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Biopiracy, the CBD and TRIPS –
The Prevention of Biopiracy

Master thesis
20 points

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Intellectual Property

Spring 2004

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(From *Rig Veda*, Hymn to the Healing Plants)

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Executive summary

Biopiracy is defined as the commercial development of naturally occurring biological materials, such as plant substances or genetic cell lines, by a technologically advanced country or organisation without fair compensation to the peoples or nations in whose territory the materials were originally discovered. The problem is growing but as of today, there is no common view on how this problem should be regulated. Two conventions that are related to the subject are the Convention on Biological Diversity (the CBD) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Some advocates that there is a conflict between these two conventions, some that there is no conflict, often with the argument that they do not deal with the same subject matter.

The paper has three purposes. It presents the subject of biopiracy in a more general view but also finds out if there is a conflict or not between the two conventions mentioned above and tries to find a solution to this problem. The main focus is on medicinal products. The third purpose is to make some practical and legal proposals in order to reduce the cases of biopiracy, which are summarized in Supplement A.

The two conventions are presented both from a general view and a specific view with focus on the respective articles being related to biopiracy. The paper further penetrates the eventual conflict between the two conventions, especially the *legal* versus the *policy* conflict. It is found that it depends on how you look at the conventions, if there is a conflict or not. Other legal perspectives are being presented, such as professional self-regulation and national regulations. The US Patent Regulation is treated separately within this section.

The case history shows actual examples of biopiracy. Biopiracy does exist and it might help to challenge an approved patent application. In order to get a broader approach to the subject, views from some significant relevant organisations are being presented.

The summary shows that those being dependent of intellectual property rights, such as large pharmacy corporations and scientists, are advocating that there is no conflict between the conventions and the “victims” of biopiracy are advocating that there is a conflict and that the protection is weak.

The conclusion is that there *might* be a conflict between the two conventions – the legal situation today is uncertain. Whatever the case may be, there is a need for biopiracy to be regulated since it *is* in fact taking place and the indigenous peoples are not being protected enough. The two conventions deal with different issues. The CBD deals with the protection of biological diversity, sustainable use of its components and the fair and equitable

sharing of the benefits arising out of the utilisation of genetic resources, and TRIPS deals with the protection of intellectual property but in some areas the two interrelate. A conceptual distinction between legal issues and policies must be drawn.

It is concluded that the US Patent Law is a big source of the biopiracy cases. The fact that the US Patent Law does not recognise use of an invention as *prior art* makes it possible for American inventors to patent such inventions that have only been *used* (and not patented or described in a publication). The USA needs to revise their Patent Law in order to prevent biopiracy.

Another alternative is to add a rule to TRIPS (which the USA is a member of) that states that a patent application can not be approved if the invention is known, used or described in a trade publication in any of the member states of TRIPS. It might also be appropriate to insert a rule in either the US Patent Law or TRIPS that forces the patent applicant to define the source country or area of the invention when applying for the patent.

The final conclusion is therefore that TRIPS and the CBD can and should be implemented in a mutually supportive way. They should not undermine each other's objectives. It is also concluded that the USA needs to revise their Patent Law in order to recognise all inventions – documented or not – in countries other than the USA as *prior art*. An alternative is to add such a rule to TRIPS, which the USA are a member of.

It is further stressed that the explorers of nature should have a great amount of respect when exploring nature. Respect can be shown in different ways. One way is to give fair and equitable sharing in accordance with the objectives of the CBD; another is to get prior informed consent from the indigenous peoples. The indigenous peoples can also secure their knowledge in a number of ways: they can document their traditional knowledge, create databases, develop a *sui generis* system and create alliances.

Abbreviations

ABS	Access and Benefit Sharing Agreements
CBD	Convention on Biological Diversity
COICA	Co-ordinating Body of Indigenous Organisations of the Amazon Basin
CPR	Common Property Rights
EFFPIA	the European Federation of Pharmaceutical Industries and Associations
EPC	the European Patent Convention
ETC	the Action Group on Erosion, Technology and Concentration
GRAIN	Genetic Resources Active International
ICC	the International Chamber of Commerce
IFPMA	the International Federation of Pharmaceutical Manufacturers Associations
IP	Intellectual Property
IPR	Intellectual Property Right
LDCs	Least Developed Countries
NGO	Non Governmental Organisation
TK	Traditional Knowledge
TM	Traditional Medicine
TRIPS	the Agreement on Trade-Related Aspects of Intellectual Property Rights
TWN	the Third World Network
UN	the United Nations
USA	the United States of America
WHO	the World Health Organisation
WIPO	World Intellectual Property Organisation
WTO	the World Trade Organisation

1 Introduction

In this chapter, a short introduction to biopiracy will be presented. The purpose, disposition, limitation, method, material and previous research on biopiracy are also presented.

Biopiracy is a problem among developing countries where indigenous peoples have great knowledge over plants that carry medicinal properties. Individual scientists or corporations go to different developing countries, learn about the indigenous peoples' knowledge about certain plants or substances, then go back to the scientist's or corporation's native country and patent it there, giving the indigenous people none or very little compensation.

There are two international conventions that can be applied when dealing with biopiracy; it is the Convention on Biological Diversity (the CBD) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The main goal of the CBD is to preserve biological diversity while the goal of TRIPS is to stimulate technological advancement, giving individual rights to the inventor through intellectual property rights (IPRs). Some say there is a conflict between the two Agreements, others say there is none. As will be shown later, it is appropriate to say that the ones claiming that there is *no* conflict are the ones who are dependent on IPRs – that is, the pharmacy corporations and scientists – and the ones saying that there *is* a conflict are the indigenous people who are the victims of biopiracy and the ones advocating their interests. This is logic. The indigenous people need the protection which the CBD and TRIPS in combination, according to them, fails to give them. The pharmacy corporations and scientists want more freedom to continue their research all over the world and protect their eventual inventions; therefore they claim that there is no conflict.

1.1 Purpose

This paper has three purposes: A *general* purpose is to highlight the subject of biopiracy and give a general overview of the subject since not many people are aware of the problem. A *specific* purpose of the paper is to find out if there is a conflict or not between the CBD and TRIPS and if this conflict affects the problem of biopiracy. The purpose of the paper is also to

make some proposals – both practical and legal – on how the biopiracy cases can be reduced in number. The purpose is not to choose side – the goal is to be as objective and neutral as possible.

1.2 Method

When writing a paper in law, there are two basic models of method to choose from: the *regulation oriented approach* and the *problem- and interest oriented approach*. These models are each being described in a three step model by the Swedish professor Peter Westberg.¹

In the *regulation oriented approach*, a certain rule is presented as an object for the examination. Thereafter, this rule is reformulated to the certain problem that the author is about to exam. The last step in the model is the exam in itself, a penetration which is usually done in the form of an analysis.

In the *problem- and interest oriented approach*, the first two steps are connected to the papers' introduction. The first step is to present the object of the paper as an actual phenomenon in our legal life. The second step is a phase of "inventory". The author shall in an appropriate and perspicuous way explain what the problem is with the phenomenon, which interests should be concerned at the treatment of the problem, what alternatives or complementary solutions there might be to the problem and so on. In the last step the actual examination is done. This can be analytical-descriptive, but it can also be synthetic, critical or constructive, the common case is a mixture of the different methods. The disposition is relatively free.

This paper is written from such a *problem- and interest oriented approach*. The approach was chosen because of the width of the subject. Biopiracy is a big subject and cannot be treated only from a certain rule or regulation. There are many aspects to the problem other than legal: human, ethical, sociological, philosophical, economical and so on. The problem- and interest oriented approach therefore fits the subject of biopiracy better than the regulation oriented approach. The regulation oriented approach has some room in the paper, since it is hard or even impossible not to look at the current regulations as a source of information as the accuracy of theories, arguments and explanations must be tested. This goes especially for the part

¹ Westberg, p.424 ff.

where the CBD and TRIPS are being compared. The examination is always normative in a way, since rules must be constructed, criticised or explained. The approach makes it possible to have a focus on the empirical part of law, something that is obvious in this paper. It is the *practical* and not the *theoretical* law that is being examined which leads the author to examine, describe and explain regularities and irregularities in the chosen subject.

1.3 Limitation

1.3.1 Pharmaceutical products

Biopiracy is a big subject – bigger than most people think. It has therefore been necessary to narrow the paper. The paper is limited to the conflict of the CBD and TRIPS in the light of pharmaceutical products. The pharmaceutical products were chosen because of their great importance to humanity: 80 per cent of the World's population depends on traditional medicine for its primary health needs.² In some parts of the paper it has been necessary to briefly highlight other areas than pharmaceutical products, such as agricultural products. An introduction to biopiracy is necessary to give the basics of biopiracy to a reader who is not fully familiar with the subject.

1.3.2 Biopiracy – not bioprospecting

It can not be stressed enough, that there is a clear difference between *biopiracy* and *bioprospecting*. You are not a biopirate, just because you are bioprospecting. Bioprospecting is the search for biological resources and accompanying indigenous knowledge – primarily for the purpose of commercial exploitation. As such, while bioprospecting is not contrary to the interests of indigenous peoples or a threat to biodiversity, it can facilitate biopiracy. In other words, bioprospecting identifies biological resources (which might be traditional knowledge) with commercial potential, while biopiracy appropriates these resources and knowledge without obtaining prior informed consent or awarding just compensation.³ Biopiracy arises first when there is a claim of the action taken without prior informed consent or awarding of just compensation. The paper deals exclusively with the cases of biopiracy.

² UN TD/BCOM.1/EM.13/2 p. 5.

³ Biopiracy.

1.3.3 Indigenous peoples

Biopiracy may occur both in developed and developing countries. This paper is limited to traditional medicine, indigenous peoples and the events when they have been victims of biopiracy. The reason for this is that indigenous peoples are the most common victims of biopiracy.

1.3.4 International and national regulations

The CBD and TRIPS are not self executing, international regulations. The national laws differ. It is of course interesting to take a look at these national laws, but it is unfortunately not possible due to limitation of size of the paper. For reasons that later will become obvious, the US Patent Law is being highlighted.

1.4 Material

The first thing I did to get oriented in the field of biopiracy was to search the Internet. There is not much traditional, legal, printed literature on biopiracy, so the primary source of information is the Internet. There are some disadvantages with the Internet: It is a changing, dynamic source; the different sources used may be erased; the ethics and laws on the Internet are not fully developed and some sources may be considered as non-serious. On the Internet, information flows freely. Compared with a printed book, it is very cheap to publish different opinions on the Internet. If you have chosen to publish your view in a book, you are taking a risk in the cost of producing the book; therefore it is fair to say that printed literature in general is more serious than material published on the Internet.

However, being aware of the above disadvantages of the Internet as a source when working on a scientific paper as the present, the Internet is a great source of information, just because it is, as mentioned above: dynamic and cheap, so minor organisations can public their views fast, easy and without any major costs. As an assurance of quality of the paper all the Internet sources used for the paper are available in printed, dated format.

