Patents and Traditional Knowledge: Facing Biopiracy

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by

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I hereby declare that I have read and understood the regulations governing the submission of Master of Law Dissertations, including those relating to length and plagiarism, as contained in the rules of this university, and that this dissertation conforms to those regulations.

Mainz, 21 February 2010 Signed by candidate

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I. Introduction

Humankind has always been dependent on Earth and its biological diversity.[1] For generations, humans have passed on their knowledge about life, livelihood, nature and biological resources, and relied upon biodiversity for many commercial products.[2] Today, biodiversity is recognised as a 'highly strategic resource with commercial potential comparable to that of petroleum or uranium'.[3]

The biotechnology sector[4] has emerged as a major industry in recent years. The possibility of altering living material to develop new kinds of medication and agricultural products is worth billions of dollars.[5] Companies around the world have expanded their study of the natural world and rely upon the knowledge and guidance of local communities who have profound knowledge of these biological resources. Scientists believe that the cure for diseases lies hidden in the 'green gold' of the Southern hemisphere.[6] Consequently, the economic value of these biological resources is regarded as very high. In fact, commerce involving biological products and processes now accounts for almost half of the world economy.[7]

About a decade ago, biological resources were commonly regarded as the 'common heritage of mankind'.[8] Researchers were able to obtain samples of biological resources from around the world and store them in laboratories for further

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[1] A.Krattiger et al. *Bioprospecting, Traditional Knowledge and Benefitsharing* in IP Handbook of Best Practices Section 16 Vol.2 (2007) 137 at 137. Available at http://www.iphandbook.org/handbook/execguide_files/ipHandbook%20Guide-Section%2016.pdf [Accessed 10 December 2009].

[2] Ajeet Mathur *Who Ownes Traditional Knowledge?* (2002) 5. Available at http://www.icrier.org/pdf/WP96.pdf [Accessed 1December 2009].

[3] Global Exchange *Biopiracy: A New Threat to Indigenous Rights and Culture in Mexico* (2007). Available at http://www.globalexchange.org/countries/americas/mexico/biopiracyReport.html [Accessed 7 November 2009].

[4] Biotechnology is a technology based on biology, agriculture, food science and medicine. A biotech company therefore a company which uses biotechnological methods for the creation of products.

[5] Sudhir D Ghatneka and Mandar S Ghatneka *Bioprospecting or Biopiracy?* (1999). Available at http://www.expressindia.com/news/fe/daily/19990208/fec08011.html [Accessed 7 November 2009].

[6] Ibid.

[7] Global Exchange (note 3).

[8] The Common Heritage of Mankind Principle has emerged in international law, which basically states that common heritage resources are owned by nobody. Yet members of the international community of nations had the equal duty to conserve these resources and a right to benefit from their utilization. See Graham Dufield *Intellectual Property, Biogenetic Resources and Traditional Knowledge* (2004) 10.

development.[9] These practices were generally referred to as bioprospecting.[10] At that point in time there was no applicable law which required permission of any kind from the countries or traditional communities of origin. Today, the rules for bioprospecting derive mainly from three sources: international treaties, national laws, and guidelines for bioprospecting.[11] The most important international agreement, in this context, is the Convention on Biological Diversity (CBD),[12] which came into effect in 1993. The CBD established and reaffirmed sovereign rights over the resources to the state where the biological resources were located.

The distribution of property rights over biological resources has given rise for concern in international law and especially among traditional communities.[13] Among other issues that arise out of the utilisation of biological resources, intellectual property rights play an important role.

The granting of patents related to biological resources, either based on the existing traditional knowledge of the developing world, or a minor variation thereof, has been the cause of great concern to the developing world. This is because the economic benefits from these patents primarily benefit the prospecting companies and do not contribute any type of compensation or recognition to those who had anterior knowledge of the plants.

