: Incorporating the CBD Principles in the TRIPS Agreement On the Road to Hong Kong' WTO Public Symposium, Geneva, April 21, 2005.
[238] the Group of Countries of the Latin America and the Caribbean.
[239] GRULAC *Traditional knowledge and the need to give it adequate intellectual property protection*, WO/GA/26/9, September 2000.

not already in the public domain. TK outside the public domain can be the subject of standardized MTAs.

A potential problem in this particular project is that the parties to the contract will be the interested company and the Government. The Government is required to share the benefits with the communities concerned, thus its willingness to actually do so will largely determine the success of the project.[240]

Nevertheless, there are examples (e.g. India) where a long established history and documentation of TK, as well as a large number of practitioners and a supporting industrial sector, conventional IPRs serve as incentives for innovation based on the documentation.

As a final observation on the issue of TK protection, international legislation regulating the issue of ABS and TK does not seem to be suitable for preserving, protecting and promoting TK. When looking closer at regional and national regimes no one model emerges, rather there are considerable variations. Different cultural and legal systems require adaptation to local conditions.

6.2 Stimulation of bioprospecting through ABS legislation

Instead of providing a flexible legal framework for facilitated access to biological resources and adequate protection for TK, ABS legislation can be seen as rigorous, in fact deterring research and possible financial benefits. However, it is the view of the author that with the tide of a very intense biopiracy discussion, the biodiversity-rich countries (mainly the South) are trying to compensate for the non-stringency of the industrialized (North) countries' IPR legislation, thereby implementing restrictive rules that unintentionally hinders scientific research, whether academic or commercial. One example is the Philippine EO247. Instead of facilitating access to genetic resources it appears to have hindered research. Since the enactment (1995), more than 30 applications have been made but several of those have been withdrawn. Only two ARAs had been approved by mid-2002, one covering parts of the University of the Philippines and the other for the International Rice Research Institute (IRRI). The only CRA to be approved was a joint undertaking between the Philippine Department of Agriculture, the University of the Philippines and the University of Utah, funded by the US National Cancer Institute and US National Institutes of Health. The research objective is to collect marine organisms, to isolate active metabolites[241] and to perform systematic inventories of the biodiversity of various habitats in the Philippine marine eco-system.[242]

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[240] *TRIPs, CBD And Traditional Medicines: Concepts And Questions*, Report of an ASEAN Workshop on the TRIPS Agreement and Traditional Medicine, Jakarta, 13-15 February 2001.

[241] **Metabolites** are the intermediates and products of metabolism. The term metabolite is usually restricted to small molecules. A primary metabolite is directly involved in the normal growth, development, and reproduction. A secondary metabolite is not directly

It has been suggested that the major industrial nations have abdicated their responsibility to institute measures to ensure equitable access and benefit-sharing arrangements. They have been slow to develop legal measures to ensure that the acquisition and use of biogenetic material and associated TK by persons, institutions and corporations in user countries are carried out in compliance with the laws in source countries and with the provisions of the CBD. For example, none of the IPR systems of the industrialized countries requires that patent applications for inventions based on genetic inventions or associated knowledge acquired in another country has to prove that the resources or knowledge were acquired in compliance with the CBD or national law in the source country.[243]

Of the different national and regional legislation surveyed here, only two are in force, the Philippine EO and the Costa Rican Biodiversity law. It would be particularly interesting to further study the implementation process of the OAU Model Law as it emphasizes the intellectual rights of communities. Opting for a *sui generis* protection system seems to be the general route of action for developing countries. Costa Rica who by many is put forward as a successful example has not yet enacted any such legislation although TK is acknowledged in the Biodiversity Law.

Notwithstanding the flaws of the current law, Costa Rica can be used as an example where bioprospecting has facilitated technology transfer and the development of domestic competence. In my opinion, this is the main advantage with national ABS legislation. It can provide, via explicit rules on benefit sharing and through mutually agreed terms an excellent platform for technology transfer. Private companies would on a contractual basis, established in good faith, contribute to the fulfilment of the obligation of the developed countries under TRIPs. To achieve those results it is necessary to create a binding legal network, on a global scale, where a PIC requirement would constitute an incentive towards compliance with national legislation governing ABS. However, a too heavy regulatory approach could stifle such development. The contract, with mutually agreed terms, flexible enough to adapt to the different capacities of parties, forms the suitable basis of a mutually beneficial bioprospecting venture.