When material from the different webpages is being used, the footnotes are somewhat different from footnotes emanating from printed literature. Since the articles found on the web (except pdf-files) do not have any page numbers, this detail can unfortunately not be added. However, when

searching the needed information, it is easy to search the specific webpage electronically with help of the Internet browser and the information needed can easily be found in such way. Therefore, I do not see this as a problem. Biopiracy is a sensitive subject, no doubt about it. The interest in biopiracy is big, but it seems like the problem is treated mostly by Non-Governmental Organisations. The explanation can be found in the above described fact that the indigenous peoples and the ones fighting for their rights say that there is a conflict between the CBD and TRIPS and that the pharmacy corporations and scientists say that there is none. There is no reason for the pharmacy corporations and scientists to do any further research and produce publications treating the conflict, since they already have their view that there is no conflict. Because of this, it is hard to find material, published by them.

This makes it a bit hard for a researcher who wants to describe the problem in a neutral, objective way, since the views of many of these organisations are quite radical. It is a common view among these NGOs that the victims of biopiracy must be protected, no matter what, from the thieves living in the West world, namely the United States of America. It is true that most of the biopiracy-cases emanate from the USA and that the indigenous people with traditional knowledge needs protection, but the organisations fighting for them many times may have a too radical view; one must therefore be careful and critical when reading and using those sources.

There are some publications concerning biopiracy that are more neutral and objective. Those are the ones produced by established international organisations such as the United Nations (UN), the European Union (EU), the World Health Organisation (WHO) and World Intellectual Protection Organisation (WIPO), but also to some extent the World Trade Organisation (WTO). Of course, it is important to be critical also when reading these sources, since most of them are pro-IPRs, but it can be expected that they are a bit more neutral and not as radical as the publications made by the NGOs.

1.5 Previous Research on biopiracy

There is only one written publication, fully dedicated to the subject of biopiracy, the book *Biopiracy – the Plunder of Nature and Knowledge* written by the Indian author Vandana Shiva. Mrs. Shiva is one of the world's most dynamic and provocative thinkers on the environment,

women's rights and international affairs. She is a physicist, ecologist and activist and has won the Right Livelihood Award, also known as the alternative Nobel Peace Prize, in 1993. She also directs the Research foundation for Science, Technology, and Natural Resource Policy, is an Associate editor of *the Ecologist*.⁴ She has her own homepage concerning mostly biopiracy [www.vshiva.net]. Another book by Mrs. Shiva, related to the subject of biopiracy is - for the interested reader who wants to learn more - *Stolen Harvest. Biopiracy* is a controversial book and it is written by a radical scientist, who is not a lawyer, but it has helped to keep the debate on biopiracy alive and many of the Internet resources cite the book or build their texts upon it.

There are also many NGOs such as the TWN, GRAIN and the ETC who all have done some impressive research about biopiracy and their results and views are found easiest on the Internet.

1.6 Disposition

In chapter 2, an introduction to the subject is given to orientate the reader on the basics on biopiracy. After this introduction, some statistic facts about the economical significance of biopiracy will be given, to show that it is in fact a big concern.

When feeling comfortable with these basic facts about biopiracy, we will move on to the legal perspective in chapter 3. Following a structure of *problem- and interest oriented approach* the two major agreements that concern biopiracy will be treated: The CBD and TRIPS. First, they will be treated separately from each other, with highlights on special provisions that are of significant importance to biopiracy and medicines. Then, they will be put together in a chapter named *Conflict between TRIPS and the CBD*. After this relatively massive part, a very relevant part will treat national laws and professional self-regulation which are two ways to deal with biopiracy. In this part, the significance of the US Patent Law will be highlighted. There are no general punishments for biopirates, but some consequences that may occur if you are being considered a biopirate will be shown in chapter 4. In chapter 5 a case history of significant medicine biopiracy cases will be given. This section is more to be seen as practical examples of biopiracy events from around the world than an analysis of legal cases in court. In chapter 6 you will find different views on biopiracy and the eventual

⁴ Shiva (1997), back cover.

conflict between the two conventions from some chosen relevant organisations in the world.

In chapter 7 the paper is summarised, an analysis on what has been said and written is given and some proposals will be made in order to make the situation better. A supplement shows a compilation of the proposals made throughout the paper.

2 Basic Facts about Biopiracy

In this chapter some basic facts about biopiracy is presented in order to orientate the reader. Statistics are being presented in order to show why it is so important to solve the biopiracy problem. Some implications of the phenomenon will be shown and in the end of the chapter, the issue of ownership is discussed.

Biopiracy – noun. The commercial development of naturally occurring biological materials, such as plant substances or genetic cell lines, by a technologically advanced country or organisation without fair compensation to the peoples or nations in whose territory the materials were originally discovered. Other forms: biopirate – noun.⁵

The above definition, taken from the Bartleby Encyclopaedia on the Internet sums up what biopiracy is all about. But is this definition enough? There must be more to it, which we are to discover. Let's start with an examination of the above definition and break it down into pieces.

The development has to be *commercial*. That is, the plant substance or genetic cell line is going to be put on the market and sold as a product or is a part or substance of another, more complex substance. Further, it has to be *naturally occurring biological materials* meaning simply that the substance has to grow in nature and not be developed through crossing genes or chemical experiments in a lab. The biopirate has to come from a *technologically advanced country or organisation*. In most cases that is a corporation or scientist, coming from a developed country. Biopiracy is a kind of theft, as the definition implies in its' *without fair compensation*. This is one of the greatest problems with biopiracy. If there was a fair compensation - which is very rare in the actual cases concerning biopiracy – the problem would be a lot smaller. However, even if there was compensation, problems and concerns would still remain, such as ethical questions about stolen traditions, sacred materials, old traditions, religious beliefs and so on.

In developing countries, farmers breed crop varieties adapted to their local soil and/or climate conditions over several decades, in some cases centuries. The local plant breeders improve their varieties through a circular model which is based on release of the varieties of the seeds for further selection.

⁵ www.bartleby.com

The traditional varieties are not fixed structures, but dynamic such from collective efforts over generations.

An interesting variety may be locally known for its particular properties and identified by a local name, although it is unusual. This may be explained by several facts: the crop does not show the quality of stability and homogeneity required by a long and expensive process, the selection of the crop is a community work, rather than a single firm or scientist, hence no single holder or “inventor” can be identified.

The so called ethnobotanists from different firms and research facilities are prospecting biological resources, which they use for research, making new and improved products i.e. agricultural, food and pharmaceutical products. The firm may genetically engineer a close substitute from the original natural variety, adding an improvement and keeping the natural varieties desirable characteristics. The new crop can then be patented and its name trademark protected. Companies apply for a patent on the collected resource or the new products, so as to prevent competitors from using it. A biotechnological company may license production of the crop in any suitable country (see below under Hoodia cactus), and even export the product to the source-country, in which case the improved variety comes into competition with the traditional one.⁶ It is also notable that the company may ask for the intellectual protection of the modified variety in the source-country in order to protect both seeds from co-existing, and the natural variety from being sold under the traditional name. In the latter case, the source country loses its rights to produce or use the original variety for any further breeding.⁷

2.1 The Issue of Ownership

Who is the owner of nature? This question must be kept in mind when dealing with biopiracy. Is it Mankind, the Nation in which the resources are located, a specific group of people or is it a single man or woman? And who is the owner of the resource if the same species is located in two different jurisdictions? There is no common or correct answer to these questions – they are on a philosophical level.

⁶ Nationmaster on the web.

⁷ Nationmaster on the web.

The CBD clearly states that the individual state has the sovereign right to exploit their own resources pursuant to their own environmental policies.⁸ To put it in other words: When interpreting the CBD, the owner of nature is the state.

TRIPS on the other hand facilitates that individual persons or organisations can patent individual species, substances or plants. Compared to the CBD, there is a clear difference. The CBD acknowledges the ownership of nature to a group of people while TRIPS acknowledges the ownership to a single inventor.

2.2 Implications of Biopiracy

If the substance patent gets approved, the implications for the source-country can be devastating. Some examples:

- Possible necessity for the farmers to use the new patented variety, implying increasing dependence on the company “owning” the seed, especially in case of monopoly;
- Prohibition of the use of the seed for any further breeding;
- Loss of biodiversity resulting from increased monoculture and monospecies culture;
- Possible financial loss when fair agreement on benefit sharing between the source country and the company achieved;
- Possible loss of traditional community knowledge, with limited compensation.

2.2.1 Loss of Employment and National Wealth

An example of how biopiracy can affect the national wealth is the Neem case. Once the patent applicant W R Grace realised the commercial potential of neem-based pesticides, it started importing neem seeds. Because of this, the price of neem rose from INR 300 to the current level of INR 3000-6000 a ton. The high price made the neem seeds unaffordable for the local farmers. The indigenous knowledge of the neem plant was merely a folk medicine and the corporation had no intention of compensating holders and developers of the neem plant’s properties in India.⁹ It is possible that *if*

⁸ The CBD, article 3.

⁹ Gupta.

the W R Grace had given compensation to India in accordance with Article 8 (j) of the CBD which proclaims equitable sharing of benefits, the patent never would have been cancelled and the W R Grace had been able to continue their production of products containing the neem.

When the American corporation RiceTec got its monopoly on some varieties of basmati rice it had serious ramifications for India and Pakistan, not only because India is losing a big part of its 45,000 ton US import market but also its position in the European market.¹⁰

A controversial case of biopiracy is the Endod patent case. The University of Toledo has the monopoly patent on Ethiopia's endod which has been cultivated and used in African countries for centuries as a soap and shampoo and as a poison for stun fish. Later, the president of the University of Toledo advised Ethiopian scientist that they can continue their own research on endod for a US\$ 25,000 license fee.¹¹

2.2.2 Loss of Cultural Value

The Basmati is the best example of loss of cultural value. Basmati is an instance of geographic appellation that belongs to India and Pakistan. It is comparable to the geographical indications such as Champagne or Havana cigars of Cuba, but has not gotten such protection. India has won the basmati patent case in at least 15 countries. So where is the problem? The Federal Trade Commission of US has declared the term *basmati* generic thereby allowing anyone in US to call their rice "basmati". Such action clearly amounts to a decrease of India and Pakistan's identity with basmati.¹²

2.2.3 Some Statistics to Show why it is so Important to Solve the Biopiracy Problem

The market potential for plants and genetic cell lines is enormous. Some figures to strengthen this point: Around 75 per cent of the more than 7,000 existing pharmaceutical products derived from plants are based on traditional indigenous knowledge. It is estimated that 90 per cent of genetic information and traditional knowledge about species are to be found in

¹⁰ Shiva (2000), p. 85-86.

¹¹ Gupta.

