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TRIPS,

Patents

and Traditional Knowledge

Handledare: Boel Flodgren

Författare: Emily Metcalf

Abstract

Through WTO membership, a large number of countries are parties to the Agreement on Trade-Related Aspects of Intellectual Property Rights, also known as TRIPs. The strongest form of IP protection is the patent, which grants a number of valuable exclusive rights when the criteria for patentability have been met. Patents are often claimed to be a means for inventors to regain the expenses they may have had during research and development of the invention. In the biotechnological industry patenting is increasing, and Traditional Knowledge is an important source of information in product development.

Complications arise when inventions are based on genetic resources or TK, which are often obtained from developing countries or indigenous communities. There are discussions of what rights to compensation the sources of the genetic resources and TK may have under the current TRIPs patent system. Many argue that TRIPs should be changed, so as to better support another international agreement, the Convention on Biological Diversity. This agreement states, amongst other things, that every State has the right to determine under what conditions access to its genetic resources and TK are to be given. It also requires prior informed consent from the sources of genetic resources and TK. By making TRIPS to include requirements of Prior Informed Consent and Benefit Sharing, it is argued by some that both indigenous communities and developing countries may benefit, as well as the environment and biodiversity.

Key Words: TRIPS, patents, Traditional Knowledge, CBD, PIC, ABS

Sammanfattning

Genom medlemskap i WTO är ett stort antal länder parter till Agreement on Trade-Related Aspects of Intellectual Property Rights, det så kallade TRIPS-avtalet. Det starkaste immaterialrättsliga skyddet uppnås genom patentsystemet, som ger ett antal värdefulla ensamrätter när kriterierna för patenterbarhet har uppfyllts. Det hävdas ofta att patent är ett sätt för uppfinnare att återfå de kostnader som han ådragit sig under forskningsprocessen. Inom bioteknikindustrin har patentsökandet ökat, och traditionell kunskap är en viktig källa till information vid produktutveckling.

Komplikationer uppkommer då uppfinningar baseras på genetiska resurser och TK, som ofta kommer från utvecklingsländer och grupper av urinvånare i dessa länder. Diskussioner förs om vilken rätt till kompensation som källorna till genetiska resurser och TK kan ha enligt TRIPs och det nuvarande patentsystemet. Många menar att TRIPs bör ändras, så att det mer stödjer ett annat internationellt avtal, the Convention on Biological Diversity. Detta avtal säger bland annat att varje stat har rätt att själv avgöra vilka villkor som ska gälla för tillgång till deras genetiska resurser och TK. Det kräver även att källan till genetiska resurser och TK ger sitt tillstånd till användningen och att de ges del av vinsterna från eventuell kommersialisering. Genom att inkludera dessa krav i TRIPS menar en del att både urinvånare och utvecklingsländer skulle gynnas, liksom miljön och den biologiska mångfalden.

Nyckelord: TRIPS, patent, traditionell kunskap, CBD, PIC, ABS

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List of abbreviations

ABS	Access and Benefit Sharing
CBD	Convention on Biological Diversity
EPO	European Patent Office
IP	Intellectual Property
IPC	International Patent Classification system
IPR	Intellectual Property Rights
NGO	Non-Governmental Organisation
РСТ	Patent Co-operation Treaty
PIC	Prior Informed Consent
ТК	Traditional Knowledge
TKDL	Traditional Knowledge Digital Library (India)
TRIPs	Agreement on Trade-Related Aspects of Intellectual Property Rights
TRMC	Traditional Medicines Resource Centre (Laos)
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation

1. Why the protection of Traditional Knowledge is an issue worth pursuing

It has been several years since I first saw the movie "Medicine Man", starring Sean Connery as the benevolent white doctor searching for the cure for cancer deep in some jungle. He lived with a tribe of people who mysteriously never contracted the disease. They themselves where oblivious as to why, although the chewing of the flowers from a certain plant was widely spread among them. The doctors' search for the cure was a race against time, as the jungle was rapidly being cut down by an evil foresting company. Only too late did he discover the ants living in the flowers.

Then, I wondered if the film could somehow be true, that "the cure" could be out there somewhere. Today, my interest has shifted somewhat. I wonder what would have happened to the tribe of people, had Connery actually found the cure for cancer. Would their contributions to his search have been recognised and rewarded?

Patenting is one way for inventors and industry to protect their inventions. Through membership in the WTO, many countries are today parties to the TRIPS agreement, which contains regulations on patent protection to be implemented by national governments. As most countries of the world are either members of the WTO or have applied for membership, these regulations also concern most developing countries. A great amount of TK originates from developing countries. Most developed countries are also parties to TRIPS. TK is often used in research and industry in these countries.

1.1 Purpose

The purpose of this essay is to clarify what protection exists for Traditional Knowledge within the TRIPS patent system today. I will focus on the situation where a patent is sought for an invention outside of the country where the TK and genetic resources were gathered. Some suggested changes to TRIPS will then be discussed to provide a view of their strengths and weaknesses regarding their abilities to provide greater protection for TK in this situation. I will mainly use an economical perspective in the evaluation of these suggestions.

1.2 Method

In this essay, I have used legal method, in that I have studied legal documents and doctrine.¹ I have also studied statements and documents from some of the international organisations concerned with Intellectual Property Rights and Traditional Knowledge, such as WIPO and the WTO.

1.3 Use of terms

1.3.1 Traditional Knowledge

Before it is possible to discuss the importance of Traditional Knowledge, it is necessary to decide what it is. There is probably no definition of TK that is complete, but there are several characteristics that tend to be used in the definitions of TK. One is that TK is often communicated orally² and that it is quite seldom organised when it does exist in written form³. TK is often collectively held by an entire community⁴. The teaching, using and spreading of the knowledge may also be connected to religious practices⁵.

The expression Traditional Knowledge also encompasses several types of knowledge. They include art and literature, songs, dance, agricultural technology and medicinal knowledge.⁶ TK that is relevant for industry is often that concerning the use of plats and animals, how to prepare them and how to care for living plants and animals⁷.

In this essay, I have chosen to focus on the traditional agricultural and medicinal knowledge of plants and animals. Reasons for this are the importance of these particular forms of knowledge to the pharmaceutical and agricultural industries in the developed countries⁸, and also that this TK is related to the patent system⁹, while the other types of TK mentioned are

¹ Lehrberg, Bert, Praktisk juridisk metod, Fjärde Upplagan, Iustus Förlag, Uppsala, 2001, p. 38

² Integrating Intellectual Property Rights and Development Policy, Report of the Commission on Intellectual Property Rights, London, September 2002, p. 75

³ Tsioumanis, Asterios; Konstadinos, Mattas; Tsioumani, Elsa, *Is Policy towards Intellectual Property Rights Addressing the Real Problems? The Case of Unauthorized Appropriation of Genetic Resources*, Journal of Agricultural and Environmental Ethics, no. 16, 2003, p. 607

⁴ Dutfield, Graham, *TRIPs-Related Aspects of Traditional Knowledge*, Case Western Reserve Journal of International Law, no. 33:2, 2001, p. 243

⁵ WIPO, Blakeney, Michael, What is Traditional Knowledge? Why Should it be Protected? Who Should Protect it? For Whom?: Understanding the Value Chain, WIPO/IPTK/RT/99/3, p. 3

⁶ Integrating Intellectual Property Rights and Development Policy, Report of the Commission on Intellectual Property Rights, London, September 2002, p. 75

⁷ Posey, Darrell A, Dutfield, Graham, Beyond Intellectual Property. Toward Traditional Resource Rights for Indigenous Peoples and Local Communities, International Development Research Centre, 1996, p. 12

⁸ Dutfield, Graham, *TRIPs-Related Aspects of Traditional Knowledge*, Case Western Reserve Journal of International Law, no. 33:2, 2001, p. 243

⁹ WIPO, Blakeney, Michael, What is Traditional Knowledge? Why Should it be Protected? Who Should Protect

more often included in discussions of folklore and copyright law¹⁰. I also choose not to include issues concerning human genetic resources, as I have found that these discussions use few arguments of a legal or economical kind, but are more concerned with the ethics or morals of using human genetic resources in scientific research and including them in trade.

1.3.2 Holders of TK

A holder of TK is any person who creates, develops or practices this knowledge in its traditional context¹¹.

Holders of traditional knowledge are in many cases, but not always, indigenous peoples.¹² Indigenous peoples are usually recognized as having lived in a certain area before colonization or invasion and they identify themselves as a separate group. They may have their own language, religion and culture and it is also common that these groups are or have been discriminated against.¹³ These groups of indigenous TK holders are generally meant to be the ones with the most to gain from increased protection for TK.¹⁴

1.3.3 Genetic resources

A genetic resource has been defined as a piece of genetic material which is or might be of value¹⁵. Genetic material is any material from plants or animals that contains "functioning units of heredity"¹⁶.

1.3.4 Protection

When using the term "protection" in this essay, I primarily mean protection against misappropriation of TK. I have also used the same term to describe the protection of the rights that TK holders may have to compensation and/or recognition of their contributions to patented inventions.

it? For Whom?: Understanding the Value Chain, WIPO/IPTK/RT/99/3, p. 3

¹⁰ WIPO, Blakeney, Michael, What is Traditional Knowledge? Why Should it be Protected? Who Should Protect it? For Whom?: Understanding the Value Chain, WIPO/IPTK/RT/99/3, p. 2-3

¹¹ Van Overwalle, Geertrui, Protecting and sharing biodiversity and traditional knowledge: Holder and user tools, 2005, Ecological Economics 53, p. 588

¹² ibid.