The value of the voluntary guidelines or codes of conducts can be discussed. When the guidelines closely follow the CBD, with some elaboration, the main value would be that of contributing to good faith. One such example is the MOSAICC. The Code of Conduct aims to facilitate access and transfer to biological resources in a mutually beneficial manner. In providing for the basic requirements for any transfer to occur, access is made easy. Where more complicated (additional) terms are needed, it is explicitly stated that for any negotiations to succeed, they depend on the good will of the respective partners to reach an overall win-win situation and the mutual understanding of each other's interest and the added value of

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involved in those processes, but usually has important ecological function. Examples include antibiotics and pigments. http://en.wikipedia.org/wiki/Metabolites, 21/03/06.

[242] Greer, D, Harvey B, *Blue genes: sharing and conserving the world's aquatic biodiversity*, 2004, p. 168f.

[243] Laird, S (ed), *Biodiversity and Traditional Knowledge: Equitable Partnerships in Practice*, 2002, p. 504.

respective contributions. The MOSAICC recognises that additional terms can involve different stakeholders such as local microbiologists, local competent authorities as well as representatives of local/indigenous communities.

Obviously a perception that prospecting can take place on mutually beneficial terms underlines this Code. The question is whether the PIC provided for in the Code enables such a win-win situation. Section II of the Code presents a model PIC application form. It refers to the CBD and accordingly PIC is applied for with the competent national authority. It does not refer to possible indigenous/local communities or other stakeholders that may need additional information presented in a way not only referring to the CBD. Although a welcome guideline, perhaps it would be beneficial to look beyond the wording of the CBD and adopt guidelines that anticipate national legislation's requirement of a PIC procedure which includes suppliers of TK. Nevertheless, any attempt to provide clarity on the difficult concepts is laudable.

My final observation to conclude this thesis is that, when approaching this subject, it is too easy to end up going in circles. One issue cannot be separated from another making it very difficult to grasp the full picture. In this complicated situation, the bioprospector is placed. It is a fact that since 1993, it is no longer legal to go to a country and pick up a small amount of soil to analyse back home. Access to biological resources must take place in compliance with national law, and in case of institutions sponsored by the state, in compliance with the CBD. It is therefore necessary, in the interests of the private sector to conduct business without undue burdens, and in the interest of countries, both developed and developing, to facilitate trade and development, for legislation governing IPRs and ABS to be sufficiently clear. A more pragmatic approach towards the issue, not influenced by the different discourses elaborated on in the introduction, would be preferable. In the mean time, while waiting for matters to develop through the continual enactment of legislation, it is advisable to make the extra effort.

7 Conclusion

The possibility of exploring biodiversity to find novel compounds that potentially could cure serious diseases has by many been seen as a great opportunity. The image of the explorer, penetrating the deep jungle, obtaining knowledge from indigenous communities in order to pinpoint the plant with the medicinal properties, still remains viable. However, bioprospecting, the search, collection and screening of biological material and associated TK and for commercial ends has a much more pragmatic side to it.

This thesis has had the objective, in giving an overview of different aspects, legal and non-legal, to answer the question on how biological resources and associated TK is protected when accessed in bioprospecting activity. Acknowledging the fact that protection of TK is inextricably linked to IPR under TRIPs, and questions of ABS, and capacity-building of developing countries, the equal purpose of the thesis has been to closer analyse provisions governing these issues in international and national law.

The main conclusion to be drawn from the material has been that although many countries are in the process of enacting legislation, they are mainly the biodiversity-rich South countries. Equal measures are not taken in the developed North. This has led to the ongoing controversy regarding introduction of a PIC requirement into patent law, requiring an amendment to the TRIPs Agreement and to the enactment of national legislation that has been criticized for being to regulatory, thereby stifling bioprospecting activity and, as a consequence deterring the sharing of benefits accrued.

Another conclusion arrived to is the importance of capacity-building in terms of domestic competence in order to reap the benefits of a more stringent IPR system as under TRIPs. Developing countries are often left with having to provide for patent protection for advanced biotechnological inventions emanating from developed countries. There are no direct benefits for the developing countries to provide such protection if they are not able to take advantage of it on a domestic level. Who benefits from biodiversity depends not just on the power of moral arguments and of the law, but also on the power of knowledge. For a society to derive maximum benefits from its biodiversity, it must have at its disposal the tools of science and technology. But in many developing countries, particularly the smallest and poorest, scientific and technological expertise are notably lacking.

TK should be a source of welfare and invention for the people themselves; instead there are a number of cases where TK has been used to develop products where no benefits have been redirected to the providers of the TK.