¹² Gupta.

developed countries. According to the WHO, up to 80 per cent of the world's population depends on traditional medicine for its primary health needs.¹³ In India, for example, there are over 600,000 licensed medical practitioners of classical traditional health systems and over one million traditional community-based health workers.¹⁴ Over 90 per cent of the food in sub-Saharan Africa is produced using customary farming practices.¹⁵ As the above examples clearly states, for the poorest segments of societies, particularly indigenous people and rural inhabitants of developing countries, traditional knowledge is indispensable for survival.

There are at least 300 million indigenous people in the world.¹⁶ Biologists estimate that there are about 50 million species in existence. Two-thirds of these have medicinal value; and they come from developing countries, where they have been conserved and developed by the indigenous cultures in these countries for centuries.¹⁷ Adding that the estimated market value of plant-based medicines sold in OECD countries is at least US\$ 75 billion¹⁸ only strengthens the importance of an overall global legal protection of the use of traditional knowledge and not the least, protection against biopiracy. It is also worth mentioning that the organic market is growing at 20 per cent per annum.¹⁹ According to the United Nations, the practice of biopiracy without any financial or other consideration means an estimated annual loss to developing countries of US\$ 5 billion in unpaid royalties.²⁰ On the other hand, the U.S. International Trade Commission argues that U.S. industry is losing between US\$100 and 300 million per year because of weak intellectual property protection in Third World Countries.²¹ The developing countries may not need cash, but they are in deep need of schools and education, sanitary facilities, health-care, sexual education and many other things that could be provided through this loss of royalties.

¹³ UN TD/BCOM.1/EM.13/2, p. 5.

¹⁴ Hafeel, V. and Shankar, D p 3.

¹⁵ UN TD/BCOM.1/EM.13/2, p. 5.

¹⁶ WIPO/INDIP/RT/98/4A.

¹⁷ Agrawal.

¹⁸ The estimated value is based on a survey done in 1985, when the value was US\$ 43 billion.

¹⁹ Parkins.

²⁰ Globalization and Sustainable Development.

²¹ Shiva, (1997) p. 10-11.

3 Biopiracy – the Legal Perspective

In this chapter, the legal perspective of biopiracy is treated. As an introduction, a short historical background will be given. After this background the international regulations are being presented. There are many regulations but the focus is on TRIPS and the CBD and the eventual conflict between the treaties. In the end, national laws and professional self-regulation are briefly reviewed. The focus in the part about national laws is on the US Patent Law.

3.1 Historical Background

Ten years ago, the legalities of obtaining samples of plants, microbes and animals were straightforward. In many instances, a researcher could simply arrive at a field site, collect samples and take them home. There was no applicable law. The majority of the actors estimated that the biodiversity erosion was the lack of the wrong definition of ownership. Before 1992, the living species were regarded as *Common Heritage of Mankind*. As common resources, private companies and individual scientists could take and use the resource without having justification or giving compensation.²² The researcher may have, at the most, been required to obtain a permit to collect from national lands, like a fishing or a hunting license. Actions from scientists such as Charles Darwin, Commodore Perry and Richard Shultes were considered fully legal and none were legally challenged. After the implementation of the CBD, principles have been set in order to strengthen the national protection against these actions.

3.2 International Regulations

Today, there are three main ways, through which biopiracy is regulated: International regulations, national laws and professional self-regulation. We are going to start to explore the international regulations.

²² Nationmaster on the web.

The two conventions that are most relevant when speaking of biopiracy and protection of Indigenous Knowledge are, as mentioned above, the CBD and TRIPS. Let's start with an examination of the CBD.

3.2.1 The Convention on Biological Diversity

A big step was made in 1994 when the Convention on Biological Diversity (the CBD) came into force. This convention gave sovereign national rights over biological resources²³. One of the advantages of it is that it enables developing countries to better benefit from their result of traditional knowledge. Under these rules, one might expect that bioprospecting implies a prior informed consent and that it must result in a shared benefits between the biodiversity-rich country and the prospecting firm. Some critics say that the CBD must establish appropriate regulations to prevent biopiracy.²⁴

Some critics even go as far as saying that the CBD along with GATT are a prescription for a monoculture of knowledge since "these instruments are being used to universalise the U.S. Patent regime worldwide, which inevitably lead to an intellectual and cultural impoverishment by displacing other ways of knowing, other objectives for knowledge creation, and other modes of knowledge sharing."²⁵ The view can be interpreted to be radical, but a conflict can be seen within the CBD. On the one hand, the CBD protects biodiversity and gives legal space for the recognition and enforcement of indigenous rights. On the other hand, in assuring a market of shared benefits emanating from natural resources, the Convention legitimises a market for owned genes and thereby diminishes biodiversity.²⁶

3.2.1.1 Members and Objectives of the CBD

The CBD is a not self executing, international treaty devised for the protection of biodiversity, guaranteeing individual states sovereign rights over biodiversity and the patterns of its utilisation. The state regulates access to their genetic resources and can deny such access, if it appears harmful to its national interests. There are currently 175 member states to the CBD (notably, the US has not ratified the Convention). Active members include several Latin American countries, as well as India, Malaysia,

²³ Convention on Biological Diversity, art 3.

²⁴ Nationmaster on the web.

²⁵ Shiva (1997) *Biopiracy* p. 9-10.

²⁶ Burrows (1998).

Indonesia, Kenya and Ethiopia.²⁷ The preamble of the CBD states that traditional knowledge, innovations and practices are of importance to the conservation of biological diversity and that indigenous and local communities have a close and traditional dependence on biological resources.

The objectives of the CBD are conservation of biological diversity, sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources²⁸. The two most important articles in the CBD, concerning biopiracy are Article 8(j) and Article 3. Article 3 recognises the sovereign rights states have in accordance with the Charter of the United Nations and the principle of international law,

“the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of area beyond the limits of national jurisdiction.”

Let us also take a look at Article 8(i) of the CBD which reads:

“[Each Contracting Party shall, as far as possible and as appropriate:] 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 utilisation of such knowledge, innovations and practices.”

Any biodiversity legislation which is aimed at implementing the CBD needs to have a principle of sovereignty as a starting point and as a working principle. This is a topic for the *national* legislation. The sovereign biodiversity property rights, embodying both biological and intellectual heritage have to be formalised and protected as existing prior to intellectual property rights. These rights can only exist where they do not infringe on the former, otherwise it becomes an infringement and violation of sovereignty.²⁹ A possible solution, as suggested by Vandana Shiva, is that ownership of biodiversity needs to be based on a combination of rights and responsibility and a co-ownership of the state and local communities.³⁰

²⁷ CEAS Consultants, p. 10.

²⁸ CBD art 1.

²⁹ Hauge meeting targets biopiracy.

³⁰ Shiva (Internet 1).

3.2.2 The Agreement on Trade-Related Aspects of Intellectual Property Rights - TRIPS

The adoption of the TRIPS Agreement in 1994 has represented a historical change in intellectual property, with profound implications in the area of pharmaceutical patents. It seems clear that it is in developing countries where the patenting of pharmaceuticals has undergone dramatic changes. About 50 countries did not confer protection for pharmaceutical products, which TRIPS obliged all WTO Member countries to do. TRIPS sets forth minimum standards to be provided for. TRIPS establishes a general framework for the interpretation of its provisions and aim at balancing the interests of innovators and users of technology in the protection of intellectual property, in a manner that enhances *social and economic welfare*.³¹

TRIPS leaves considerable room in certain areas to legislate at the national level and, in particular, to adopt measures that may mitigate eventual negative effects of the introduction of pharmaceutical product patents.³²

Article 8.1 is of significant interest:

“Members may, in formulating or amending their national laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.”

3.2.3 Exclusions from Patentability

TRIPS does not define what an invention is; therefore, WTO Members may exclude from patentability substances which exist in nature, such as pharmaceutical products. TRIPS specifically excludes “diagnostic, therapeutical and surgical *methods*³³ for the treatment of humans”.³⁴ Article 27.2 states in addition to this that:

“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

³¹ TRIPS Art 7.

³² Correa, Carlos.

³³ Italics done by author.

³⁴ TRIPS art 27.3 a.

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 domestic law.”

Many developing countries have made use of some or all of these provisions in implementing TRIPS, thereby restricting the scope of patentability in a manner consistent with TRIPS. Examples of these are Argentina, Brazil, Mexico and Andean Group countries.³⁵ More on Article 27 below.³⁶

3.2.4 Patents on Formulations and Therapeutical Uses

The registration of patents on formulations and/or on therapeutical uses, close to or after the expiration of the original patent on an active ingredient, allows to extend – at least to some extent – monopoly rights well beyond the expiration of the original patent, thus giving rise to the so called “ever-greening” of pharmaceutical patents.³⁷ Some developing countries have been flooded by thousands of applications claiming protection for processes, second uses of known products and formulation of products. Many of these applications should be rejected if the patentability requirements were properly applied. This is where we find one part of the core of biopiracy. It is quite natural that many developing countries lack a developed system or proper authorities that can handle the applications in a correct manner. It is therefore easy for the biopirates to apply for patents in these countries. The transition to a full regime of patentability may be made in a progressive manner by carefully defining the scope of protection to be granted. In addition, the laws are in many cases not clear enough with respect to the patentability of certain alleged inventions. One very important aspect relates to the protection of *uses* of known products. TRIPS does not oblige such uses, but only products and processes.³⁸ A clear rule excluding the patentability of uses of an existing substance may permit to address the problem of biopiracy.

3.2.5 Transitional Periods

Developing countries, Least Developed Countries and economics in transition, were recognised transitional periods to implement TRIPS.³⁹ The

³⁵ Correa (1998).

³⁶ See page 23.

³⁷ Correa (1998).

³⁸ TRIPS art 27.1 and 28.

³⁹ TRIPS art. 65.

implication was obligatory for the former countries on January 1, 2000. Products which are not patentable as of that date need to be protected as from year 2005. These periods were included to allow developing countries time to elaborate and adopt the required legislation, and to design any other policies necessary to minimise the possible negative effects of the new rules. These transitional periods are automatic but unfortunately many developing countries have been under pressure by some developed countries to accelerate the pace of reforms, so as to give immediate or even retroactive application to the TRIPS standards. Many developing countries are still having a hard time in implementing TRIPS in the area of pharmaceuticals. They are facing a number of legal and administrative problems, and need to take decisions on how to deal with several important issues in the framework of TRIPS. It is clear that the transitional periods established by TRIPS were not enough. The developing countries need to change their legislation, their infrastructure for administration of IPR needs to be developed and other measures are required to reduce the eventual economic loss resulting from the new framework. Many of the patent offices have received an increased number of applications, and need to face complex issues relating to the patentability particularly of new uses, as well as to set forth rules to define the scope of the protection to be conferred.