 ¹³ WIPO, Blakeney, Michael, What is Traditional Knowledge? Why Should it be Protected? Who Should Protect it? For Whom?: Understanding the Value Chain, WIPO/IPTK/RT/99/3, p. 3-4

¹⁴ ibid, p. 3

¹⁵ Convention on Biological Diversity, article 2.

¹⁶ ibid.

1.3.5 Patent rights

When a patent is awarded, the patentee gains several exclusive rights over the invention. These rights include producing the invention, marketing and selling it in the country where the patent is valid. The patent holder also has the right to control importing of the invention from other countries.¹⁷ Patents are a form of IPR, which gives the patent holder a strong form of protection, often over inventions of great value¹⁸.

1.3.6 Benefits

As will later be discussed, many want benefit sharing requirements incorporated in TRIPs. Generally, these benefits are those that come from commercialising a product. These are often expected to take the form of money¹⁹, but non-monetary benefits, such as technology transfer and participation in research, may be of equal importance²⁰

¹⁷ Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), art. 28

¹⁸ Richerzhagen, Carmen; Holm-Mueller, Karin, *The effectiveness of access and benefit sharing in Costa Rica: Implications for national and international regimes*, Ecological Economics 53, 2005, p. 449

¹⁹ Van Overwalle, Geertrui, Protecting and sharing biodiversity and traditional knowledge: Holder and user tools, 2005, Ecological Economics 53, p. 596

²⁰ ibid.

2. Why the TRIPS patent system is important for the protection of Traditional Knowledge

Modern biotechnology has raised the value of genetic resources, and of the knowledge connected to it.²¹ The importance of intellectual property is therefore increasing, which is obvious in many international forums.²² IPRs are connected to many other issues, such as human rights, food and agriculture, biodiversity, biotechnology, culture, trade, and economic development.²³ Here, the implications of stronger TK protection on biodiversity, biotechnology and economic development will be discussed.

2.1 Biotechnology and biodiversity

Biotech-companies gather genetic resources to which they have been guided by local communities, and may later gain patents for and commercialize products based on these resources. Generally, the communities providing the resources and TK are not given a share of the benefits arising from the commercialization of the product. Also, since a genetic resource usually has to be modified or improved compared to the original genetic resource and many substances are also synthesized, the community may be deprived of the income they might have had from their own use of the resource. Thirdly, they must pay for the use of the new product if they wish to make use of the improvements made.²⁴

TK regarding plants and their healing properties has guided researchers when developing many of the modern medicines used today²⁵. Modern farming practices have led to a homogenisation of crops. Through the traditional use of plants and animals, some diversity in genetic resources has been preserved. This may be of great value as more resilient crops are sought after.²⁶ Many industrial sectors have shown great interest in genetic resources²⁷.

²¹ WIPO, Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, WO/GA/26/6, p. 1

²² ibid.

²³ WIPO, Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, WO/GA/26/6, p. 1

²⁴ Tsioumanis, Asterios; Konstadinos, Mattas; Tsioumani, Elsa, Is Policy towards Intellectual Property Rights Addressing the Real Problems? The Case of Unauthorized Appropriation of Genetic Resources, Journal of Agricultural and Environmental Ethics, no. 16, 2003, p. 608

²⁵ Integrating Intellectual Property Rights and Development Policy, Report of the Commission on Intellectual Property Rights, London, September 2002, p. 73

²⁶ bin Osman, Mohamad, Access to Genetic Resources and Benefit-sharing, International Expert Workshop on Access to Genetic Resources and Benefit Sharing, Record of Discussion, 2004, pp. 319-320

²⁷ Richerzhagen, Carmen; Holm-Mueller, Karin, *The effectiveness of access and benefit sharing in Costa Rica: Implications for national and international regimes*, Ecological Economics 53, 2005, p. 448

Pharmaceutical as well as cosmetic and seed companies are involved in the use of these resources²⁸. This is evidence of the value of traditional knowledge regarding genetic resources to industry and trade. Given the value of TK and genetic resources, it would be motivated to work for their preservation. This could be done through rewarding TK holders for their contributions.²⁹

2.2 Environmental concerns and poverty reduction

The genetic resources of the world are not spread evenly. Areas rich in biodiversity are often located in developing countries.³⁰ The potential value of biodiversity to the biotechnological industry³¹ is a possible income for developing countries and for indigenous peoples within them. Granting holders of TK and/or the countries containing the genetic resources rights to a share of profits resulting from commercialization of products derived from "their" genetic resources could be a way to reduce poverty. At the same time, providing poor people with an income may reduce harm to the environment, as poverty is an important reason for reducing biodiversity³². The practices of indigenous peoples would also be encouraged, and TK could continue to be developed. Such encouragement may prove necessary, as many indigenous communities are abandoning their traditional ways of life and thereby their TK may be lost³³.

2.3 TRIPS

The Agreement on Trade Related aspects of Intellectual Property rights (TRIPS) is a WTO document concerned with brands, copyright, patents, and other forms of protection for IP. Most countries in the world are WTO members, and several await membership³⁴. Ratification of the WTO Agreement is required from new members to the WTO. TRIPS is included in this agreement, so that all of today's members are parties to TRIPS.³⁵ The TRIPS agreement establishes a minimum standard of protection, which parties are obliged to implement in their national legislation. Since national implementation is allowed to vary somewhat, so that the

²⁸ Richerzhagen, Carmen; Holm-Mueller, Karin, *The effectiveness of access and benefit sharing in Costa Rica: Implications for national and international regimes*, Ecological Economics 53, 2005, p. 448

²⁹ Posey, Darrell A, Dutfield, Graham, Beyond Intellectual Property. Toward Traditional Resource Rights for Indigenous Peoples and Local Communities, International Development Research Centre, 1996, p. 104

³⁰ Tsioumanis, Asterios; Konstadinos, Mattas; Tsioumani, Elsa, Is Policy towards Intellectual Property Rights Addressing the Real Problems? The Case of Unauthorized Appropriation of Genetic Resources, Journal of Agricultural and Environmental Ethics, no. 16, 2003, p. 607

³¹ ibid.

³² Richerzhagen, Carmen; Holm-Mueller, Karin, *The effectiveness of access and benefit sharing in Costa Rica: Implications for national and international regimes*, Ecological Economics 53, 2005, p. 448

³³ Integrating Intellectual Property Rights and Development Policy, Report of the Commission on Intellectual Property Rights, London, September 2002, p. 75

³⁴ Seth, Torsten, WTO och den internationella handelsordningen, Studentlitteratur, Lund, 2004, p. 58

³⁵ ibid, pp. 49-50

actual protection provided can differ from what is stated in TRIPS, though it may never be weaker. $^{36}\,$

The patent system provides the strongest form of IPR³⁷, and it is a well established system in many countries, especially in the developed world. This should mean that including TK in the patent system ought to be easier than establishing an entirely new form of protection. New forms of protection could also be at risk of colliding with the existing patent system, an integration of stronger TK protection into it could potentially cause less conflict.

The TRIPS agreement has established a minimum standard of protection that is binding for all parties. In practice, this includes all members of the WTO³⁸. Some countries have been granted extensions of the time they have before they must implement TRIPS. This concerns a number of developing countries, and especially those classified as least developed countries.³⁹ They are nonetheless bound to implement TRIPS at some time in the future. Additions and/or changes to the TRIPS text meant to increase the protection for TK and its holders have been suggested. Some of these suggestions will be further discussed in chapter 4.

Patents for genetic material are often practically impossible to obtain for the holders of TK. Both practical and policy reasons lie behind this. Practical reasons are the difficulties to meet the technological demands of novelty, inventive step and industrial applicability. These problems are common in developing countries as technology is often not as advanced. Policy reasons may for example be use of the possible exclusions from patentability. For example, all inventions containing genetic resources in the form they occur in nature are excluded from patentability in countries parties to the Andean pact.⁴⁰ See chapter 3.2 for further explanation.