On the other hand IPRs are vital for R&D based industries, the pharmaceutical industry being a classic example. For them bioprospecting is not a get-rich-quick scheme. It takes many years of analysis and testing that typically cost hundreds of millions of dollars. Many medicines that are developed from plant and animal extracts are a result of arduous research efforts, unexpected research results or trial-and-error experimentation.

Bioprospecting can be done responsibly. Development of products based on the genes, chemical compounds and structures of natural organisms can benefit not only consumers and commercial firms, but farmers, local communities and natural ecosystems as well.

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Supplement A

National case studies

Even though the issue discussed in this thesis ultimately is transnational in its nature, it is also interesting to study how the issue is dealt with on a national level. How well can a developing country compete on an international market and at the same time protect its national resources in terms of biological resources and associated TK?

Division of developing countries

Bhagavan[244] divides developing countries into three categories according to their science and technology. These countries are members either of the strong, medium or the weak South. The strong countries includes India, China, Mexico and Brazil, which are all moving into high-technology fields such as the third generation biotechnologies. The medium countries are above all Indonesia, Malaysia and Argentina, while the weak countries are those that are as technologically dependent on the developed countries now as they were before decolonization.

India

India is a rapidly developing country but also a country of mass poverty. However, it exports products that command a high price on the international market such as basmati rice and Darjeeling tea. The country also exports medicinal and aromatic plants, an industry that is rapidly expanding. On top of that, India has developed significant capacities in industrial chemistry and the life sciences.
Biodiversity as such is important for all the socio-economic sectors of the population. A vast majority depend on biodiversity for their livelihood; it provides food and medicines and can be a tradable commodity.[245] Only about 30 per cent of the population in India have access to pharmaceuticals[246], and about 8000 plant species are used medicinally.[247] India is an important exporter of medicinal plants; however, medicinal plants and herbal formulations are sold for a much higher price in foreign markets than what Indian exporters receive. Hence there is scope for India

[244] Bhagavan, M. R, 'Introduction' in Bhagavan M.R. (ed) *New Generic Technologies in Developing Countries*, Macmillan Press, Basingstoke, 1997, pp 3-4.
[245] Dutfield, *Intellectual Property, Biogenetic Resources and Traditional Knowledge*, Earthscan, London 2004, pp. 167-169.
[246] Lanjouw, 1998, The introduction of Pharmaceutical product patents in India: 'Heartless Exploitation of the Poor and Suffering'?, NBER Working Paper No. 6366, National Bureau of Economic Research, Cambridge, p.23.
[247] Pradeep, 1998, "Making Science of Mumbo-Jumbo", http://ces.iisc.ernet.in/hpg/envis/doc98html/bioddo1124.html, 21/03/06.

to capture a greater value from this sector, which could be achieved through industrial refinement such as:

- *Isolating pure active compounds for formulation into drugs;*
- *Isolating intermediates for the production of semi-synthetic drugs; or*
- *Preparing standardized galenicals (extracts powders, tinctures, etc.)*[248]

This value would not necessarily stem from foreign markets. With a population of over one billion and a middleclass of about 200 million India could itself constitute a substantial market for many of these goods.[249]

India has Biodiversity legislation and separate IPR legislation enacted. The Patents Act, amended as of 2005, stipulates that non-disclosure of origin and the invention claim being anticipated having regard to TK in India or elsewhere constitute grounds for opposition.[250] The Biodiversity Act prohibits anyone to apply for any IP protection, in India or elsewhere without the prior approval of the National Biodiversity Authority. The National Biodiversity Authority may impose benefit-sharing conditions upon the approval.[251] Those benefit sharing conditions include joint intellectual property right to the National Biodiversity Authority or identified benefit claimers, transfer of technology, joint research or the location of research or production in India.[252]

India is one of the most advanced developing countries in terms of scientific capabilities. It has research capabilities in a broad range of biotechnologies and biotechnological applications which has attracted firms to set up R&D centres in India.[253]

India has seen a number of high-attention cases where patents have been awarded abroad (mainly the US and the EU) for products and processes closely related to Indian TK. A classic example is the Neem-case or the Kani Tribe-case. There has also been profitable health products developed based on Indian TK, an example is reserpine, a tranquillizer and antihypertensive product derived from the medicinal plant *Rauwolfia serpentine*. Another Indian medicinal plant that have been the source of patents, one in the US[254] and one European patent[255], awarded to the Indian company Darbur for a polyherbal composition including extracts of *Phyllanthus*, is the niruri plant, Latin name *Phyllantus amarus* used for treating various ailments including jaundice.