According to some researchers, TRIPS does not extend any protection to the traditional knowledge of indigenous people. An amendment to the TRIPS implementing legislation allows the US Trade Representatives to pursue action against a country under section 301 of the Trade Act of 1974, even if that country is in compliance with its TRIPS obligation. This means that the US can issue economic sanctions against any country who attempts to protect its indigenous peoples' knowledge and biodiversity.⁴⁰

In order to develop a legal framework for the protection of pharmaceuticals that – as required by Article 7 of TRIPS – ensures a balance between the interests of producers and users of technology, several issues should be carefully examined at the national level, including the limitations to patentability, the admissibility of exceptions to exclusive rights, particularly for commercial experimentation and parallel import, and the provision of compulsory licenses.

⁴⁰ Gupta.

3.3 Conflict between TRIPS and the CBD

As mentioned in the introduction to the paper, some say that there are no tensions between TRIPS and the CBD and that they are compatible, others say that they are not. It is therefore interesting to put the two conventions against each other to find out what the situation really is, or at least, find arguments for and against to get closer to the truth and eventually find a solution to biopiracy.

3.3.1 The Legal Relationships

Most business organisations and patent experts claim that there is no conflict between the two conventions. Others see it as an open question. The claim that there is a conflict between the CBD and TRIPS can, in part be clarified by drawing a conceptual distinction between legal and policy conflicts. Rules of law are often clear, but legal principles tend to be more abstract and can stand in tension with one another. This tension can be accommodated through a process of ordering and interpretation.⁴¹ It might be true that there is no *legal* conflict between the two treaties but it would also be wrong to put an end to all discussion by saying that, in the absence of legal incompatibility, there cannot be a problem with the implementation of both Agreements. There is a considerable *interaction* between both treaties, so TRIPS and the CBD can and should be implemented in a mutually supportive way.⁴²

The CBD covers three levels: genetic resources, species, and ecosystems of which all are of use or value for humanity and all goals are equal. For the pharmaceutical industry, chemicals of medicinal value identified in individual species are the target. The CBD has no enforcement mechanism and has no dispute settlement procedure, such as TRIPS.

The objective of TRIPS are: *to* create minimum standards of intellectual protection that all states wishing to be parties to the WTO trading system must recognise⁴³; *to* ensure that states make available to rights holders institutional procedures to enforce their intellectual rights⁴⁴ and, *to* provide a

⁴¹ CEAS Consultants, p. 54.

⁴² WT7CTE/W/223 p. 2.

⁴³ TRIPS Parts I and II.

⁴⁴ TRIPS Part III.

procedure for regulating disputes between states concerning their obligations under the agreement⁴⁵.

3.3.2 Interpretation

There are some observations that are relevant to the interpretation of TRIPS and the CBD. Firstly, the CBD came into force in 1993 and TRIPS in 1995 and neither treaty states that it is subject to the other. Article 22 of the CBD states that the CBD shall not affect the rights and obligations of any Contracting Party deriving from any existing international agreement. TRIPS was not in existence at the time the CBD came into force. Article 30 of the *Vienna Convention on the Law of Treaties* deals with the interpretation of successive treaties relating to the same subject matter.

But are the CBD and TRIPS dealing with the same matter? It is doubtful and there is an ongoing debate. TRIPS deals with standards on intellectual property law and the CBD with control over biological diversity. If we are to follow the Vienna Convention, then TRIPS would rule, since special rules go before general and new treaties go before older.⁴⁶ TRIPS is a more detailed treaty than the CBD which requires its contracting parties to take measures to meet the goals of the convention and tend to create obligations of a general kind.

Article 16(5) of the CBD recognises that IPRs “may have an influence on the implementation” of the CBD. It obliges states to cooperate in order to ensure that IPRs are “supportive of and do not run counter to” the objectives of the CBD. It also states that the technology transfer process is to be consistent with “the adequate and effective protection of IPRs”. The measures that states can enact under Article 16(3) in order to gain access to technology must comply with the principle of mutually agreed terms and be consistent with international law.⁴⁷ To put it in short: Article 16 of the CBD preserves the entitlements of IP owners *as they are defined in international law*, such as TRIPS. TRIPS does not refer to the principles of the CBD as regards access to genetic resources and the sharing of the benefits arising from their use. On the other hand, there is nothing in TRIPS that would prevent the sharing of the benefits arising from IP protection over inventions incorporating genetic resources or the protection of TK. At the

⁴⁵ TRIPS Part V.

⁴⁶ Vienna Convention art. 30.4(a) and 30.3.

⁴⁷ CEAS Consultants, p. 56.

same time, it is true that TRIPS does not provide for direct tools to establish a link between IP protection and compliance with the principles of the CBD. The European Union has the view that, with regard to their implementation, TRIPS and the CBD should not undermine each other's objectives, rather be implemented in a mutually supportive way.⁴⁸

One must not forget that there is a considerable amount of interaction between the rights referred to in TRIPS and the subject matter of the CBD, such as patents and technology, geographical indications and habitats and so on. Geographical indications is perhaps one way to meet the goals of the CBD since the CBD recognises the existence of geographically defined areas that are regulated to achieve conservation objectives.

3.3.3 Article 27 of TRIPS

The strongest overlap between IPRs and biodiversity-related matters is in sector 5 of TRIPS which deals with patents. Article 27 requires Members to recognise both product and patent processes without any discrimination as to the field of technology, which includes biotechnology. Article 27.2 allows members to exclude from patentability inventions so as to protect ordre public or morality. Ordre public and morality include the protection of human, animal or plant life or health and the avoidance of serious prejudice to the environment. In making use of Article 27.2 Members will need to bear in mind their general obligation under Article 8 of TRIPS to adopt measures that are "consistent with the provisions of this Agreement". This makes it possible for a Member of TRIPS who finds biopiracy to be against the protection of ordre public or morality to prevent biopiracy through Article 27.2 of TRIPS and thereby exclude the patentability. In this sense, the CBD and TRIPS interact in a perfect manner. It is though, a fundamental axiom of EU and US patent law that exceptions to patent law are to be narrowly construed.⁴⁹

3.3.4 Article 27.3(b) of TRIPS

WTO Members have discretion as to the patentability of plants, animals, biological processes for the production of plants or animals and plant varieties. If they choose not to grant patent protection for plant varieties they are obliged to provide protection by means of an effective *sui generis*

⁴⁸ WT/CTE/W/223 p. 8.

system. The Article makes mandatory patent protection for micro-organisms and non-biological and microbiological processes for the production of plants and animals.⁵⁰ It is believed that some developed countries will try to remove Article 27.3(b) from TRIPS, so that there will be virtually no restrictions at all on the patenting of life-forms. This might turn into real chaos; the biopiracy-cases will increase and the developing countries will be run over.

The major IP jurisdictions are moving towards a system of multiple protection for biological resources. In a US case⁵¹, the US Court of Appeal concluded that patents over plants and seeds for new varieties of hybrid and inbred corn were patentable subject matter under 35 USC 101. The EPC contains an express prohibition on the patenting of plant varieties, but it is an ongoing trend that European patent law is evolving in a way that allows this prohibition to be overcome by means of the drafting of patent claims.

3.3.5 Legal Issues

According to the DG TRADE European Commission, the interaction between the CBD and TRIPS raises three key questions:

1. Is there a conflict between the provisions of the two agreements?
2. Does the use of IPRs in biotechnology and genetic material undermine the CBD objectives of conservation, sustainable use, indigenous knowledge and benefit sharing?
3. If the answer to 2 is yes – does TRIPS permit states to adjust their national IP laws in ways that prevent the uses of IPRs that are inconsistent with CBD objectives?

It is hard to sustain the claim that there is a direct legal conflict between the two key agreements. There is nothing in the provisions of either agreement that would prevent a state from fulfilling its obligations under both. For example: Article 3 of the CBD recognises the sovereign rights of states to exploit their own resources. IPRs are one means by which such resources may be exploited. The CBD obliges members to develop economic

⁴⁹ CEAS Consultants p. 59.

⁵⁰ CEAS Consultants p. 59.

⁵¹ Pioneer Hi-Bred International Inc. v J.E.M. Agriculture Supply.

incentive measures for the conservation and sustainable use of biological diversity. IPRs clearly qualify as such measures.⁵² The link between the two Agreements relates *inter alia* to the importance of protecting various forms of knowledge that may be utilised for fulfilling the objectives of the CBD. There is a need to protect and more widely apply scientific and technical knowledge about biological and genetic material including the biodiversity related knowledge, innovations and practices of indigenous and local communities.

On the other hand, many NGOs such as the Third World Network argue that there are inherent tensions between the granting of intellectual property rights under TRIPS with the objective of the CBD. Article 16(5) of the CBD recognises that IPRs can have a negative effect on the implementation of the CBD provisions, and urges Parties to cooperate to ensure that the IPRs are supportive and do not run counter to the CBD objectives.⁵³

Answering question two above, the answer here will be in the light of biopiracy. A main question is whether or not a given biological resource is or is not the subject of legal ownership. The CBD gives us no answer to this. The CBD does make clear, however, that this is a matter for states to determine using their sovereign authority over natural resources. It is possible for a corporation to use IPRs to gain control over a biological resource, without breaking any legal obligations, as can be seen below in the case history of biopiracy.⁵⁴

Article 3 of the CBD establishes sovereign rights over biological resources and commits Member countries to conserve them, develop them for sustainability and share the benefits resulting from the use. In the CBD, sustainable use of biological resources means finding new drugs, crops and industrial products, while conserving the resources for future studies. The core of the CBD is that sovereign rights are tempered by providing access to genetic resources, in exchange for a share of the benefits, including access to biotechnology.

To satisfy the three goals, which are *conservation*, *development* and *benefit sharing*, the principle of sovereign rights is best applied through what have become known as Access and Benefit Sharing Agreements (ABSs).⁵⁵ Under the CBD, prior informed consent is the standard for ensuring a fair and

⁵² CEAS Consultants, p. 62.

⁵³ Intellectual property rights, TRIPS Agreement and the CBD.

⁵⁴ See page 29 below!

⁵⁵ Gollin, Michael (2001).

equitable ABS. The source country must know in advance what will be done with the resource, and what benefits they will share. Benefit may include support for research and conservation, contributions of equipment and materials, assistance to indigenous and local communities, up front fees, milestone payments and royalties.⁵⁶

3.3.6 Respect

The problem can, however be solved through one simple principle: Respect. Intellectual property can be a suitable instrument for implementing the CBD. IPRs can encourage the use of genetic resources by promoting biotechnological innovation. IPRs generate financial benefits further to commercial exploitation. So provided that the CBD, national legislation and contractual arrangements on access and benefit-sharing are fully respected, there is scope for congruence of interests between users, through the use of IPRs, given that the latter contribute to creating benefits stemming from the use of genetic resources in the form of financial returns or access to the relevant technology.⁵⁷ The indigenous people will get their share through benefit-sharing from the pharmaceutical corporations who will produce and distribute the medicines based on indigenous knowledge and/or traditional medicine; a capability that a small under-developed country lacks. The world will be a healthier place and both the pharmaceutical corporations and the indigenous people will get their share. It is very simple in theory, but just as hard in practice.