It has been argued that protecting TK through patents is impossible due to the fact that much TK is collectively held and that it has been gradually developed over longer periods of time with many people involved, so that a single "act of invention" cannot be traced.⁴¹ This argument is contested by others, who refer to the use of the patent system by companies. Companies generally have a number of people involved in product development and research, and prefer to view inventing as a process. The result of this process is an invention belonging to the company, not the individual inventors, as the inventive process is viewed as a collective and gradual effort. Therefore the collective nature of TK ought not to be a hindrance to patent protection.⁴²

³⁶ Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), art. 1

³⁷ *Integrating Intellectual Property Rights and Development Policy*, Report of the Commission on Intellectual Property Rights, London, September 2002, p. 63

³⁸ Seth, Torsten, WTO och den internationella handelsordningen, Studentlitteratur, Lund, 2004, p. 50

³⁹ ibid, p. 323

⁴⁰ Van Overwalle, Geertrui, Protecting and sharing biodiversity and traditional knowledge: Holder and user tools, 2005, Ecological Economics 53, pp. 590

⁴¹ Berglund, Marko, *The Protection of Traditional Knowledge related to Genetic Resources: The Case for a modified patent application procedure*, SCRIPT-ed, vol. 2, issue 2, June 2005, p. 207

⁴² Dutfield, Graham, *TRIPs-Related Aspects of Traditional Knowledge*, Case Western Reserve Journal of International Law, no. 33:2, 2001, p. 254 - 255

3. Protection for Traditional Knowledge as provided by TRIPS

Today, TRIPS does not explicitly provide protection for Traditional Knowledge as such. The only way to gain protection for TK is through some other form of IP protection. One such form is the patent system, which grants the patent holder exclusive rights over the patented invention. Through this system, it is possible for holders of traditional knowledge to gain protection by obtaining patents for inventions containing their knowledge. There are several problems regarding the possibilities of obtaining a patent for TK, especially for the traditional holders. These problems are mainly connected to the criteria for patentability, but also to the financial resources and educational level of traditional communities. Problems arise especially when the prior art search is conducted for patents sought in countries other than the country where the genetic resource and TK came from, and when the would-be patentee is someone other than the original TK-holder.

3.1 Criteria for patentability and formal requirements

The criteria for patentability according to TRIPS are that the invention is new and involves an inventive step. It must also be industrially applicable.⁴³ The "inventive step" and "capable of industrial application"-criteria may also be expressed as "non-obvious" and "useful" respectively⁴⁴. This last criteria will however not be discussed further, as it is not of particular relevance to TK. There will also be some discussion of what is meant by prior art.

There are also several requirements regarding formalities which the patent application needs to meet. For instance, every patent application must contain a description of the invention, detailed enough so that a person skilled in the art can carry out the invention.⁴⁵ Another formal requirement that is of special importance to the TK issue is that of revealing the inventor⁴⁶.

The main difference between the first and second types of requirements is that the first have to do with the invention itself, the so-called substantial requirements. If these requirements are not met; if the invention is not new, does not involve an inventive step or is not industrially applicable, then it is not regarded as a patentable invention. The second type of requirements

⁴³ Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), art. 27.1

⁴⁴ ibid. (footnote)

⁴⁵ Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), art. 29.1

⁴⁶ WIPO, Initial Report on the Technical Study on Disclosure Requirements Related to Genetic Resources and Traditional Knowledge, WIPO/GRTKF/IC/4/11, p. 19

is concerned mostly with the shape of the application. The formal requirements need to be fulfilled, for the processing of the application to continue.⁴⁷

3.1.1 The novelty criterion

In order to be regarded as new, the invention must not be known to the public before the patent was applied for.⁴⁸ The exact meaning of "novelty" is determined nationally, which means that each WTO member country may decide what level of invention is required.⁴⁹ Novelty could imply that the invention should not be known nationally, or that it is not previously known anywhere in the world. This last approach is used in national legislation in most of the developing countries who have implemented $TRIPS^{50}$.

A problem that arises when a patent is sought for traditional knowledge is the fact that many ethnobotanists and -pharmacists have already published the medicinal and other uses of plants and animals by traditional communities as part of their research⁵¹. Since the novelty criterion makes it impossible to obtain a patent when the information has already been published⁵², many traditional communities find themselves unable to obtain patents for their TK as they have shared it with people from outside their community who have then published it as part of their research. This is of course a problem also for others who wish to obtain patents for TK, not only for the traditional communities.

3.1.2 Inventive step

The inventive step, or non-obviousness⁵³, of the invention usually means that a mere discovery is not enough to obtain a patent. The invention should provide further development of what exists or is already known⁵⁴. Hereby follows that when patents are allowed for living material, such as plants and animals, they are usually not allowed in their original form. Some alteration or modification must be made. A few countries do however allow patents for genetic resources in the form they occur in nature.⁵⁵ This makes it possible to obtain a patent directly for a genetic resource that has been discovered through the use of TK.

⁴⁷ WIPO, Initial Report on the Technical Study on Disclosure Requirements Related to Genetic Resources and Traditional Knowledge, WIPO/GRTKF/IC/4/11, p. 13

⁴⁸ UNCTAD-UNCTSD, Resource Book on TRIPS and Development, 2005, Cambridge University Press, p. 359 ⁴⁹ ibid. p. 390

⁵⁰ ibid, p. 362

⁵¹ WIPO, Blakeney, Michael, What is Traditional Knowledge? Why Should it be Protected? Who Should Protect it? For Whom?: Understanding the Value Chain, WIPO/IPTK/RT/99/3, p. 9

⁵² WIPO, Initial Report on the Technical Study on Disclosure Requirements Related to Genetic Resources and Traditional Knowledge, WIPO/GRTKF/IC/4/11, p. 19

⁵³ Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), art. 27.1 (footnote)

⁵⁴ UNCTAD-UNCTSD, Resource Book on TRIPS and Development, 2005, Cambridge University Press, p. 359 ⁵⁵ ibid, pp. 388-389

Much of the existing TK may thus be of great value to science and industry. Some of it might be used as a basis for further research into the uses of for instance a certain medicinal plant. This research may lead to the discovery or development of a substance that is patentable. In such a situation, the TK in itself is not patentable, but has nonetheless led to a patentable invention.

3.1.3 Prior art

Closely related to the novelty and inventive step criteria is the notion of prior art. Before a patent is granted, a search of what is previously known in the particular field of science is conducted. The result of this search determines if the invention is to be regarded as new, and if it involves an inventive step, and is thus the basis for granting the patent.

What is considered prior art varies somewhat between different national legislations. Usually, prior art is considered to be anything that is published, such as older patent applications and grants or literature, in the country where a patent is sought⁵⁶. If the invention can be found to be part of the prior art, then the invention is not considered new and a patent should not be granted. Problems arise when the invention exists as undocumented common knowledge, or TK, in another country than the one where the patent is sought. Also, prior use is generally regarded as part of prior art and therefore an invention that is already in use cannot gain a patent, as it does not fulfil the novelty criteria⁵⁷. Prior use does not have to be documented or published. All countries do not include prior use abroad in their patent examination⁵⁸. Thereby patents may be granted for inventions although they are part of traditional practices and TK in other countries. Even if prior use abroad were enough grounds to not grant a patent, proof of such use is hard to find⁵⁹.

3.1.4 Disclosure of invention

All patent applications must include a description of the invention that is clear enough so that a person skilled in the art may reproduce the invention⁶⁰. Should the description not be clear enough, the application may be turned down. An unclear application could also provide grounds for later revoking the patent. The reason for this is that this requirement is considered

⁵⁶ Koktvedgaard, Mogens; Levin, Marianne, Lärobok i Immaterialrätt, 8ed, Norstedts Juridik, Stockholm, 2004, pp. 260-261

⁵⁷ *Integrating Intellectual Property Rights and Development Policy*, Report of the Commission on Intellectual Property Rights, London, September 2002, p. 83

⁵⁸ ibid.

⁵⁹ Van Overwalle, Geertrui, *Protecting and sharing biodiversity and traditional knowledge: Holder and user tools*, 2005, Ecological Economics 53, p. 598

⁶⁰ Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), art. 29.1

to provide one of the most basic effects of the patent system. When an inventor is granted monopoly over his invention, albeit one that is limited in time, the inventor also has to make it possible for the public to make use of the invention after the period of exclusivity runs out⁶¹. As the invention is disclosed further technological development is facilitated⁶².

A problem relating to inventions involving genetic material is that the description is seldom enough to reproduce the invention. Instead, actual access to the genetic material would be necessary.⁶³ In cases where it would be necessary to reveal the source of the genetic material in order carry out the invention, several countries require this to satisfy the disclosure requirement.⁶⁴ Several countries require that patent applicants provide a sample of the genetic material to be deposited and accessed by the public.⁶⁵ There are however no requirements regarding deposits or disclosure of origin in TRIPS.⁶⁶

3.1.5 Inventor

One of the formal requirements for patents is that the inventor or inventors are identified as such in the application⁶⁷. This requirement is an important basis for patent protection, as the patent rights originate from the act of invention⁶⁸ and are awarded to the inventor or his employer⁶⁹. Another motive for patents is that they provide inventors with a means to regain the resources they spent on their research and product development⁷⁰. None other than the inventor or someone with a relevant relation to the inventor, such as an employer, may gain a patent for the invention⁷¹.

If TK is part of the inventive step of an invention, or the entire inventive step, the provider of the TK should be acknowledged in the patent application as an inventor. The provider of TK may then be entitled to partial or full ownership of the patent. If the patent application does not reveal the provider of such TK, this may be grounds for revocation or invalidation of the patent.⁷² Should TK be used as a lead for further research, but not provide any other

⁶¹ UNCTAD-UNCTSD, *Resource Book on TRIPS and Development*, 2005, Cambridge University Press, p. 449 ⁶² ibid, p. 448

⁶³ ibid, p. 453

⁶⁴ WIPO, Initial Report on the Technical Study on Disclosure Requirements Related to Genetic Resources and Traditional Knowledge, WIPO/GRTKF/IC/4/11, pp. 20-21

⁶⁵ UNCTAD-UNCTSD, *Resource Book on TRIPS and Development*, 2005, Cambridge University Press, p. 453 ⁶⁶ ibid.