The economic value of biological diversity and the mechanisms of assigning it to the countries and communities of origin has, consequently, become a contentious issue in international law.[14] Accordingly, it is the developing countries that accuse the industrialised countries of misappropriating their biological resources and traditional knowledge related to these resources. This behaviour is generally referred to as 'biopiracy'.[15]

For developing countries, one reason given for the prevalence of biopiracy is the patent system. It is alleged that patent law fails to deal with the complex questions

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[9] Michael A. Gollin *Biopiracy: The Legal Perspective* (2001). Available at http://www.actionbioscience.org/biodiversity/gollin.html [Accessed 7 November 2009].
[10] See a more detailed definition of the term'bioprospecting' in the following chapter.
[11] Gollin (note 9).
[12] Convention on Biological Diversity (CBD) 1760 UNTS 79; 31 ILM 818 (1992).
[13] Philippe Cullet *Property Rights Over Genetic Resources: India's Proposed Legislative Framework* (2001) 2. Available at http://www.ielrc.org/content/a0102.pdf [Accessed 18 November 2009].
[14] Michael Hassemer *Genetic Resources* in Silke von Lewinski *Indigenous Heritage and Intellectual Property* (2004) 152.
[15] See a detailed analysis of the term in the following chapter.

arising out of the protection of traditional knowledge and biological resources on the one hand, and the granting of patents on the other. People in developing countries accuse the patent system of unacceptably favouring industrialised countries by granting those patents allowing the exploitation of traditional peoples by means of capitalising on their knowledge. However, the line between lawful bioprospecting and unlawful biopiracy seems to be thin, with several issues remaining unresolved so far.

This thesis investigates the controversy surrounding the biopiracy debate by principally examining whether or not the patent law favours biopiracy; and if so, what can be done to prevent this from happening. The starting point of this discussion will be the examination of the key issues involved, including the issue of ownership over biological resources. An overview of patent history will be given, as well as an analysis of selected patent legislations, including the Agreement on Trade Related Aspects of Intellectual Property Rights[16], the European Patent Convention[17] and the United States Patent Law.[18] This thesis will then progress, analysing some of the cases that are commonly referred to as biopiracy. Ultimately, it will be concluded that patent law, in fact, does favour biopiracy. At the same time, future options for the protection of traditional knowledge will be identified and analysed.

II. Identifying the Key Elements

To understand the complexity of the biopiracy debate, it is important to have a closer look at the key elements involved. The following chapter identifies the main issues surrounding the concept of biopiracy, starting with defining and contrasting bioprospecting and biopiracy.

A. Bioprospecting and Biopiracy

Bioprospecting has played an important role in worldwide economic and social development[19] and can generally be referred to as the 'searching and collecting of

[16] Agreement on Trade Related Aspects of Intellectual Property Rights (1995) 33ILM 81.
[17] Convention on the Grant of European Patents 'European Patent Convention' (EPC) of 1973.
[18] United States Patent Act (1952) 35 U.S.C.
[19] Uma Suthersanen *Legal and Economic Considerations of Bioprospecting* in Michael Blakeney *Perspectives on Intellectual Property: Intellectual Property Aspects of Ethnobiology* (1999) 48.

biological resources for the purpose of commercial development'.[20] On the contrary, biopiracy refers to the 'failure of acknowledging the origin of biological resources and indigenous knowledge in an appropriate manner in the course of bio-prospecting'.[21]

Meanwhile, the question of how to distinguish these two practices from one another arises. The answer depends upon the differentiation between legitimate and unfair exploitation of traditional genetic resources.[22] Yet, this dividing line is hard to establish due to vagueness in the way the term is applied.[23]

Nevertheless, it is of utmost importance to clarify and agree upon what is meant by biopiracy in order to determine what can, and should, be done to overcome the practice of biopiracy. A radical view would consider any act of bioprospecting an act of biopiracy.[24] As a consequence, the only solution to overcome biopiracy would be the denial of access to biological resources entirely.[25] On the contrary, if biopiracy is regarded as a mere 'disturbance', there would be no need for such a ban to be enforced rigorously.[26]

Meanwhile, if the problem is that patent law encourages biopiracy, measures have to be taken to prevent biopiracy.[27] Nevertheless, to conclude that every act of bioprospecting is also an act of biopiracy seems to be farfetched. Bioprospecting involving prior informed consent from the country of origin, benefit sharing in some form, and efforts to protect traditional knowledge holders and their rights, can hardly be regarded as biopiracy.