3.4 National Laws

There are a lot of national biodiversity-related laws and regulations where countries have begun to exercise their sovereign rights over biological resources as established or exported without obtaining permission and satisfying certain conditions in the CBD. Many of these laws create a new category of poaching, in which biological materials are collected or exported without obtaining permission and satisfying certain conditions such as benefit sharing.⁵⁸

The national laws are too many and differ too much, both in language and provisions, in order to be treated within the frames of this paper, but it is

⁵⁶ Gollin, Michael (2001).

⁵⁷ WT/CTE/W/223 p. 8.

⁵⁸ Gollin (2001).

important to know that they do exist. There is however, one very important aspect as to national laws – the US Patent Law.

3.4.1 The Need for Change in the US Patent Laws

Most of the biopiracy cases emanate from scientists or corporations coming from the USA⁵⁹. There is an explanation: Article 102 of the US Patent Law, which defines *prior art* does not recognise technologies and methods in use in other countries as prior art. If knowledge is new for the USA, it is novel, even if it is part of an ancient tradition of other cultures and countries. The same goes for Section 102 of the US Patent Act of 1952 which defines prior art:

Novelty and loss of right to patent.

A person shall be entitled to a patent unless: The invention was known or used by others in this country or patented or described in a publication in this or a foreign country before the invention thereof by the applicant for patent.

OR

The invention was patented or described in a trade publication in this or a foreign country or in public use or on sale in this country more than one year prior to the date of the application for patent in the United States.

Use in a foreign country does not constitute *prior art* in US patent law. The US Patent Law is committed to award patent to the *true, first* inventor but is also discriminating by disregarding foreign inventions. This is indeed an old-fashioned look on inventions and other objects regarding patents. In the digital era of today, it takes seconds for information to flow from one part of the world to another so it is not at all difficult for anyone to gain access to other peoples' culture and traditions. Many developing countries are developing databases to list all the possible objects of biopiracy, just to make access easier to such information, so as to prevent biopiracy. It is clear that prior use in foreign countries is as good a prior art as anything else that is available in tangible form.

Neither the Convention on the Grant of European Patents (the EPC), nor Japan's Patent law contains a geographical prior art distinction. Japan removed their distinction in 1999. Having said this, in combination that the

⁵⁹ See below in the Case History, page 33.

major part of the biopiracy cases emanates from the USA, the USA needs to revise their patent law.

In order to stop the biopiracy cases, the USA must change their law so that use in a foreign country is *prior art*. If this is done, it will be impossible to win a national patent in the USA if the product already exists elsewhere.

Another alternative is to add a rule to TRIPS (which the USA is a member of) that states that a patent application can not be approved if the invention is known, used or described in a trade publication in any of the member states of TRIPS. Some of the indigenous people have started to document their knowledge in order to prevent others from claiming that the knowledge is not prior art.

A third solution might be that in the patent applications concerning inventions emanating from bioprospecting, it has to be mandatory to name the source of the invention and that prior informed consent has been approved to the bioprospector. If the bioprospector has gotten prior informed consent, then he or she can not be challenged as a biopirate.

3.5 Professional Self-regulation

Many institutions and professional organisations have started to implement natural products research policies for their members, and these policies have quasi-legal or contractual status.⁶⁰ The botanical gardens of Kew and Missouri, the biotech companies Shaman and Mosanto and the professional groups such as the Third World Network and the Declaration of Belem of the International Society of Ethnobiology are all examples of such policies.

⁶⁰ Gollin (2001).

4 Consequences of being considered a biopirate

This chapter shows examples of different consequences of being considered a biopirate. Those are legal penalties, cancelled patents on natural product inventions, loss of profits from illegal removal of biological material, lack of clean title to biological material, denial of access to samples and blacklisting.

4.1 Legal Penalties

The ultimate legal sanction – criminal penalties – may apply. It may and has happened that hunters have been jailed or fined for poaching or trespassing. In the biodiversity context, there is at least one case. A researcher was temporarily detained in Australia for unauthorised collection of plant materials.⁶¹ As the development in the field runs nowadays, we are likely to see more countries where collecting of biological materials without benefit-sharing agreement is likely to find its way into the list of criminal violations in some countries, so that biopiracy could result in a jail sentence, but as for now, the legal penalties are few and relatively gentle.

4.2 Cancelled Patents on Natural Product Inventions

Patents on natural product inventions are subject to attack unless all public knowledge about the species in question and its use are fully disclosed. An ongoing trend is that organisations of the bioresource-rich but economically poor countries of the developing world demonstrate a willingness to attack natural product patents on the basis of traditional knowledge, motivated by principles of justice, rather than the economic forces usually underlying patent disputes. Such examples of importance are the patents of Neem⁶², Turmeric⁶³, Ayahuasca⁶⁴, the Hoodia cactus⁶⁵ and the Tepezcohuite⁶⁶,

⁶¹ Gollin (2001).

⁶² 65 patents are filed on the Neem.

⁶³ U.S. Pat. 5,401,504.

⁶⁴ U.S. Pat PP 05751.

⁶⁵ WO 9846243.

⁶⁶ U.S. Pat. 4,883,663 and U.S. Pat. 5,122,374.

which all can be read about below. There are a lot more but these are the most important.⁶⁷

4.3 Loss of Profits from Illegal Removal of Biological Material

If a researcher removes biological material illegally from a source country, and then profits from the material, the source country or affected person could recover all or some of the profits, in a national court, based on a theory of misappropriation and related doctrines. Thus, there is a legal risk for someone who fails to reach agreement on an ABS before taking a sample home. A court is likely to impose more onerous conditions than one that could be negotiated at the outset, when success is still a highly unlikely outcome.⁶⁸

4.4 Lack of Clean Title to Biological Material

A clean title means that the biological material was obtained legitimately, and with prior informed consent from whoever had initial control over it. If there is no clean title, the value of the material is severely reduced. The collector can not pass it on to collaborators, partners or other third parties. There is more to it; if the supplier certifies that a sample was properly obtained, and it was not, the recipient could assert a contractual claim for damages back against the collector.

4.5 Denial of Access to Samples

As a practical matter, if a collector does not agree to provide an equitable share of benefits, in advance, to the source of biological samples, the collector may well be denied access to the samples.⁶⁹ The long term consequences will be that the possibilities for fieldwork will dry up.

⁶⁷ For a detailed list of substances, their names in native and English language, their corresponding use and patent numbers, see www.vshiva.net/archives/biopiracy/pirates.htm.

⁶⁸ Gollin (2001).

⁶⁹ Gollin (2001).

4.6 Blacklisting

He or she who breaks the rules will suffer from bad reputation. He or she will find it increasingly difficult to find doors open for further research. A company who one associates with biopiracy may end up with weak patents, be exposed in media, lose sources of supply, face the prospect of consumer and government boycotts, import barriers, loss of market share and may face financial penalties.⁷⁰

⁷⁰ Gollin (2001).

5 A case history of Significant Medicine Biopiracy Cases

This chapter will show some examples of biopiracy cases, where plants or substances derived from plants have been patented by citizens who are non-resident to the country in which the plant or substance was found. These cases are not to be seen as legal cases from court, but as practical events that have taken place around the world. As we are about to discover, it might help to challenge patents that infringe on a community's rights to a plant or substance.

5.1 Tepezcohuite

What is it? The Tepezcohuite is a thorny tree with a wide distribution, but the only place where it holds healing properties is in Chiapas, Mexico. It is primarily used to treat skin lesions, especially for healing burns. It has anti-inflammatory, anti-bacterial, anaesthetic and epidermal regeneration properties and is nicknamed “the Miracle Plant”.

The patent: Dr. Leon Roque, a former Chiapa filed a patent in 1986 for the powder obtained from the roasted bark. He was granted a U.S. patent⁷¹ in 1989.

Remarkable notices: Mexico is a significant country and a frequent target for bioprospectors. Mexico contains 34 out of 36 identifiable ecoclimates, is home to 25 out of 28 categories of recognized soils and contains 14,4 per cent of all the living species in the world. Dr. Roque's patent describes the traditional usage; it is only an addition being that of a sterilising step. This means that all the powder produced under traditional methods is an infringement of his patent. Roque approached an industrialist who now claims to have been granted a monopoly on the production of Tepezcohuite by the Mexican government.⁷² For the locals of Chiapas, prices have rushed high and wild resources have been depleted. Locals have to compete for access to the tree with those commercialising it for the Mexican Tepezcohuite market. Dr. Roque's patent is still valid.⁷³

⁷¹ US Pat 4,883,663

⁷² Of Patents & Pi@ates.

⁷³ Biopiracy in Mexico

5.2 The Neem

What is it? It is a fast-growing evergreen tree that contains a number of potent compounds, notably a chemical found in its seeds named azadirachtin. This compound makes it useful in many fields including leprosy, diabetes, constipation, contraception, mosquito-repellent and even as an antiseptic tooth brush.

The patent: Robert Larson, a timber importer filed a patent⁷⁴ for pesticides based on Neem and transferred the rights to the American corporation *W R Grace and Co.*

Remarkable notices: The Neem patent is one of the few biopiracy patents that have been revoked and it was done so by the European Patent Office. The US Neem patent of W R Grace is still valid.⁷⁵

5.3 The Hoodia Cactus

What is it? Hoodia (and the similar Trichocaulon) are two succulent plants indigenous to southern Africa. For long, they have been used by San and Khoi shepherds of the harsh arid environments of southern Africa to reduce hunger and thirst. The South African Army also uses it to suppress appetite. CSIR, one of Africa's largest scientific and technological research institutions and the UK Company Phytopharm have entered into an agreement to develop an appetite suppressant, which has been named *P57* derived from Hoodia. As we all know, obesity is one of the main public health problems in developed countries, so the market potential is huge.

The Patent: The international patent application WO 9846243 claims monopoly use of the *P57* appetite suppressant agent of the extracts of Hoodia or Trichocaulon and its use in pharmaceutical appetite suppressants.

Remarkable notices: The *P57* promises large profits for all research institutions involved. The projects earn royalties of what they describe as "hundreds of millions of Rand per annum for the lifetime of the patent".⁷⁶ Later, Pfizer entered into a US\$32 million license agreement with Phytopharm for the rights to the *P57* and Pfizer expects to make the

⁷⁴ US Pat. 5,124,349 and 4,556,562.

⁷⁵ Gupta.

⁷⁶ Of Patents & Pi@ates.

remarkable sum of US\$ 2-3 billion annually out of the drug.⁷⁷ No proportion of projected royalties has been earmarked for conservation, or for benefit sharing with holders of traditional knowledge about the plant. The cultivation is undertaken by commercial farmers, not by those who have traditionally nurtured the resource, or even by resource-poor farmers.⁷⁸ There are about 100,000+ San people, still living. Phytopharm's chief executive, Richard Dixey, told the *Financial Times*, "We are doing what we can to pay back, but it's a really fraught problem...especially as the people who discovered the plant have disappeared."⁷⁹ It turned out that he was wrong. The San people filed legal demands for compensation in 2001, and a benefit-sharing agreement is in the process of being negotiated through CSIR.⁸⁰

5.4 The Jamun

What is it? It is a plant; known for its anti-diabetic properties. It is common knowledge and everyday practice in India. Their use in the treatment of diabetes is documented in authoritative treatises such as the "Wealth of India", and the "Treatise on Indian Medicinal Plants".