⁶⁷ Dutfield, Graham, *TRIPs-Related Aspects of Traditional Knowledge*, Case Western Reserve Journal of International Law, no. 33:2, 2001, p. 254

⁶⁸ WIPO, Initial Report on the Technical Study on Disclosure Requirements Related to Genetic Resources and Traditional Knowledge, WIPO/GRTKF/IC/4/11, p. 19

⁶⁹ ibid, p. 12

⁷⁰ Bently, Lionel; Sherman, Brad, *Intellectual Property Law*, 2nd edition, Oxford University Press, 2004, p. 328

⁷¹ WIPO, Initial Report on the Technical Study on Disclosure Requirements Related to Genetic Resources and Traditional Knowledge, WIPO/GRTKF/IC/4/11, p. 19

⁷² ibid.

contribution to the process leading up to the invention, this means holders and providers of TK do not count as inventors⁷³.

In cases where the inventor is not correctly named, the consequences vary according to national laws. The patent may be partially or fully awarded to the person who is found to be the true inventor.⁷⁴

3.2 Exclusions from patentability

According to TRIPS, certain exclusions from patentability may be made. These exclusions may be for "*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*".⁷⁵ This exception is mainly meant to make possible hindering patents on plants and animals in their unaltered form, and patenting of plant varieties, not as a hindrance to patents involving genetic resources in altered forms. Some form of protection must be provided for plant varieties, either in the form of patents, or by some form of sui generis system⁷⁶. Parties to the Andean pact have excluded all inventions containing genetic resources in their naturally occurring form from patentability. This includes isolated parts of the resource.⁷⁷ It is however still possible to gain patents for synthesized inventions or versions of substances.

These exceptions could protect TK holders from misappropriation nationally, but gives little help when patentees come from abroad. Though national legislation can make it impossible to gain a patent on a plant variety, it may still be possible to gain a patent for it in another country⁷⁸. Only three countries allow patents on plants (the US, Australia and Japan)⁷⁹, however these countries have highly developed biotechnological industries. This is especially true regarding the US.

⁷³ WIPO, Initial Report on the Technical Study on Disclosure Requirements Related to Genetic Resources and Traditional Knowledge, WIPO/GRTKF/IC/4/11, p. 20

⁷⁴ ibid, pp. 19 and 24

⁷⁵ Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), article 27.3 (b)

⁷⁶ ibid.

⁷⁷ Van Overwalle, Geertrui, *Protecting and sharing biodiversity and traditional knowledge: Holder and user tools*, 2005, Ecological Economics 53, p. 590

⁷⁸ UNCTAD-UNCTSD, *Resource Book on TRIPS and Development*, 2005, Cambridge University Press, pp. 388-389

⁷⁹ Integrating Intellectual Property Rights and Development Policy, Report of the Commission on Intellectual Property Rights, London, September 2002, p. 63

4. How the TRIPS patent system could be made to better protect Traditional Knowledge and its holders

What may be done to better protect TK and its holders differs somewhat depending on whether a short or long term perspective is applied. In the short run, TK holders could be helped to access the current IPR systems and thereby gain protection for their knowledge⁸⁰. This may be done by NGOs⁸¹. In the long run, new standards for protection may be developed so that TK which is not included in the current IPR systems can gain protection⁸². This will be a legislative task for international negotiators and organisations such as the WTO, WIPO, UN and such. National governments will also have to play an important role in implementing such protection.

This chapter is mainly concerned with the measures that may be taken in order to provide better protection for TK in the long run. First, a number of reasons stated for why TRIPS should be changed are presented. The chapter is concluded with a short discussion of the possibilities for making these changes.

4.1 Changes to TRIPS

It has been claimed that the TRIPS patent system already provides the means to protect TK through the possibility of challenging patents that have been granted or are being applied for.⁸³ There are some examples of such processes concerning TK and related genetic material where the patents have been revoked. Collecting genetic material is today quite ill reputed, something which might be affecting biotechnology negatively. By changing TRIPS, this reputation may change, which could be positive for the biotechnological industry. Some have pointed to the relationship between the TRIPS and the CBD, as many countries are parties to both agreements⁸⁴. The CBD contains a number of requirements not included in TRIPS, some

⁸⁰ WIPO, Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, WO/GA/26/6, p. 6-7

⁸¹ Berglund, Marko, *The Protection of Traditional Knowledge related to Genetic Resources: The Case for a modified patent application procedure*, SCRIPT-ed, vol. 2, issue 2, June 2005, p. 209

⁸² WIPO, Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, WO/GA/26/6, p. 6-7

⁸³ WTO, Council for Trade-Related Aspects of Intellectual Property Rights, *The Relationship Between the TRIPs Agreement and the Convention on Biological Diversity*, IP/C/W/368/Rev.1, p. 11

⁸⁴ http://www.cbd.int/convention/parties/list.shtml, 2007-05-22, 10.50 and http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm, 2007-05-22, 10.44

of which are concerned with TK and genetic resources. Whether or not there is a conflict between these two agreements is a debated issue.

4.1.1 Turmeric, neem and hoodia

It has been claimed that wrongfully granted patents are rare⁸⁵, and few examples of successful challenges can be found⁸⁶. The cases most commonly cited are those of turmeric, neem and hoodia. It has been suggested that the patent system already provides enough measures to deal with the problem of wrongfully granted patents through possibilities of challenging granted patents and revoking them⁸⁷. As the cases below were resolved by using these measures, it is argued that the patent system does not need any changes⁸⁸.

In the turmeric case, an American patent was awarded to two Indian researchers, for the use of turmeric in the healing of wounds. This patent was challenged by the Indian Council of Scientific and Industrial Research, as turmeric had been used in traditional Indian medicine for a very long time. Information on this traditional use of turmeric had also been published in India. Therefore the invention could not be considered new, and the patent was revoked.⁸⁹

The patent on neem oil as a way of protecting plants from fungal infections was granted by EPO. Indian farmers, backed by a number of NGOs, challenged this patent. Neem already was and had been used in this way by several generations of Indian farmers. The patent was revoked on grounds of not being new.⁹⁰

Hoodia is a cactus which can be used to reduce appetite. It has traditionally been used by the San people of South Africa. The appetite reducing substance was isolated and patented by the South African Council for Scientific and Industrial Research (CSIR) who then sold a licence to a pharmaceutical company who in turn sold a licence to another company. The San people threatened to sue, as they believed their TK concerning hoodia had been stolen. This led to an agreement where the San people were given the right to a certain part of any profits arising from the commercialisation of hoodia products. No hoodia products have yet been released by the pharmaceutical companies involved.⁹¹

⁸⁵ WTO, Council for Trade-Related Aspects of Intellectual Property Rights, *The Relationship Between the TRIPs Agreement and the Convention on Biological Diversity*, IP/C/W/368/Rev.1, p. 11

⁸⁶ ibid, p. 12

⁸⁷ ibid, p. 16

⁸⁸ ibid, pp. 11 and 16

⁸⁹ Integrating Intellectual Property Rights and Development Policy, Report of the Commission on Intellectual Property Rights, London, September 2002, p. 76

⁹⁰ ibid.

⁹¹ ibid, p. 77 and

Protecting Traditional Knowledge: the San and Hoodia, Bulletin of the World Health Organization , vol. 84, May 2006

The lack of successful cases as an indication of the effectiveness of the patent system has been contested. Many developing countries and groups of TK holders lack the knowledge and resources required to keep track of patent applications and grants in order to detect any possible misappropriation.⁹² Challenging the patents post-grant is also a costly process⁹³. This may be too great an obstacle for developing countries and for traditional communities. In two of the cases above, the TK holders received help from NGOs or their government in challenging the patents. Without this help the patents might not have been challenged and therefore not revoked.⁹⁴

Another motivation for changing TRIPS is that the patent system today provides measures to re-examine and revoke an already granted patent, should its validity be challenged. Suggestions to changes to TRIPS are mainly concerned with preventing these patents from being granted in the first place and ensuring that interests of TK holders and developing countries are respected. This is perceived by many as a better solution, as it would save time and money otherwise laid on legal processes which could have been avoided⁹⁵.

Many claim that protecting TK through national law is not enough, as this would provide no means of international enforcement. A way to ensure that regulations concerning TK are respected internationally would be needed since a lot of genetic material and TK is used outside their countries of origin.⁹⁶ Voluntary contracts could work in cases where all parties are acting in good faith, but it would be difficult to deal with those who have decided to act in bad faith⁹⁷, or parties who do not wish to share benefits arising from commercialisation and who therefore choose not to make contractual arrangements.