Hence, a better way to establish a line between bioprospecting and biopiracy is to allege that biopiracy is 'the deliberate and intentional commercialisation and

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[20] Misaki M Koyama and Mariam Mayet *Bioprospecting, Biopiracy and Indigenous Knowledge: Two Case Studies from the Eastern Cape Province, South Africa* (2007) 11.
[21] Ibid.
[22] Graham Dutfield and Uma Suthersanen Global Intellectual Property Law (2008) 334.
[23] Graham Dutfield *International Expert Workshop on Access to Genetic Resources and Benefit Sharing I. Identification of Outstanding ABS Issues: Access to GR and IPR. What is Biopiracy?* (2004) 2. Available at http://www.canmexworkshop.com/documents/papers/1.3.pdf [Accessed 20 February 2010].
[24] Dutfield and Suthersanen (note 22) at 335.
[25] Ibid.
[26] Ibid.
[27] Ibid.

patenting of biological resources without regard to the source of origin of the indigenous knowledge and most importantly the consent of its holders'.[28]

B. Traditional Knowledge

There have been several attempts to define the above term, but so far no official or agreed definition exists.[29] Traditional knowledge captures many aspects of a culture and is constantly interacting with external influences. The concept, therefore, varies according to context, and 'existing definitions often reflect the specific intellectual, political and socio-economic context prioritised by the body defining the term'.[30]

Most commonly, the term 'traditional knowledge' refers to 'knowledge associated with the environment rather than knowledge related to cultural works and expressions'.[31] Obviously, traditional knowledge exists in every society across the world, regardless of their stage of development. Nevertheless, many people associate 'traditional knowledge' with knowledge held by tribal communities that are outside the 'cultural mainstream' of the countries where these tribes live.[32] This conclusion is a result of the assumption that these tribes' culture has not changed a great deal during the last few centuries.[33] By using 'traditional knowledge' in this way, the term applies best to the knowledge of indigenous and tribal communities as defined under the International Labour Organization Convention 169 Concerning Indigenous and Tribal People in Independent Countries. In the context of this convention, 'tribal peoples' refers to people *'whose social, cultural and economic conditions distinguish them from other sections of the national community, and whose status is regulated wholly or partially by their own customs or traditions or by special laws or regulations.'*[34] 'Indigenous people' then refers to people *'who are*

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[28] Koyama and Mayet (note 20).

[29] Weerawit Weeraworawit *International Legal Protection for Genetic Resources, Traditional Knowledge and Folklore: Challenges for the Intellectual Property System* in Christophe Bellmann et al. *Trading in Knowledge:Development, Trade and Sustainability* (2003) 159.

[30] Tzen Wong et al. *Traditional Knowledge, Access to Genetic Resources and Benefit-Sharing* Practice Note UNDP (2004) 6. Available at http://www.energyandenvironment.undp.org/undp/indexAction.cfm?module=Library&action=GetFile&DocumentAttachmentID=2270 [Accessed 20 February 2010].

[31] Graham Dutfield *Legal and Economic Aspects of Traditional Knowledge* in Keith E. Maskus and Jerome H. Reichmann *International Public Goods and Transfer of Technology: Under a Globalized Intellectual Property Regime* (2005) 496.

[32].Graham Dutfield *Intellectual Property Rights, Biogenetic Resources and Traditional Knowledge* (2004) 92.

[33] Ibid.

[34] International Labour Organization Convention 169 Concerning Indigenous and Tribal Peoples in Independent Countries 72 ILO Official Bull. 59; 28 ILM 1382 (1989) Article 1 (a).

regarded as indigenous on account of their descent from the populations which inhabited the country, or a geographical region to which the country belongs, at the time of conquest or colonisation or the establishment of present State boundaries and who, irrespective of their legal status, retain some or all of their own social, economic, cultural and political institutions.'[35] This interpretation of 'traditional knowledge' results in the term 'indigenous knowledge' being used instead of or interchangeably with 'traditional knowledge'.[36]

It can be concluded that traditional knowledge is a difficult term to define. People have also tried to shed light on its meaning either by describing what it is not, rather than what it is. Furthermore, attempts have been made to identify different features that construct 'traditional knowledge' as completely opposite to scientific knowledge, as the latter term is understood in urban, western, westernised or secular societies.[37]

Meanwhile, the CBD avoids a definition altogether, adopting the long-winded phrase 'knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles'.[38] According to the World Intellectual Property Organization, the term 'traditional knowledge' refers to the '*content or substance of knowledge resulting from intellectual activity in a traditional context, and includes the know-how, skills, innovations, practices and learning that form part of traditional knowledge systems, and knowledge embodying traditional lifestyles of indigenous and local communities, or contained in codified knowledge systems passed between generations*'.[39] This knowledge is not specific to any area, but rather includes agricultural and medical knowledge, and knowledge associated with biological resources.[40]