The patent: A US patent⁸¹ was granted in 1999 to Cromak Research Inc., based in New Jersey, USA. The assignees are three non-resident Indians.⁸²

Remarkable notices: The indigenous knowledge and use of the Jamun consist of *prior art*, that is, no patent should be given where prior art exists, since patents are supposed to be granted only for new inventions on the basis of novelty and non-obviousness. As explained above, Article 102 of the US Patent Law, which defines *prior art* does not recognise technologies and methods in use in other countries as prior art. Because of this, the Jamun could be patented in the USA.

5.5 Turmeric

What is it? To many people from India, Turmeric is considered as a magic cure-all. This orange root has been used for thousands of years to treat

⁷⁷ ETC group Communiqué.

⁷⁸ Of Patents & Pirates.

⁷⁹ Firm, David.

⁸⁰ ETC group Communiqué.

⁸¹ US Patent No. 5,900,240.

⁸² Shiva (1999).

sprains, inflammatory conditions and wound healing. It is a key component of ayurvedic medicine.

The patent: Two US Scientists were granted a US patent⁸³ on the use of turmeric for healing wounds, claiming this to be novel. They did acknowledge in their application that “turmeric has long been used in India as a traditional medicine for treatment of various sprains and inflammatory conditions”, but they also claimed that there was no research on the use of turmeric as a healing agent for external wounds. The Indian government challenged the patent as theft and because of their evidence, the US Patent and Trademark office rejected the full patent claim in 1997.⁸⁴

Remarkable notices: If granted, the US patent would have prevented Indian companies from marketing turmeric for wound healing in the USA. The Indian government is increasingly concerned about biopiracy of other natural resources by foreign companies. Local communities are already victims, due to high market prices on turmeric.⁸⁵

5.6 Ayahuasca

What is it? It is used by the Amazon basin for medicinal use and religious ceremonies and it is central for many groups in the region. According to their cosmology, this is a sacred plant that has bestowed upon their knowledge about nature, cures for many illnesses and hallucinations that show “past and future”.⁸⁶

The patent: The US citizen Loren Miller claimed to have discovered a new variety in Ecuador, and in 1986 the Plant Medicine Corporation was granted US patent PP 05751 on it.⁸⁷ Miller named the product *Da Vine*.⁸⁸ The patent granted exclusive rights to sell and develop new varieties of the plant. Miller’s intention was to set up a laboratory in the Equatorial Amazon. The COICA⁸⁹ challenged the patent on the grounds of lack of novelty and distinctiveness, that it is found in an uncultivated state and as a sacred

⁸³ U. S. Pat. 5,401,504.

⁸⁴ Gupta.

⁸⁵ Of Patents & Pi@ates.

⁸⁶ Of Patents & Pi@ates.

⁸⁷ Of Patents & Pi@ates.

⁸⁸ ETC group Communiqué.

⁸⁹ Co-ordinating Body of Indigenous Organisations of the Amazon Basin.

element of many indigenous cultures of the Amazon⁹⁰. In May 1997, the COICA's fifth congress agreed to launch a public awareness campaign. They declared Miller an enemy of Amazonian indigenous peoples, prohibiting him from entering their territories and warning Miler that they could not guarantee his physical safety in the event of entering those territories. In November 1999, the patent was cancelled.

Remarkable notices: As mentioned above, the CBD gives the (contracting) nations sovereignty over its own biological resources. So unless Miller can prove he obtained the plants with official authorisation, his patent contravenes Ecuadorian law, since Ecuador is a part of the CBD. It would also contravene the right of communities to exercise control over their own resources, to be previously informed of the goals and extent of the extractions, and to grant their previous informed consent.⁹¹

⁹⁰ ETC group Communiqué.

⁹¹ Of Patents & Pi@tes.

6 Views from some significant, relevant organisations

Below, views from some relevant organisations on whether there is a conflict or not between the CBD and TRIPS are being presented. The views are nothing else but views – they are not to be considered as doctrine. When reading the following chapter, please keep in mind that it is the respective organisation's view that is being presented – not the author's. The goal of the paper is still to present the issue of biopiracy in a neutral way.

6.1 The International Chamber of Commerce

The ICC surely needs no further introduction. The ICC takes a strong pro-IPR stance. Since both agreements have been ratified by an overwhelming numerical majority of UN Members, the ICC believes that it is unlikely that there should be significant conflicts between them. TRIPS supports, by promoting IP, the CBD's objective. If there is a conflict between the two, the relevant applicable rules are found in the Vienna Law on Treaties and TRIPS is taking precedence.⁹² The ICC firmly believes that the protection of IP stimulates international trade and investment and encourages transfer of technology, which all are essential for economic growth.

6.2 International Federation of Pharmaceutical Manufacturers Associations (IFPMA)

Of course it is interesting to see what the pharmaceutical industry's view is, since they are the ones producing and distributing the possible substances that are objects of biopiracy. The IFPMA represents the multinational research-based pharmaceutical industry and other manufacturers of prescription medicines, worldwide. It has a close working relationship with the EFPIA (see below).

The IFPMA states that the research-based pharmaceutical industry is highly dependent on IP; that without patent protection the world would have been deprived of the innovative pharmaceutical developments; that patent protection for pharmaceuticals provides a broad range of benefits both to patients and to the economy and that TRIPS therefore is to be welcomed.⁹³

⁹² CEAS Consultants, p. 31.

⁹³ IFPMA, *Intellectual Property: Patents and Pharmaceuticals*.

The IFPMA is excluded from having representative status at the CBD, being seen as an interested party whose goals do not support the CBD.

6.3 European Federation of Pharmaceutical Industries and Associations (EFPIA)

The EFPIA represents the European pharmaceutical industry and has both national pharmaceutical industry associations and companies in its membership. The EFPIA argued strongly in 1999 for full and complete implementation of the obligations of TRIPS and noted that if TRIPS were to be included in a new WTO Round the mandate for negotiation “must be clearly limited to improvements in the level of IP protection”.⁹⁴

6.4 Non-Governmental Organisations

There is one thing that unites most of the efforts from the NGOs: The desire to recognise the collective aspect of indigenous and local community stewardship and to provide those communities with different forms of control over their knowledge. The different NGOs vary of course in their perspectives on issues as neo-liberal economic policy and IPRs. One very interesting fact is that indigenous peoples find western configurations of IP highly problematic, but do not find the word *property* inapplicable to their own societies since they do not treat it as synonymous with absolute ownership.⁹⁵ The NGOs have an influence in the debate of TRIPS and biodiversity. They have become increasingly better at understanding the complex issues involved and have become influential in setting the agenda on important issues. Campaigning by NGOs has also helped to make developed country governments more modest about what they want from TRIPS-related negotiations. Due to the activism of NGOs, industrialised countries are these days on the defensive, wanting to preserve what they have, rather than seek more.⁹⁶

6.5 The European Union

The EU suggests that the problem should be solved first at a national level, then at an international level. “It is the duty of the WTO Members and the

⁹⁴ EFPIA, *TRIPS and the Millennium Round* 1999.

⁹⁵ CEAS Consultants, p. 51.

⁹⁶ CEAS Consultants, p. 52.

CBD signatories to honour their commitments under both Agreements at national level”. Since both agreements allow for a significant degree of flexibility with regard to their implementation at national level, they leave scope for a balance in the way they are applied. The EU also suggests that “the CBD must be implemented at national level by establishing the core conditions for access to national genetic resources and determining minimum conditions for benefit-sharing”. This can be done through legislative, policy and/or administrative measures. The details of each deal can be set out in the contractual arrangements, such as an ABS.

At an international level, it is important for governments to ensure policy coherence in all forums dealing with issues relevant to the interplay between TRIPS and the CBD in order to ensure an integrated approach across institutions. It is also important to underline that legislative, administrative and policy approaches on the one hand and contractual approaches on the other hand should not be set against one another. If all stakeholders, government, scientific and research institutes, companies and indigenous and local communities could cooperate on a national and international level, then the problem of biopiracy would be solved.⁹⁷

6.6 The Third World Network Meeting in 2001

The TWN had a meeting in Montreal in March 2001 where the Panel of Experts on Access and Benefit Sharing made a statement, concerning the harmonisation of TRIPS and the CBD. They did not come to any conclusions about the role of intellectual property rights in the implementation of access and benefit sharing at its first meeting. Since many of the worlds’ citizens demand such access and benefit sharing, they met again. During their meeting, they pointed out six major problems. The sixth – patents on life – is not relevant in the context of biopiracy and indigenous peoples will not be treated here.

- 1) The Conflict of Rationale, Origins and Overall Framework
TRIPS is a commercial treaty with commercial objectives that to a large extent benefit strong private firms. The CBD was prompted mainly by the growing concern over the rapid worldwide loss of biodiversity; a recognition of the important role of traditional knowledge and the rights of local communities that develop and hold the knowledge, and the need to

⁹⁷ WT/CTE/W/223.

regulate access to and the sharing of benefits deriving from the conservation and sustainable use of biodiversity.

2) National Sovereignty versus Rights of IPR Holders

According to the CBD, countries have the right to regulate access of foreigners to biological resources and knowledge, and to determine benefit sharing arrangements.⁹⁸ TRIPS on the other hand enables persons or institutions to patent a country's biological resources in countries outside the country of origin of the resources or knowledge. It is therefore obvious that TRIPS facilitates the conditions for misappropriation of ownership or rights over living organisms, knowledge and processes on the use of biodiversity takes place.⁹⁹

3) Community Rights versus Private, Individual Rights

Looking at the preamble of TRIPS, it recognises that "intellectual property rights are private rights". This is, of course, the main subject of IPRs. If another person or organisation would make, sell or use the product or to use or sell a process, it is an offence, except with the owners permission, which is usually given only on license or payment of royalty.

The TWN has the view that IPRs have the effect of preventing the free exchange of knowledge, of products of the knowledge, and their use or production. "This system of exclusive and private rights is at odd with the traditional social and economic system in which local communities make use of, and develop and nurture, biodiversity. In many communities in non-developed countries, this kind of knowledge of say, a plant carrying healing properties, is used and freely exchanged within the community. Knowledge is shared and held collectively and passed on and added to from generation to generation."¹⁰⁰

The CBD has provisions that acknowledge this and also that aim at protecting community rights.¹⁰¹ The contribution and nature of community knowledge and community rights are not recognised by TRIPS. Instead, TRIPS favours private individuals and institutions, enabling them to acquire rights, including rights over the products or knowledge, whose development was mainly carried out by the local communities. Once again, we find a

⁹⁸ CBD, especially art 3 and art 8 (j).