4.1.2 Biopiracy and the development of technology

Patenting is said to be the only way to protect biotechnology, as it is a quickly developing sector and technologies are easy to copy⁹⁸. Statistics show that the number of biotechnology patents is increasing⁹⁹. At the same time, the process of gathering genetic resources for use in product development and inventions is not well accepted in provider countries, and many NGOs oppose it¹⁰⁰. The gathering of genetic resources is often referred to as "biopiracy", though there are different definitions of what constitutes biopiracy. Some mean that biopiracy

⁹² WTO, Council for Trade-Related Aspects of Intellectual Property Rights, *The Relationship Between the TRIPs Agreement and the Convention on Biological Diversity*, IP/C/W/368/Rev.1, p. 12

⁹³ ibid, p. 11

⁹⁴ ibid, p. 12

⁹⁵ ibid, pp. 12 and 35

⁹⁶ ibid, p. 23

⁹⁷ ibid, p. 24

⁹⁸ Tsioumanis, Asterios; Konstadinos, Mattas; Tsioumani, Elsa, Is Policy towards Intellectual Property Rights Addressing the Real Problems? The Case of Unauthorized Appropriation of Genetic Resources, Journal of Agricultural and Environmental Ethics, no. 16, 2003p. 614

⁹⁹ WIPO, Initial Report on the Technical Study on Disclosure Requirements Related to Genetic Resources and Traditional Knowledge, WIPO/GRTKF/IC/4/11, p. 4 (footnote)

¹⁰⁰ Richerzhagen, Carmen; Holm-Mueller, Karin, *The effectiveness of access and benefit sharing in Costa Rica: Implications for national and international regimes*, Ecological Economics 53, 2005, p. 450

is the result of insufficiencies in patent examinations due on inaccessibility of TK for patent examiners, which leads to wrongfully granted patents. Others suggest that even patents granted in accordance to national patent laws may be biopiracy, in cases where inventions are based on genetic resources and TK but PIC and benefit sharing have not taken place.¹⁰¹

Should TRIPS provide a way for provider countries and TK holders to profit from the collecting of genetic resources and following patenting and commercialisation of products based on TK and genetic resources, the image of biotechnology companies might improve, and further development of the biotechnology industry may benefit from it. Making national access regulations more homogenous could both prevent national regulations from becoming too strict and therefore driving biotechnology companies away, as well as giving provider countries a higher level of security¹⁰². An international system for the protection of TK and genetic resources would provide greater transparency compared to a situation with different national systems, and it would be easier for companies to have an overview of what would be required of them¹⁰³.

4.1.3 TRIPS and the CBD

The Convention on Biological Diversity is an international agreement striving to achieve conservation of biological diversity¹⁰⁴, which came into force in 1993¹⁰⁵. Parties to the CBD agree that prior informed consent is required for access to genetic resources¹⁰⁶ and that benefits from commercialisation of products derived from genetic resources should be shared with the source of such resources¹⁰⁷. The CBD also gives each country sovereign rights over all genetic resources in that country¹⁰⁸, and states that the contributions made by indigenous peoples to the preservation of biodiversity should be respected¹⁰⁹.

Most countries parties to TRIPS have also signed the CBD¹¹⁰. This ought to make them obligated to implement both agreements, or at least make sure that the implementation of one does not conflict with the other¹¹¹. The CBD is not legally binding for the parties; it only

¹⁰¹ Integrating Intellectual Property Rights and Development Policy, Report of the Commission on Intellectual Property Rights, London, September 2002, p. 74

¹⁰² Richerzhagen, Carmen; Holm-Mueller, Karin, *The effectiveness of access and benefit sharing in Costa Rica: Implications for national and international regimes*, Ecological Economics 53, 2005, p. 451

¹⁰³ WTO, Council for Trade-Related Aspects of Intellectual Property Rights, *The Relationship Between the TRIPs Agreement and the Convention on Biological Diversity*, IP/C/W/368/Rev.1, p. 26

¹⁰⁴ Convention on Biological Diversity, art. 1

¹⁰⁵ bin Osman, Mohamad, Access to Genetic Resources and Benefit-sharing, International Expert Workshop on Access to Genetic Resources and Benefit Sharing, Record of Discussion, 2004, pp. 319

¹⁰⁶ Convention on Biological Diversity, art 15.5

¹⁰⁷ ibid, art 15.7

¹⁰⁸ ibid. 15.1

¹⁰⁹ ibid, art 8(j)

¹¹⁰ http://www.cbd.int/convention/parties/list.shtml, 2007-05-22, 10.50 and

http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm, 2007-05-22, 10.44

¹¹¹ Integrating Intellectual Property Rights and Development Policy, Report of the Commission on Intellectual Property Rights, London, September 2002, p. 83

provides guidelines for national legislation concerning the granting of IPR regarding biological resources. Still, the CBD and TRIPS have regulations regarding closely related areas of jurisdiction. There are requirements in the CBD concerning patenting of genetic material and TK that do not exist in TRIPS. This concerns the CBD requirements of prior informed consent and of benefit sharing.¹¹² The meaning of these requirements will be further discussed below in 4.2. Since TRIPS is a binding document, including these requirements in TRIPS could make their implementation obligatory to parties to TRIPS. Changing TRIPS would not be easy; reasons for this will be further explained below in 4.3.

Today, there is no consensus as to whether there is a conflict between TRIPS and the CBD. In this issue, there are four main views; that national implementation of the two agreements is enough to satisfy them both, that further study into the issue is needed before this question may be answered, that there is no conflict, but more could be done to ensure that the implementation of each agreement supports the other, and finally that there is a conflict between the two agreements so that TRIPS needs to be changed.¹¹³

According to the first view, there is no conflict between the TRIPS agreement and the CBD. Neither agreement mentions the other; therefore there can be no conflict between them.¹¹⁴ Parties to TRIPS are free to also implement the CBD, and implementation through national legislation is enough to satisfy both agreements. National law is also considered enough to protect TK, as TRIPS does not stand in the way of implementing both agreements¹¹⁵. The patent system is regarded as a useful tool when it comes to benefit sharing, as it may provide a basis for voluntary contracts.¹¹⁶ In negotiating contracts in each individual case, there would be more room to adjust for different interests depending on the exact circumstances. Such a system would be advantageous as it could be implemented faster than TRIPS could be changed.¹¹⁷ There would also be more possibilities for national differences, which may be positive in places where there is concern that stronger IP law would come into conflict with economic development¹¹⁸.

Some who argue that there is no conflict between the CBD and the TRIPS agreement want more research into whether national legislation is enough to deal with the protection of TK and related genetic resources. They also point to possible measures to deal with possible misappropriation other than changing TRIPS, such as increased cooperation between patent offices and information sharing.¹¹⁹

Others, who also agree that there is no conflict between the two agreements, still find that some changes to TRIPS may be needed to make sure that it is supportive of the CBD and that

¹¹² WTO, Council for Trade-Related Aspects of Intellectual Property Rights, *The Relationship Between the TRIPs Agreement and the Convention on Biological Diversity*, IP/C/W/368/Rev.1, p. 13

¹¹³ ibid, p. 4

¹¹⁴ Integrating Intellectual Property Rights and Development Policy, Report of the Commission on Intellectual Property Rights, London, September 2002, p. 84

¹¹⁵ WTO, Council for Trade-Related Aspects of Intellectual Property Rights, *The Relationship Between the TRIPs Agreement and the Convention on Biological Diversity*, IP/C/W/368/Rev.1, p. 4-5

¹¹⁶ ibid.

¹¹⁷ ibid, p. 16

¹¹⁸ ibid, p. 17

¹¹⁹ ibid, p. 5

any potential conflicts are avoided when implementing the two agreements.¹²⁰ They especially want to include disclosure of origin requirement, as well as proof of PIC and benefit sharing arrangements.¹²¹

Lastly, there are those who believe that there is a conflict between the requirements in the CBD and the TRIPS agreement. They mean that by providing the possibility of patenting genetic material, private parties may gain rights over genetic resources. This, they claim, is inconsistent with the CBD principle of every country's sovereign right over their genetic resources.¹²² They also claim that since the TRIPS agreement does not require disclosure of origin of genetic resources and TK, proof of PIC and benefit sharing, as is required in the CBD, TRIPS is unsupportive of the CBD¹²³.

4.2 New requirements for the granting of patents

As we have seen, it may be perceived that TRIPS does not provide adequate protection for TK. Therefore, it has been suggested that changes be made to TRIPS patent regulations. These suggestions of changes are mainly concerned with the formal requirements on patent applications, that is, the information that must be contained in a patent application. Today, it is enough that an invention is new, involves an inventive step and that the invention is industrially applicable. The suggested changes are that proof of prior informed consent, disclosure of origin and some scheme for benefit sharing should be included in a patent application involving genetic resources. Failure to comply with these regulations would not mean the invention is nor patentable, but would rather lead to that the application is not further processed due to it being incomplete¹²⁴. Some also want to demand more of the prior art search conducted by patent agencies before granting patents¹²⁵.

Many want the TRIPS regulations to be closer to the CBD text. The CBD grants the State sovereign rights over their national genetic resources¹²⁶. Rights of indigenous holders of TK are not regulated. Strengthening these groups may be necessary for, or a positive side-effect of, stronger protection for TK. As States realize the value of TK, the status of indigenous communities and their knowledge may rise. There may also be risk of another kind of misappropriation, that by the State itself. There are no guarantees that any income or benefits that the State may have from providing access to TK is shared with the indigenous communities providing the TK. In the past, many indigenous groups and communities have

¹²⁰ WTO, Council for Trade-Related Aspects of Intellectual Property Rights, *The Relationship Between the TRIPs Agreement and the Convention on Biological Diversity*, IP/C/W/368/Rev.1, p. 7

¹²¹ ibid.