However, with the present trend towards a growing domestic pharmaceutical industry, the Indian pharmaceutical companies are not primarily interested in natural product research as an approach to drug discovery. The Biodiversity Bill is making Indian biodiversity less

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[248] Dutfield, 2004, p. 170.
[249] Ibid.
[250] India, The Patents (Amendment) Act, No. 15 of 2005, Article 25.1 (j) and (k).
[251] India Biodiversity Bill, 2002, Bill No. 93-C of 2000, Chapter II, Article 6, (1) and (2).
[252] Ibid, Chapter V, Article 21 (2).
[253] Including the Swedish/British firm AstraZeneca, Dutfield, 2004, supra f.n. 246, p.175.
[254] US Patent No. 4673575, 'Composition, pharmaceutical preparation and method for treating viral hepatitis'.
[255] EP0890360 'A polyherbal pharmaceutical composition useful in the treatment of conditions associated with hepatitis E and hepatitis B virus infections'.

accessible to foreign companies so it is likely that patents deriving from domestic biological resources will be held by Indians. This could serve as an encouragement to invest into natural product R&D.[256]

Kenya

Contrary to India, Kenya has patent protection somewhat more compatible to TRIPs. It has also provided for plant variety protection since 1972. Similar to India is the large export of natural products, some which benefit the national economy because of its high value in international markets and others that give no substantial benefits to the economy despite of the high market value.[257]

Kenya is not a megadiverse country such as India, however it is according to Kenya's Ministry of Environmental Conservation, and the most species dense country in Africa.[258] However, most of Kenya's exports of natural goods are not natural products based on indigenous biological resources but rather resources introduced to Kenya during the colonial period (from the 1880s to 1963).[259] This means that natural compounds could represent a potential value added to the Kenyan economy.

Dutfield points out several disadvantages in comparison to India. Firstly there is very little invested into R&D, and it is only funded by government initiatives. The private sector is not involved. Technological capacities are limited with few qualified chemists who would benefit the country in terms of domestic R&D. In this environment, commercialization of TK is unlikely. In any case TK would only be exploited when no domestic capacity to make use of the knowledge exists. The likelihood of foreign corporations applying for patents in a manner more consistent with biopiracy than bioprospecting is more imminent. IP protection. When combined with early patent protection for chemicals, the lack of scientific graduates makes the situation non-beneficial for bioprospecting in Kenya. Without initial inventiveness in life-sciences patents do not provide for encouragement of invention.260 India is an example of taking advantage of weak IP protection in order to build up its domestic science and technology capacities to a point where stronger protection of IPRs can provide incentives for further invention. Kenya on the other hand has little to gain from allowing patent protection for all fields of technology as there are next to no domestic companies to benefit from that.[261]

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[256] Dutfield, 2004, p.199.
[257] Ibid, p. 204.
[258] Kenya Ministry of Environmental Conservation, Draft First National Report to the conference of parties (COP), National Biodiversity Strategy and Action Plan, March 1998, p. 17. Available at: http://www.biodiv.org/doc/world/ke/ke-nr-01-en.pdf, 22/03/06.
[259] See e.g. http://www.unitedinternationalpress.com/Kenya/ken_i.html, 22/03/06.
[260] For an overview of the mutual development of life sciences and patent law see Dutfield, 2003, *Intellectual Property Rights and the Life Science Industries: A Twentieth Century History*, Ashgate, Aldershot.
[261] Dutfield, 2004, pp. 217-218.

Supplement B

The following is an extract from the GRAIN webpage:
http://www.grain.org/nfg/?id=380, Last visited 01/05/06

TK in free trade agreements, FTAs
9 March 2006
What does traditional knowledge have to do with "free trade"? It depends. For some people, traditional knowledge can be bought and sold, so it should have everything to do with it. For others, it's something to keep *out* of the market, so it should have nothing to do with it. Yet a lot of people are trudging around the middle grounds and ambiguities of this conflict. While trying to promote some sort of "rights" to traditional knowledge, they stay within the dominant framework of private property and usually end up proposing some adapted form of intellectual property rights. This makes it often misleading to speak of "protection" in relation to traditional knowledge. Protection of what? Corporate rights to exclude, own and sell? Or collective rights to use, share, improve and further develop knowledge in the context of local livelihoods? At the international level, governments have been debating whether and how to set up globally agreed rules on traditional knowledge for many years. This has been playing out at various institutions like the WTO, WIPO, the CBD and FAO, with occasional spats at UNESCO, the UN Commission on Human Rights or elsewhere. The debate, while technically boring and seemingly far removed from concrete realities, is actually fundamental. Smack in the centre is this monstrous ideological and cultural clash between looking at traditional knowledge as "intellectual property", thereby privatising it to serve corporate economic and development strategies, and looking at it as a collective heritage of peoples and communities that States have no business regulating, much less governing. While industrialised countries block any global agreement on this, because they're happy to profit from the commercial use of traditional knowledge without constraints, the pervasive neoliberal agenda of privatisation is slowly but steadily winning the day. To see it happening, we have taken a look at several of the bilateral and regional FTAs that governments are now signing like mad behind people's backs.