⁹⁹ Intellectual property rights, TRIPS Agreement and the CBD.

¹⁰⁰ Intellectual property rights, TRIPS Agreement and the CBD.

¹⁰¹ CBD, especially Art 8.

main core-problem of biopiracy. TRIPS and the enactment of patent laws relating to biological materials in some countries have facilitated the misappropriation of the knowledge and resources of indigenous and local communities, and the biopiracy cases have since then, increased. This is in strong counter with the CBD's goal to oblige countries to recognise local community rights and fair benefit sharing. One of the main objectives of establishing the CBD was to counter the possibility of biopiracy, but one of the real effects (not the main objective) of TRIPS has been to enable the practice of such misappropriation.

4) Prior Informed Consent of States and Communities versus Unilateral Patents

Article 15.4 of the CBD states that "access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party". Collectors of biological resources or of knowledge, relating to these, have to provide sufficient information of their work and how it is intended to be used, and obtain consent before even starting their work.¹⁰² In many countries the laws state that the prior informed consent of the state as well as the relevant local communities has to be obtained, that is, consent can also be denied and that consent is conditional on mutually-agreed terms for benefit sharing between the collector, the state and the local communities.

In TRIPS on the other hand, there is no provision that applicants for patents or other IPRs over biological resources have to obtain prior informed consent. There is no recognition in TRIPS of the rights of the country in which the biological resource or knowledge of its use is located. In short: CBD has set up a prior informed consent-system as a check against misappropriation or biopiracy, TRIPS on the other hand facilitates the possibility of such misappropriation by not recognising the need for and thus omitting a mechanism of prior informed consent. If prior informed consent has been awarded in an appropriate way and it is included in the patent application that so has been done, the applicant can never be challenged to be a biopirate.

5) Benefit Sharing Arrangements

The CBD recognises the sovereign rights of states over their biodiversity and knowledge, and thus gives the state rights to regulate access, and this in

¹⁰² Intellectual property rights, TRIPS Agreement and the CBD.

turn enables the state to enforce its rights on arrangements for sharing benefits.¹⁰³ Access should be on mutually agreed terms, subject to prior informed consent, countries providing the resources should fully participate in the scientific research and each country shall take legislative, administrative or policy measures with the aim of “sharing in a fair and equitable way the results of research and development, and the benefits arising from the commercial and other utilisation of genetic resources with the contracting party providing such resources. Such sharing shall be upon mutually agreed terms.”¹⁰⁴

Reading article 15.7 in the CBD gives the impression that sharing of benefits is an issue on the national level. If a pharmacy corporation shares its benefits with the indigenous people, the money will be awarded the state in which the indigenous people live. It is however not sure that the money will in fact reach the indigenous people.

TRIPS has no provision for the patent holder on claims involving biological resources or related knowledge to share benefits with the state or communities in countries of origin. As today, there is not much a country of origin can do if a corporation or person obtains a patent in another country based on the biological resource or related knowledge of the country of origin.¹⁰⁵ A legal challenge can be launched but thinking of the high costs of a trial might scare the underdeveloped country off from doing so. Even if the state has the money, it may not have the resources to track down all the patents that are based on their product and even if they do, there is no guarantee for success.

6.7 WHO Strategy for Traditional Medicine 2002-2005

The WHO Traditional Medicine Strategy was published in July 2002 and provides a comprehensive framework for the WHO to collaborate with Member Countries. The strategy was developed through broad consultation with the WHO regional offices and Member Countries, WHO Expert Committees and Collaborating Centres for Traditional Medicine, as well as through work with a broad range of partners with diverse interests in TM. The TM Strategy incorporates four objectives: policy; safety, efficacy and

¹⁰³ CBD Article 15.

¹⁰⁴ CBD Article 15.7.

¹⁰⁵ Intellectual property rights, TRIPS Agreement and the CBD.

quality; access and rational use¹⁰⁶, on which policy is the only relevant objective that will be treated below.¹⁰⁷

6.7.1 Policy on Traditional Medicine

The WHO says a policy on TM would provide a sound basis for action. Many countries, especially in the South-East Asia region have national policies which regulate herbal products, hospitals' TM services as well as research and professional councils of the practitioners.

As the WHO points out the knowledge ingrained in TM has been generated throughout the centuries and has been the result of work by practitioners in treating patients from their own communities. This knowledge is owned by the community and is to be used for its benefit. The WHO therefore significantly stresses that protection and preservation of this knowledge is important and that it is the responsibility of the countries. The WHO also says that:

“Protection of TM requires a different system from the current agreement on Intellectual Property Rights [the author’s emphasis] which is driven by commercial short-term rewards, such as patents and monopoly rights for the innovator, with the ultimate aim of benefit to the society” [and that] “indigenous knowledge requires a different model [since it] has developed gradually and has no innovator and is owned by the community and should be freely available.”¹⁰⁸

The WHO certainly has a point. Regular inventions and “discoveries” usually emanate from one single person or organisation, compared to TM which usually emanate from centuries of knowledge and development, usually from several people or communities. It is therefore difficult to apply the existing conventions (such as TRIPS and the CBD) on TM.

6.8 The WTO and its Role in Biopiracy

Some people say that WTO and its politics on biopiracy has been the “last nail to the coffin”¹⁰⁹ They have the opinion that the State’s responsibility towards its people is being sold to the transnational corporations and that it transfers the sovereign power of decision-making on biodiversity given by

¹⁰⁶ WHO SEA/RC55/13 p.1.

¹⁰⁷ For further reading: see WHO SEA/RC55/13.

¹⁰⁸ WHO SEA/RC55/13.

¹⁰⁹ Agrawal.

the CBD, to powers outside the country. One author says that “The market forces have been unleashed without appropriate checks and balances by the State” and that “The WTO and its IPR regime have now appeared as the new colonisers in the post-colonial era.”¹¹⁰ But is this really true?

This view on the WTO seems to be a bit radical. What the WTO tries to do is to establish a global protection for IPRs; it is not to rob the Third World Countries from their biodiversity. It is therefore sad that TRIPS, emanating from the WTO, possibly has such an *effect* on the biodiversity that the CBD wants to protect. It is also true that patents on biodiversity imply that corporations which own the patents get exclusive right to the protection and distribution of seeds, livestock and medicine and that it establishes monopolies on food and health. On the other hand: Would the pharmacy industry continue to develop medicine if they were not sure to get the profit of it for the first years that the product exists on the market? Would they continue to spend billions of dollars on research? No, the reason why the pharmacy industry keeps developing new medicine is simply – money. Without payback on previous research, the research can not continue and the incitements to do so become less. Payback on research must exist.

TRIPS is infringing on the Common Property Rights to biodiversity and biodiversity-related knowledge, since the whole idea of TRIPS is to give individuals and corporation monopoly rights. But is it possible to find a balance between the interests?

The Indian Minister of Trade and Commerce told a forum on IP a couple of years ago that the industrialised countries are using TRIPS as a tool to prevent developing countries having used reversed engineering and other methods of imitative innovation during their own process of industrialisation.¹¹¹ Looking at TRIPS this way gives another aspect to the problem. According to the Indian Minister, TRIPS is not only used for biopiracy, but also for preventing developing countries from developing. He names it *Technological Protectionism* and says that:

“The industrialised countries extensively used reverse engineering and other methods of imitative innovation during their own process of industrialisation. After having fully used that, they closed the door to the developing countries by restricting them, thereby making technological catching-up more difficult than before.”¹¹²

¹¹⁰ Agrawal.

¹¹¹ Singh.

¹¹² Singh.

The issue of Geographical Indications has been given priority in the TRIPS negotiations by European countries, but the privilege is still being denied to similar products of developing countries. The answer to this must be that the developing countries do not have the required professional help in the field of IP and that they because of this have not been able to show their meaning in a convincing way during the WTO meetings concerning TRIPS.

At the end of 2001 the rules for patents on medicine changed. During the WTO meeting in Doha, Qatar the interpretation of TRIPS was discussed. According to the new agreement, signed by all 142 members of the WTO, the interpretation of TRIPS shall not be used so that it prevents member states from protecting the health of the people in the member states. The text reads “TRIPS can and shall be interpreted in such way that it supports the Members right to protect the common health and above all support the affordability of medicine for all”.¹¹³ The major thought of this agreement was to develop licenses for production of cheap copies of patent protected medicine – that is – it was not to protect from biopiracy. But can not this formulation be used to protect from biopiracy? “...*Supports the Members right to protect the common health...*” Wouldn't it be appropriate to say that in order to protect the common health, biopiracy must be prevented? Not only do we protect the victims of biopiracy, we would also create a better basis for the bioprospectors in order for them to continue their important research.

¹¹³ Oldebäck.

7 Conclusions

The specific purpose of this paper is to find out if there is a conflict or not between the CBD and TRIPS and if this conflict affects the problem of biopiracy. The question seems to be possible to answer in a lot of ways. There are many views on the issue but there is a general trend that can be found: People being dependent on their indigenous knowledge and/or find themselves being victims of biopiracy have the view that there *is* a conflict between the CBD and the TRIPS or at least that the two regulations do not fully protect them from biopiracy. People being dependent on IPRs such as pharmacy corporations and scientists have the view that there is *no* conflict. This has been stressed on a number of places in the paper.

Regarding the conflict, the author's conclusion is the following: It is fair to say that there both is and is not a conflict. It depends on the way you look at the issue. The problem indeed exists – there are many indigenous people who have been victims of biopiracy, such as those shown in the case history and who have lost employment and national wealth as well as cultural value. The question is: is the existence of biopiracy due to the conflict between the two conventions?

The two conventions deal with different issues. The CBD deals with the protection of biological diversity, sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources. TRIPS deals with the protection of intellectual property. However, in some areas the two conventions tend to interrelate, such as article 27.2 of TRIPS which states that members may exclude from patentability inventions which may be a threat to ordre public or morality, including protecting human, animal or plant life or health. This is an article on the “governmental” level, so it can not be used as a defence by the ones who consider them selves being victims of biopiracy unless it has been implemented by the countries involved. In making use of Article 27.2 Members will need to bear in mind their general obligation under Article 8 of CBD to adopt measures that are “consistent with the provisions of this Agreement”. In this sense, the CBD and TRIPS interact in a perfect manner and we are close to a solution.

Following the *Vienna Convention on the Law of Treaties*, TRIPS shall apply, no doubt, but this is only if the two treaties are dealing *with the same*

matter. This is where the problem is. There is no common view that they are dealing with the same matter. If there was one, the Vienna Convention could be applied and the problem would be solved. It is possible that in a future case of biopiracy the court will decide that the two treaties deal with the same matter. If so, the Vienna Convention will apply leading to TRIPS as the applicable convention. In the cases shown in the paper, the outcome was due to national legislation.