¹²² ibid, pp. 7-8

¹²³ Integrating Intellectual Property Rights and Development Policy, Report of the Commission on Intellectual Property Rights, London, September 2002, p. 84

¹²⁴ WTO, Council for Trade-Related Aspects of Intellectual Property Rights, *The Relationship Between the TRIPs Agreement and the Convention on Biological Diversity*, IP/C/W/368/Rev.1, p. 33

¹²⁵ ibid, p. 13

¹²⁶ Convention on Biological Diversity (CBD), art. 15.1

suffered different forms of abuse. Because of this, some doubt that benefits would be passed on to TK holders.¹²⁷

4.2.1 Prior informed consent

It has been suggested that when genetic material is included in an invention for which a patent is sought, the source of that genetic material should give consent. When applying for a patent, applicants could be made to provide some form of evidence of having obtained such consent, either from the source, that is, from the relevant authority such as a government agency in the country where the genetic resource was obtained. This requirement would support the requirements of the CBD, should it be implemented. It could also aid in benefit sharing schemes and hinder misappropriation.¹²⁸

Today, it is often assumed by researchers conducting sampling that biotechnology is too complicated for indigenous peoples or people in developing countries to understand. Therefore so no real attempts are made to provide information about the research for which sampling is being conducted.¹²⁹ This means *informed* consent cannot take place, which could be considered a violation of the requirement of prior informed consent in the CBD.

The US has argued that a requirement of prior informed consent would not help developing countries. They claim that such a requirement would rather stand in the way of the further development of technology, as it would make it more expensive to obtain patents.¹³⁰ Instead, the requirement of prior informed consent could be met though the use of contracts and ordinary national contract law. Changes to TRIPS are therefore not considered to be necessary in this regard.¹³¹ Other countries seem to be of the opposite opinion. In India, for example, patent applicants must obtain the consent of the National Biodiversity Agency¹³². Countries part of the Andean pact have similar requirements, prior informed consent must be obtained both from the government and from TK holders¹³³.

¹²⁷ Berglund, Marko, The Protection of Traditional Knowledge related to Genetic Resources: The Case for a modified patent application procedure, SCRIPT-ed, vol. 2, issue 2, June 2005, p. 210

¹²⁸ UNCTAD-UNCTSD, *Resource Book on TRIPS and Development*, 2005, Cambridge University Press, p. 453

¹²⁹ Tsioumanis, Asterios; Konstadinos, Mattas; Tsioumani, Elsa, *Is Policy towards Intellectual Property Rights Addressing the Real Problems? The Case of Unauthorized Appropriation of Genetic Resources*, Journal of Agricultural and Environmental Ethics, no. 16, 2003, p. 610

¹³⁰ UNCTAD-UNCTSD, *Resource Book on TRIPS and Development*, 2005, Cambridge University Press, p. 454

¹³¹ WTO, Council for Trade-Related Aspects of Intellectual Property Rights, *The Relationship Between the TRIPs Agreement and the Convention on Biological Diversity*, IP/C/W/368/Rev.1, p. 17

¹³² UNCTAD-UNCTSD, *Resource Book on TRIPS and Development*, 2005, Cambridge University Press, p. 455 ¹³³ ibid, p. 456

4.2.2 Access and benefit sharing

Several ways to regulate access to traditional knowledge and genetic resources have been suggested. One involves the use of voluntary contracts instead of making any changes to TRIPS. Another is to use TRIPS to make benefit sharing systems part of national legislation.

Voluntary contracts between individual companies and TK holders could also provide benefit sharing¹³⁴, as parties are not likely to enter into a contract where they received nothing. A contract system would be separate from IP law, and the use of it would not be dependent on whether or not a patent is actually granted. Benefits arising from commercialisation of any products based on genetic resources and traditional knowledge could therefore be shared, regardless of the IPR situation. TRIPS would not need changes in order for this solution to come into force 135 .

There are several problems connected to the voluntary contract solution. Negotiating power of parties may differ, especially when one of them is a developing country or an indigenous group.¹³⁶ The government of the provider country often does not have the resources to forcefully negotiate with biotechnology companies, as the latter have better access to professional negotiators and legal experts¹³⁷. Few communities realise the potential value of their TK. This may also weaken their bargaining position.¹³⁸ A remedy to this problem has been proposed. Any contracts or agreements of benefit sharing entered into by traditional or indigenous communities could be revised by the authorities.¹³⁹ This may however be perceived as a declaration of incapacity of indigenous peoples, and such a solution may not be well received.

Since the hoodia case, which received a lot of attention, some communities do have knowledge and hopes of the potential economical value of their TK¹⁴⁰. Sometimes it is the TK holders themselves who contact companies or other organisations in order to find out the commercial value of their knowledge¹⁴¹. Their hopes are often somewhat exaggerated.¹⁴² The probability of developing a successful product out of sampled genetic resources is only between one in 5-10 000.¹⁴³ Such exaggerated hopes may easily lead to disappointment with

¹³⁴ WTO, Council for Trade-Related Aspects of Intellectual Property Rights, *The Relationship Between the* TRIPs Agreement and the Convention on Biological Diversity, IP/C/W/368/Rev.1, p. 17 ¹³⁵ ibid.

¹³⁶ WTO, Council for Trade-Related Aspects of Intellectual Property Rights, *The Relationship Between the* TRIPs Agreement and the Convention on Biological Diversity, IP/C/W/368/Rev.1, pp. 25-26

¹³⁷ Richerzhagen, Carmen; Holm-Mueller, Karin, The effectiveness of access and benefit sharing in Costa Rica: Implications for national and international regimes, Ecological Economics 53, 2005, p. 451

¹³⁸ WTO. Council for Trade-Related Aspects of Intellectual Property Rights, The Relationship Between the TRIPs Agreement and the Convention on Biological Diversity, IP/C/W/368/Rev.1, p. 26

¹³⁹ ibid, p. 29

¹⁴⁰ Integrating Intellectual Property Rights and Development Policy, Report of the Commission on Intellectual Property Rights, London, September 2002, p. 80

¹⁴¹ Posey, Darrell A, Dutfield, Graham, Beyond Intellectual Property. Toward Traditional Resource Rights for Indigenous Peoples and Local Communities, International Development Research Centre, 1996, p. 12

¹⁴² Integrating Intellectual Property Rights and Development Policy, Report of the Commission on Intellectual Property Rights, London, September 2002, p. 80

¹⁴³ Richerzhagen, Carmen; Holm-Mueller, Karin, The effectiveness of access and benefit sharing in Costa Rica: Implications for national and international regimes, Ecological Economics 53, 2005, p. 450

the patent system and with the companies involved. This would probably happen regardless of whether benefit sharing contracts were part of a voluntary system or required by TRIPS.

Many countries have implemented benefit sharing systems in their national laws. This indicates that they are expected to work.¹⁴⁴ The CBD states that the State has sovereign right over its genetic resources and that the State has the right to decide how access to them is to be granted. The State may therefore also declare itself entitled to a share of any benefits.¹⁴⁵ The CBD does not say that the State should make sure benefits are shared with the actual TK holders and providers of genetic material at the local level. Here, national legislation would have to go further than the CBD requires to ensure that benefits reach TK holders.¹⁴⁶ Any ABS-system would need strong governmental institutions to support and maintain them. Many developing countries lack these institutions, so the establishment of effective ABSsystems would be especially expensive for them.¹⁴⁷

The ABS-systems already in place are often perceived by companies as being complicated and expensive. This has led many to search for alternative locations for their research¹⁴⁸. which could in turn lead to fewer opportunities for the provider countries to benefit from research and resource gathering activities. The costs of further research and product development for companies are also high, and they are of great importance for the finalised product. The size of the share of benefits awarded to TK holders must be compared to how much resources were laid on further research into the TK or genetic material before the invention was commercialised¹⁴⁹.

It would take a long time before benefits may be realised, should a royalty based system be used for calculating the size of benefits to be shared. In many industries, product development and trials take several years. For pharmaceutical companies, for example, it takes 10-15 years before a product can be commercialised. If benefit sharing is to encourage preservation of TK and genetic resources, the time between providing TK and samples of the genetic resource and receiving share of benefits would need to be shortened.¹⁵⁰ Still, the patent system provides an important base for all benefit sharing systems, as the exclusive rights it grants makes obtaining these benefits possible¹⁵¹.

¹⁴⁴ Richerzhagen, Carmen; Holm-Mueller, Karin, The effectiveness of access and benefit sharing in Costa Rica: *Implications for national and international regimes*, Ecological Economics 53, 2005, p. 448 ¹⁴⁵ Convention on Biological Diversity, art 15.1

¹⁴⁶ Richerzhagen, Carmen; Holm-Mueller, Karin, The effectiveness of access and benefit sharing in Costa Rica: Implications for national and international regimes, Ecological Economics 53, 2005, p. 449, and Van Overwalle, Geertrui, Protecting and sharing biodiversity and traditional knowledge: Holder and user tools, 2005, Ecological Economics 53, p. 592

¹⁴⁷ Richerzhagen, Carmen; Holm-Mueller, Karin, The effectiveness of access and benefit sharing in Costa Rica: Implications for national and international regimes, Ecological Economics 53, 2005, p. 451

¹⁴⁸ ibid.