Current patterns
The issue of traditional knowledge has come up in a dozen or so FTA drafting processes over the last couple of years. In half of those cases, specific provisions on traditional knowledge were signed. While the limited number of experiences prevents us from drawing broad conclusions, there is a clear pattern currently at play.
In all cases, the main concern expressed by governments trying to insert traditional knowledge into bilateral or regional free trade agreements is preventing or stopping its "misappropriation" ("biopiracy", as some people call it). And in all cases, they try to do this by proposing new twists and turns for rules on "intellectual property rights" (IPRs) such as patents,

copyrights, trademarks and geographical indications. At that point, however, one of two things happens, depending on whether or not the negotiating team across the table is the United States. All trade negotiators who manage to get traditional knowledge in an FTA discussion with the United States share the same plan: to create new mutually agreed rules and conditions on how corporations and public researchers get US patents on biodiversity and traditional knowledge coming from their own countries. These are typical "North-South" discussions: Peru facing the US; Colombia and Ecuador facing the US; Thailand facing the US; and 34 Latin American countries facing the US (plus Canada). In these cases, the proposals on traditional knowledge brought forward by the Southern government(s) amount to disciplining the grant of patents in the United States through special provisions on disclosure of origin, prior informed consent and benefit-sharing related to the commercial use of genetic resources and traditional knowledge *(see box 1)*. The US, not surprisingly, rejects this formula. Even if it wanted to accept it, which it does not, the US government is under politically-mandated "advice" from its biotech industry not to.

When the "negotiating" partner across the table is *not* the United States, discussions take a different direction. All the FTAs in this category address the issue by acknowledging a role for independent systems of legal “rights” related to traditional knowledge. In some cases, this means devising common frameworks or tools among the countries involved. In other cases, the parties simply agree that each government may grant rights over traditional knowledge, and may potentially cooperate to that end, but without specifying common rules or tools

Table 1: Some FTA processes addressing traditional knowledge

SIGNED DEALS	**STATUS**
Trans-Pacific Strategic Economic Partnership Agreement New Zealand , Brunei, Chile, Singapore	Signed 3 June 2005 In force as of 1 January 2006
New Zealand-Thailand Closer Economic Partnership Agreement	Signed 19 April 2005 In force as of 1 July 2005
US-Dominican Republic-Central America Free Trade Agreement (US-DR-CAFTA) Dominican Republic , Guatemala, El Salvador, Honduras, Nicaragua, Costa Rica, USA	Signed 5 August 2004 Not yet in force
US-Peru Trade Promotion Agreement	Signed 7 December 2005 Not yet in force
Economic Cooperation Organisation Trade Agreement (ECOTA) Afghanistan, Azerbaijan, Iran, Kazakhstan, Kyrgyz Republic, Pakistan, Tajikistan, Turkey, Turkmenistan and Uzbekistan	Signed 17 July 2003
Panama-Taiwan Free Trade Agreement	Signed 21 August 2003

UNDER NEGOTIATION OR IN PROCESS	STATUS
Free Trade Agreement of the Americas (FTAA) All countries of the American hemisphere except Cuba	Since 1994. Last draft agreed in November 2003.
US-Andean Trade Promotion Agreement Colombia , Ecuador and US, with Bolivia as observer. Peru was originally included.	Since 2004. May end in individual bilateral agreements
US-Panama Free Trade Agreement	Since 2004
US-Thailand Free Trade Agreement	Since 2004
Bay of Bengal Initiative for Multi-Sectoral Technical and Economic Cooperation (BIMSTEC-FTA) Bangladesh, Bhutan, India, Nepal, Sri Lanka and Thailand	To come into force 1 July 2006
South Asia Free Trade Agreement (SAFTA) Bangladesh, India, Maldives, Nepal, Pakistan, Sri Lanka	Was supposed to come into force 1 January 2006