A conceptual distinction between *legal* and *policy* conflicts must be drawn. As mentioned in the paper, rules of law are often clear, but legal principles tend to be more abstract and can stand in tension with each other. There is an interaction between the two treaties; therefore TRIPS and the CBD can and should be implemented in a mutually supportive way. TRIPS and the CBD should not undermine each other's objectives, something to keep in mind when implementing the rules of TRIPS, such as article 27.2. As long as the Members keep this in mind, a solution to the problem might be near.

One possible solution is of course to start all over and develop a specific convention dealing only with biopiracy. The resources demanded for this is however big and there are many interests that have to be balanced. Another problem is to create balance between the interests of the CBD and TRIPS so that the objectives of the new biopiracy convention will not be in conflict with the existing two conventions. If that is the case, the problem has only gotten worse.

In general, the pharmaceutical industry is pro-IPR. And why shouldn't they? The research will not continue if there is no assurance of payback through patent protection, enabling the pharmacy companies to build up a monopoly on the product in question. The only company the author have discovered in the research which seeks to reconcile the possible conflict between the CBD and TRIPS is the Danish life-science corporation Novo Nordisk. They have formulated a list of guiding principles, in order to "do our utmost to live up to for al material covered by the CBD".¹¹⁴ It is clear, that just because you are pro-IPR, it does not have to mean that you are opposed biological diversity.

Respect is something that has been mentioned in the paper that we must keep in mind when exploring nature. Respect for our respective native (and global) heritage; respect for the people not living with the same values as

¹¹⁴ CEAS Consultants, p. 39.

we do; respect for nature and so on. If the organisations exploring nature in order to extract or develop new substances do this with respect, another step is taken in order to solve the biopiracy issue. Respect can be made in different ways. One way is to follow the CBD objective, stated in article 1 to give fair and equitable sharing of the benefits arising out of the utilisation of genetic resources. Another way is to be sure to get *prior informed consent* from the people in whose country you are about to bioprospect.

The biggest problem is the Article 102 of the US Patent Law and The US Patent Act of 1952. The fact that the US Patent Law does not recognise use of an invention as *prior art* makes it possible for American inventors to patent such inventions that have only been *used* (and not patented or described in a publication). The USA need to revise their Patent Law in order to prevent biopiracy. No inventions that are being used, patented or described in a publication anywhere in the world – inside or outside the USA – should be patentable in the USA.

Another alternative is to add a rule to TRIPS (which the USA is a member of) that states that a patent application can not be approved if the invention is known, used or described in a trade publication in any of the member states of TRIPS. Some of the indigenous people have started to document their knowledge in order to prevent others from claiming that the knowledge is not prior art.

Insert a rule in either the US Patent Law or TRIPS that forces the patent applicant to define the source country or area of the invention when applying for the patent. If the applicant in addition to states in the application that he or she has been awarded *prior informed consent*, he or she can not be accused of being a biopirate.

There are some options for the developing countries that they can consider in order to increase their protection against biopiracy: Documentation of traditional knowledge has been mentioned above, something that India has done in database; create a registration and innovation system; develop a *sui generis* system and the creation of alliances of “source”-countries in order to strengthen their power against the biopirates.

One final remark: In the least developed countries the main problem is not patent protection, but rather malfunctioning institutions, acute poverty, armed conflicts and no or little infrastructure. These countries do not have

the resources needed to implement neither the CBD nor TRIPS in an appropriate way – they have enough problems already...

Pharmaceutical products emanating from nature are extremely important to mankind – just look at the figures presented in section 2.1.3 above. Two thirds of the 50 million species in existence have potential medicinal value. Mankind has two basic objectives: to survive and to reproduce. The survival objective can be strengthened through medicine and this is the reason why it is so important for us to preserve the knowledge of plants having these abilities. We must remember that scientists and pharmaceutical corporations have to keep doing their research in order to make the world healthier and this includes bioprospecting. Bioprospecting can however be done in a legal, moral and appropriate way. Remember – bioprospecting is not the same as biopiracy.

The issue of biopiracy must be solved and a major insight is that the world has to come together and realise that these plants and substances actually can save lives. Be joyful, you plants that bear flowers and those that bear fruit...

Supplement A

Proposals on how to prevent biopiracy (in no order of preference)

Practical aspects to keep in mind:

Bear in mind in the use of Article 27.2 TRIPS, the general obligation under Article 8 of the CBD to adopt measures that are consistent with the provisions of the CBD.

Respect our native heritage when doing bioprospecting.

Get *prior informed consent* from the source country or people/s of the substance you are doing research about.

Make a conceptual distinction between legal and policy conflicts.

TRIPS and the CBD can and should be interpreted in a mutually supportive way. They should not undermine each other's objectives.

Legal changes:

The USA need to change their patent regulation in order to redefine *prior art* so that all existing inventions or usages of substances etcetera are being considered as *prior art*.

Add a rule to TRIPS that states that a patent application can not be approved if the invention is known, used, or described in a trade publication in any of the member states of TRIPS.

Insert a rule in either the US Patent Law or TRIPS that forces the patent applicant to define the source country or area of the invention when applying for the patent.

Insert a rule in the US Patent Law or TRIPS that forces the patent applicant to seek prior informed consent in the source country and to state the consent in the application in order to be sure, not to be considered as a biopirate.

Indigenous peoples or other victims of biopiracy should document their knowledge. If that is done, the inventions will be considered *prior art* according to the US Patent Law, since documentation in a country inside or outside the USA prevents patenting in the USA of such an invention.

Educate underdeveloped people in the field of intellectual property and give them aid in order to build an effective system for patenting of inventions.

Bibliography

- Agrawal, Rakesh.** "The WTO & Biopiracy". *G21*. <www.g21.net/asia25.htm> (1 Oct. 2003).
- Biopiracy: A New Threat to Indigenous Rights and Culture in Mexico**
<www.globalexchange.org/countries/mexico/biopiracyReport.html.pf> (30 Sep. 2003).
- Burrows, Beth.** "Biopiracy, Patenting and International Trade Agreements."
Synthesis/Regeneration 15. Winter 1998. <www.greens.org/w-r/15/15-14.html> (30 Sep. 2003).
- Correa, Carlos M.** "Recent developments in the field of pharmaceutical patents: implementation of the TRIPs agreement." December 1998.
<www.haiweb.org/campaign/novseminar/correa2.html> (5 nov. 2003)
- Correa, Carlos M.** *Implementing the TRIPs agreement in the patents field. Options for developing countries*. The Journal of World Intellectual Property, vol. 1, No. 1.
- ETC group Communiqué** March/April 2002 Issue #75. "Captain Hook Awards – 2002."
<www.etcgroup.org> (5 Dec. 2003)
- Firm, David.** "African Cactus could help fight obesity," *Financial Times*, April 11, 2001.
- Globalization and Sustainable Development.** What Regulators Are Needed? Fact Sheet 5.B. WTO and the Environment.
<www.envirodev.org/librairie/pedago/mond_1999/trade/_ins/insfact5b.html> (30 Sep. 2003).
- Gollin, Michael A.** "Biopiracy: The Legal Perspective". *Actionbioscience*. February 2001.
<www.actionbioscience.org/biodiversity/gollin.html> (30 Sep. 2003).
- Gupta, Ankur.** "Biopiracy and (Mis)Appropriation of Traditional Knowledge."
Department of Computer Science, The University of Texas at Austin.
<www.cs.utexas.edu/users/ankur/paper.html> (30 Sep. 2003).
- Hafeel, V. and Shankar, D.** Revitalising indigenous health practices, *COMPAS Newsletter*, February 1999.
- Hauge meeting targets biopiracy.** *The Scientist* April 24, 2002.
<www.biomedcentral.com/news/20020424/04/> (30 Sep. 2003)
- Intellectual property rights, TRIPs Agreement and the CBD.** Montreal, 19-22 March 2001. <www.twinside.org.sg/title/benefit.htm> (30 Sep. 2003).
- Nationmaster on the web** <www.nationmaster.com/encyclopedia/biopiracy> (30 Sep. 2003).
- Of Patents & Pi@tes.** Patents on life: the final assault on the commons. July 2000.
<www.grain.org/publications/pirates-en-p.htm> (30 Sep. 2003)
- Oldebäck, Annika.** "Regler för läkemedelspatent mjukas upp efter WTO-möte". *Janus webb – Stockholms läkemedelskommittéers nättjänst*.
<www.janusinfo.org/imcms/servlet/GetDoc?meta_id=1113> (1 Oct. 2003).
- Parkins, Keith.** "Biopiracy and Intellectual Property Rights".
<www.heureka.clara.net/gaia/genetix.htm> (30 Sep. 2003).
- Shiva, Vandana.** "The US Patent System Legalizes Theft and Biopiracy." *The Hindu*, July 28, 1999. <www.organicconsumers.org/Patent/uspatsys.cfm> (30 Sep. 2003).
- Shiva, Vandana (Internet 1).** "The Draft Biological Diversity Legislation. An anti-National, anti-People law".
<www.shiva.net/archives/biopiracy/draft_biodiv_legislation.htm> (30 Sep. 2003)

Shiva, Vandana. *Biopiracy – The Plunder of Nature and Knowledge*. South End Press. Boston 1997.

Shiva, Vandana. *Stolen Harvest – The Hijacking of the Global Food Supply*, South End Press. Boston 2000.

Singh, Someshwar. “WTO sanctions theft of intellectual rights of poor by rich”.

<www.twinside.org.sg/title/theft.htm.> (30 Sep. 2003)

The American Heritage Dictionary of the English Language: Fourth edition.

<www.bartleby.com/61/76/B0267650.html.> (30 Sep. 2003).

Westberg, Peter. Avhandlingsskrivande och val av forskningsansats – en idé om rättsvetenskaplig öppenhet. Ur Festskrift till Per-Olof Bolding. Stockholm 1992.

Official reports

Review of article 27.3(b) of the TRIPS agreement, and the relationship between the trips agreement and the convention on biological diversity (CBD) and the protection of Traditional Knowledge and folklore. “A Concept Paper”. WTO Committee on Trade and Environment. 14 February 2003. **WT/CTE/W/223**

Study on the relationship between the agreement on TRIPS and biodiversity related issues – Final report for DG TRADE European Commission. Submitted by **CEAS Consultants** (Wye) Ltd. Centre for European Agricultural Studies in association with Geoff Tansey and Queen Mary Intellectual Property Research Institute. September 2000.

Systems and national experiences for protecting Traditional Knowledge, innovations and practices. United Nations Conference on Trade and Development 30 October – 1 November 2000. **UN TD/BCOM.1/EM.13/2**

WHO Strategy for Traditional Medicine 2002-2005. 11-13 September 2002. **WHO SEA/RC55/13**.

WIPO Roundtable on Intellectual Property and Indigenous Peoples Geneva, July 23 and 24, 1998. **WIPO/INDIP/RT/98/4A**.