¹⁴⁹ Berglund, Marko, The Protection of Traditional Knowledge related to Genetic Resources: The Case for a modified patent application procedure, SCRIPT-ed, vol. 2, issue 2, June 2005, p. 208

¹⁵⁰ Richerzhagen, Carmen; Holm-Mueller, Karin, The effectiveness of access and benefit sharing in Costa Rica: Implications for national and international regimes, Ecological Economics 53, 2005, p. 450

¹⁵¹ WIPO, Initial Report on the Technical Study on Disclosure Requirements Related to Genetic Resources and Traditional Knowledge, WIPO/GRTKF/IC/4/11, p. 9

4.2.3 Databases and the prior art search

There are several databases containing TK¹⁵². One such database is the TKDL in India. This database was established after the turmeric patent was challenged and revoked. The TKDL is focused on traditional Indian medicine, and is organised in a manner similar to that of the IPC, so as to facilitate information searches by international patent examiners.¹⁵³ Another TK collection initiative can be found in Laos, where the governmentally initiated TRMC gathers medicinal TK. All communities collaborating will have a share of benefits, should they arise as a result of TK or genetic resources from the TRMC.¹⁵⁴ There are also several NGO initiatives to help indigenous peoples to document their TK and establish databases. Ecociencia in Ecuador collects TK and keeps it in closed databases. Companies interested in gaining access to TK may make benefit sharing easier.

Using databases in the prior art search is voluntary today¹⁵⁶. This could also be made a requirement in TRIPS. Mandatory database searches by patent examiners as parts of the prior art search could both help prevent wrongful patents from being granted, as well as ensure that providers of TK are rewarded¹⁵⁷.

Establishing and maintaining databases of TK would however be an ever ongoing project, as there is a great amount of TK. Gathering the TK may be difficult, especially when it is only transmitted orally. Language may also be a barrier.¹⁵⁸ Also, TK is dynamic¹⁵⁹. It is continuously developed by its users and holders. Updating the databases at the same pace as the knowledge evolves would be an enormous challenge. Databases would thus be expensive¹⁶⁰. These costs could however be covered by access fees¹⁶¹ or similar arrangements between those managing the databases and those who use it. It would probably still be unrealistic to believe that all TK could ever be documented¹⁶².

¹⁵² Posey, Darrell A, Dutfield, Graham, *Beyond Intellectual Property. Toward Traditional Resource Rights for Indigenous Peoples and Local Communities*, International Development Research Centre, 1996, p. 30

 ¹⁵³ Integrating Intellectual Property Rights and Development Policy, Report of the Commission on Intellectual Property Rights, London, September 2002, p. 81

¹⁵⁴ ibid, p. 82

¹⁵⁵ Dutfield, Graham, *TRIPs-Related Aspects of Traditional Knowledge*, Case Western Reserve Journal of International Law, no. 33:2, 2001, p. 259

¹⁵⁶ WTO, Council for Trade-Related Aspects of Intellectual Property Rights, *The Relationship Between the TRIPs Agreement and the Convention on Biological Diversity*, IP/C/W/368/Rev.1, p. 13

 ¹⁵⁷ Integrating Intellectual Property Rights and Development Policy, Report of the Commission on Intellectual Property Rights, London, September 2002, p. 82

¹⁵⁸ WTO, Council for Trade-Related Aspects of Intellectual Property Rights, *The Relationship Between the TRIPs Agreement and the Convention on Biological Diversity*, IP/C/W/368/Rev.1, p. 12-13

¹⁵⁹ Berglund, Marko, *The Protection of Traditional Knowledge related to Genetic Resources: The Case for a modified patent application procedure*, SCRIPT-ed, vol. 2, issue 2, June 2005, p. 207

 ¹⁶⁰ WTO, Council for Trade-Related Aspects of Intellectual Property Rights, *The Relationship Between the TRIPs Agreement and the Convention on Biological Diversity*, IP/C/W/368/Rev.1, p. 13

¹⁶¹ Posey, Darrell A, Dutfield, Graham, Beyond Intellectual Property. Toward Traditional Resource Rights for Indigenous Peoples and Local Communities, International Development Research Centre, 1996, p. 29

 ¹⁶² Integrating Intellectual Property Rights and Development Policy, Report of the Commission on Intellectual Property Rights, London, September 2002, p. 83

4.2.4 Disclosure of origin

It has been suggested that a requirement concerning disclosure of origin should be made a part of TRIPS. The requirement would mean that when an invention is based on a genetic resource or TK, the origin of this must be revealed in the patent application.¹⁶³

Today, disclosure of origin is indeed sought or recommended in many national patent laws¹⁶⁴ but there are seldom any legal consequences for those who do not provide this information¹⁶⁵. This is sometimes said to have to do with the fact that disclosure of origin may not be necessary for a person skilled in the art to be able to carry out the invention¹⁶⁶. When the source of the genetic resource is a plant or animal which is rare, the application does tend to reveal the country of origin, as it would otherwise be difficult for a person skilled in the art to reproduce the invention. With rather common genetic resources as the base for inventions, the origin is seldom revealed.¹⁶⁷

In cases where patents are not granted for genetic material in the form it occurs in nature, not disclosing the origin of genetic material used in an invention could lead to the wrongful granting of a patent. The patent examiner will have great difficulty in determining whether or not the invention is actually an invention or if it only a discovery, which ought not to gain patent protection. Such a patent could of course still be challenged and revoked, should this be discovered.¹⁶⁸ The process of investigating prior art ought also to be made simpler, should disclosure of origin be compulsory. Patent investigators could narrow and concentrate their searches somewhat.¹⁶⁹

National legislation may not be enough, as some patents are based on genetic resources and TK that were removed illegally and in secret¹⁷⁰, so called biopiracy¹⁷¹. A mandatory requirement that all patent applications should contain information of the origin of any genetic resources and TK used in the invention for which a patent is sought could strengthen national ABS regulations¹⁷². If disclosure of origin were obligatory, it would be simpler to verify that

¹⁶³ WTO, Council for Trade-Related Aspects of Intellectual Property Rights, *The Relationship Between the TRIPs Agreement and the Convention on Biological Diversity*, IP/C/W/368/Rev.1, p. 28

¹⁶⁴ WIPO, Initial Report on the Technical Study on Disclosure Requirements Related to Genetic Resources and Traditional Knowledge, WIPO/GRTKF/IC/4/11, pp. 20-21

¹⁶⁵ ibid, p. 26

¹⁶⁶ ibid, p. 22

¹⁶⁷ ibid, pp. 21 and 27

¹⁶⁸ UNCTAD-UNCTSD, *Resource Book on TRIPS and Development*, 2005, Cambridge University Press, p. 366-367

¹⁶⁹ WTO, Council for Trade-Related Aspects of Intellectual Property Rights, *The Relationship Between the TRIPs Agreement and the Convention on Biological Diversity*, IP/C/W/368/Rev.1, p. 35

¹⁷⁰ Integrating Intellectual Property Rights and Development Policy, Report of the Commission on Intellectual Property Rights, London, September 2002, p. 83

¹⁷¹ Van Overwalle, Geertrui, *Protecting and sharing biodiversity and traditional knowledge: Holder and user tools*, 2005, Ecological Economics 53, p. 588

¹⁷² bin Osman, Mohamad, Access to Genetic Resources and Benefit-sharing, International Expert Workshop on

genetic material and TK were obtained in accordance with national legislation in the country of origin.

The biotechnological industry consists of a relatively small number of very large companies, and a rather large number of small ones. The large companies tend to cooperate with the smaller ones, and mergers happen frequently. Genetic resources may thereby pass between several companies before ending up as part of a finished product. Requiring disclosure of origin could make it easier to keep track of these genetic resources and thus to make benefit sharing schemes less complicated to enforce.¹⁷³

Problems with disclosing origin may also arise when the genetic resource has been obtained from a collection instead of from its original source location. Botanical gardens, herbariums and gene banks are examples of such collections¹⁷⁴. Using genetic material from collections is common practice, and may complicate locating the real origin of the resource as collections have often been gathered over a long period of time¹⁷⁵. Where genetic resources have been gathered more recently it is probably unlikely that the origin of sampled genetic resources is completely unknown. Companies researching genetic material should want to know as much as possible about a genetic resource, in order to find TK related to it. Also, since the CBD came into force requiring benefit sharing with countries providing genetic resources, most collections are believed to contain this information. Exceptions from the requirement of disclosing origin could be made in cases where it has proven truly impossible to find.¹⁷⁶

India's patent act requires disclosure of origin, an application may be rejected and a patent revoked should it be found not to meet this requirement.¹⁷⁷ It is not clear whether making failure to disclose the origin of genetic material to be grounds for rejecting patent applications and revoking patents is permitted by the current TRIPS text, as this requirement is mentioned in neither of articles 27 or 29¹⁷⁸. These articles are concerned with patentable subject matter, and conditions on patent applicants, respectively¹⁷⁹. Therefore, it is possible that such grounds for invalidation may be counter to TRIPS. The EC also requires that patent applications concerning genetic material contain disclosure of origin if it is known and deemed appropriate, but there are no consequences to the granting of the patent or to the rights conferred by the patent in cases where the origin is not revealed¹⁸⁰, and this requirement is not legally binding for the members of the EC¹⁸¹. It is mainly developing countries who wish to

Access to Genetic Resources and Benefit Sharing, Record of Discussion, 2004, pp. 322

¹⁷³ Richerzhagen, Carmen; Holm-Mueller, Karin, *The effectiveness of access and benefit sharing in Costa Rica: Implications for national and international regimes*, Ecological Economics 53, 2005, p. 451

¹⁷⁴ Posey, Darrell A, Dutfield, Graham, Beyond Intellectual Property. Toward Traditional Resource Rights for Indigenous Peoples and Local Communities, International Development Research Centre, 1996, pp. 22-24

¹⁷⁵ Integrating Intellectual Property Rights and Development Policy, Report of the Commission on Intellectual Property Rights, London, September 2002, p. 85

¹⁷⁶ ibid.

¹⁷⁷ UNCTAD-UNCTSD, *Resource Book on TRIPS and Development*, 2005, Cambridge University Press, p. 455

¹⁷⁸ ibid, p. 453

¹⁷⁹ Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), art. 27 and 29

¹⁸⁰ Directive 98/44/EC of the European Parliament and of the Council of July 6 1998 on the legal protection of biotechnological inventions, recital 27

¹⁸¹ WIPO, Initial Report on the Technical Study on Disclosure Requirements Related to Genetic Resources and Traditional Knowledge, WIPO/GRTKF/IC/4/11, p. 20

have TRIPS to include an obligatory requirement of disclosure of origin for patent applicants¹⁸².

4.2.5 Self-regulating patent offices

Patent offices could be made to investigate complaints regarding patents they have previously granted themselves, instead of referring complainants to national courts. This might provide a solution to the lack of resources that may hinder some complainants, especially those from developing countries. This could provide a both quicker and cheaper way of challenging granted patents.¹⁸³

There are several problems attached to this approach. One is that patent offices might prove reluctant to admit to having made mistakes when first granting a patent. Another is that some might not want to conduct another investigation into the same patent for financial or other reasons; a new investigation might not actually take place, only a re-evaluation of the same material. Issues of loyalty might also arise, where different departments within the same organisation do not wish to reveal the mistakes of others. It may prove difficult to reach a sufficient level of transparency in patent re-evaluations, should self-regulating patent offices be introduced.

4.3 Is change possible?

Making changes to TRIPS would be a very complicated process. In order to make changes that alter the obligations of the countries already parties to TRIPS, a majority of 2/3 of the Ministerial Conference¹⁸⁴, which meets at least once every other year¹⁸⁵, must vote to bring the suggestion in front of the WTO General Council. There, a majority of 2/3 is also required to pass the changes. However, these changes only become binding to the countries voting for it. Those who vote against are not bound by it.¹⁸⁶

As countries are generally opposed to anything that reduces their national sovereignty¹⁸⁷, it is probably very unlikely to see these changes to TRIPS take place. Even though the majority of WTO members are developing countries, they constitute a large group with many different interests. Their cooperation is limited, though their interests in IPR issues are often more

¹⁸² UNCTAD-UNCTSD, Resource Book on TRIPS and Development, 2005, Cambridge University Press, p. 457

¹⁸³ UNCTAD-UNCTSD, Resource Book on TRIPS and Development, 2005, Cambridge University Press, p. 367

¹⁸⁴ Seth, Torsten, WTO och den internationella handelsordningen, Studentlitteratur, Lund, 2004, p. 57-58

¹⁸⁵ ibid, p. 52

¹⁸⁶ ibid, p. 57-58

¹⁸⁷ Seth, Torsten, WTO och den internationella handelsordningen, Studentlitteratur, Lund, 2004, p. 53

similar than in other areas. ¹⁸⁸ There is however increasing cooperation between developing countries in the area of TK protection outside of the WTO¹⁸⁹.

 ¹⁸⁸ Seth, Torsten, *WTO och den internationella handelsordningen*, Studentlitteratur, Lund, 2004, p. 70
 ¹⁸⁹ Quach, Uyen; Thorsteinsdottír, Halla; Renihan, James; Bhatt, Archana; Costa von Aesch, Zoë; Singer,

Peter.A; Daar, Abdallah.S, *Biotechnology patenting takes off in developing countries*, International Journal of Biotechnology, vol. 8, nos ½, 2006, p. 56-57

5. Conclusions

In this chapter, I have gathered some of my own reflections and conclusions.

5.1 International Negotiations

The issue of patenting genetic resources and of related TK is discussed in several international fora. This entails a certain amount of work done more than once. In many cases, the results of lengthy negotiations are simply recommendations that are non-binding to the parties involved. Why does this continue to happen? Would it not be better to gather these resources in one joined effort to reach a binding agreement, which would be followed?

5.2 The Value of Biotechnology

The value of biotechnology to humanity is undoubtedly great, and can probably not be measured using money only. Many modern medicines are based on or have been developed using some sort of genetic resources. A lot of these genetic resources have been obtained from developing countries, using TK as a guide. Lives are being saved, money is being made, but some are left behind. Do the positive effects brought on by the contributions of a strong biotechnological industry motivate the negative ones?

If it was compulsory to reveal the source of any genetic resources used, the prior art search might also be made to include prior use as well as common knowledge and TK in the country of origin of genetic resources and TK. Should the prior art search include prior art in the country of origin, and should the fact that the invention is common or traditional knowledge there prevent patents from being granted, this may in turn dampen technological development. When companies find it harder to gain patents for inventions based on genetic resources and TK from other countries, they might simply stop searching for these resources.

5.3 Contracts and badwill

Companies who do not comply with regulations regarding benefit sharing and PIC may experience significant badwill from customers. Increased awareness amongst consumers has led to greater importance for companies to be perceived as acting in accordance with consumers morals.¹⁹⁰ This ought to make them more likely to ensure PIC and enter into voluntary contracts regarding benefit sharing as well as respecting these contracts. The fear of badwill may also provide enough incentive for companies to comply with national regulations regarding PIC and benefit sharing¹⁹¹. When the inventions lead to pharmaceutical products however, customers may not have many alternatives. Given the choice of buying medicine that could save your life, but which is provided by a company which does not share its profits with TK holders, or not buying the medicine, I believe most people take the second option.

It can also be added that although many companies have their own guidelines in dealing with parties in developing countries, few actually follow them¹⁹². In regard to pharmaceuticals therefore, it might not be possible to rely on the market forces and the power of consumers. As a large part of the medicines used today are based on TK, changes to the current IP systems may be motivated.

5.4 Objectives and principles of TRIPS

The objectives of TRIPS state that: "*The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation… in a manner conducive to social and economic welfare…*".¹⁹³ According to the principles "*measures…may be needed to prevent the abuse of intellectual property rights by right holders…*¹⁹⁴ Based on this, it could be argued that in order to be truly consistent with its own objectives and principles, TRIPS should provide for better protection for TK and stronger rights for its holders. Benefit sharing could increase the welfare of developing countries, and especially indigenous peoples within them. Requiring of disclosure of origin of TK and genetic material would hopefully reduce misappropriation and "biopiracy", practices which must be considered as abuse of IPR.

¹⁹⁰ Van Overwalle, Geertrui, *Protecting and sharing biodiversity and traditional knowledge: Holder and user tools*, 2005, Ecological Economics 53, p. 601

¹⁹¹ Integrating Intellectual Property Rights and Development Policy, Report of the Commission on Intellectual Property Rights, London, September 2002, p. 85

¹⁹² Berglund, Marko, The Protection of Traditional Knowledge related to Genetic Resources :The Case for a modified patent application procedure, SCRIPT-ed, vol. 2, issue 2, June 2005, p. 212

¹⁹³ Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), art. 7

¹⁹⁴ ibid. art. 8

5.5 A case for higher requirements on applicants

Monopoly rights should only be awarded in exceptional cases in a free market, as they may have many adverse effects through distorting prices and reducing the spreading of goods. The rights awarded to the person obtaining a patent are also quite valuable, and are of great importance to industry. Therefore, requirements on patent applicants should be high in order to ensure that patents are not granted wrongfully. The process of challenging and possibly revoking an already granted patent is expensive and burdensome, especially for parties in developing countries. Most TK and genetic resources are found in these countries, which could mean that many wrongfully granted patents go unchallenged. More pressure could be applied to patent applicants to ensure their applications contain the information needed to ensure the correct granting of patents and sharing of benefits arising from patents to holders of TK used. This ought to be cheaper than challenging patents post-grant, and the costs would be carried by those who wish to obtain the monopoly rights and make use of the patent system instead of by those knowledge may have been exploited. This, I believe, would be no more than fair.

5.6 The Medicine Man

Had Sean Connery's doctor indeed found the cure for cancer deep in the jungle in that movie, the tribe probably would not have been awarded any rights to the cure through the patent system of today. They could hardly be said to have contributed to the doctor's search more than by assisting him in gathering the flowers, which is hardly enough to count as contributing to the inventive process. Hopefully, Sean Connery's doctor would have made sure that the people he had lived amongst for years would at least be abled to continue living in the manner they wished, away from the threats of the foresting company. Although the movie example does not completely cover the circumstances I have studied, it may still provide an illustration of some of the problems associated with TK and genetic resources. The holders of TK can not be said to receive sufficient acknowledgement through the TRIPS patent system as it is today.

TK holders ought not to have to rely on the benevolence of those who use TK in inventions and patented products. It is time to find a way to satisfy both the biotechnological industry's demand for genetic resources, and the needs of those who hold the knowledge of them. Perhaps some of the suggestions to changes to TRIPS could provide just that.

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