The aforementioned attempts to define traditional knowledge lead to the conclusion that the concept of traditional knowledge is 'too varied to have a single definition as such a definition would be prejudicial to the various forms of

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[35] Ibid Article 1 (b).
[36] Dutfield (note 31) at 498.
[37] Dutfield (note 32).
[38] See Article. 8 (j) of the CBD.
[39] See WIPO Revised Draft Provisions for the Protection of Traditional Knowledge, Article 3.
[40] Manuel Riuz *The International Debate on Traditional Knowledge as Prior Art in the Patent System: Issues and Options for Developing Countries* (2002) 3. Available at http://www.ciel.org/Publications/PriorArt_ManuelRuiz_Oct02.pdf [Accessed 10 December 2009].

knowledge that are held by traditional communities'.[41] Within the context of this thesis, however, the term 'traditional knowledge' refers to knowledge linked to biological resources.

C. Biological Resources

In many cases, biological resources are closely associated with traditional knowledge and both issues often cannot be clearly distinguished.[42] In fact, gained knowledge about the plants in a certain area is in many cases more valuable than the biological knowledge itself.[43]

Article 2 of the CBD defines 'biological resources' as 'genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity', whereby 'genetic resources' are defined as 'genetic material of actual or potential value'.[44] This genetic material includes genes that are found in plants and animals and also chemicals found in animals and plants, since these chemicals are based on genetic information.[45]

D. Ownership over Biological Resources

Yet, the question remains, who owns these biological resources? The CBD does not identify the stakeholders of biological resources, but rather places legally binding obligations on national governments that are party to the CBD.[46] Therefore, national governments have the authority to establish legal obligations for other stakeholders.

It is necessary to distinguish between ownership of territories, ownership of biological resources and ownership of traditional knowledge. The connection between territories, land tenure and access to biological resources located within them is of great importance and local communities are faced with the complex task of understanding the legal practices involved.[47] Not all of the local communities have ownership titles, some communities have only usufruct rights and others have

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[41] Juhi Chowdhary *Intellectual Property and Traditional Knowledge* (2007). Available at http://www.legalserviceindia.com/article/l98-Intellectual-Property-and-Traditional-knowledge.html [Accessed 18 June 2009].
[42] Hassemer (note 14) at 163.
[43] Ibid.
[44] See Article 2 CBD.
[45] Sudhir D Ghatnekar and Mandar S Gathnekar *Bioprospecting or Biopiracy*? (1999). Available at http://www.expressindia.com/news/fe/daily/19990208/fec08011.html [Accessed 5 November 2009].
[46] Hassemer (note 14) at 161.
[47] Grethel Aguilar *Access to Genetic Resources and Protection of Traditional Knowledge in Indigenous Territories* in Christophe Bellmann et al. *Trading in Knowledge: Development Perspectives on TRIPS, Trade and Sustainability* (2003) 177.

no rights at all.[48] Furthermore, there are communities that divide their land into personal holdings and others that have a system of communal ownership.[49] In some countries, ownership of land includes property rights related to biological resources; whereas in other countries, rights over biological resources are not included.[50] Also, several countries believe biological resources to be assigned to the public domain and not to the land owner.[51]

Therefore, it can be concluded that the regulations regarding ownership over, and access to biological resources can vary in different countries. Yet, Article 8 (j) of the CBD has to be taken into account, which obliges members to *'respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity.'* Hence, the CBD establishes the obligation to respect and maintain traditional lifestyles, which should be interpreted as 'including the tenure of resource intensive land on which these populations have lived through generations'.[52]

E. Reason for the Protection of Traditional Knowledge

Meanwhile, the prevention of biopiracy is not the only reason for the protection of traditional knowledge. In fact, there are several other reasons which can be divided into legal, moral and utilitarian considerations.[53]

Legally, the compliance with international treaties on biodiversity and human rights is of great importance. From a utilitarian point of view, the protection of such knowledge is important for conservation purposes since the maintenance of biodiversity is of great value for the worldwide community.[54] Another reason for this protection is the purpose of maintaining the practices and knowledge embodying traditional lifestyles.[55] The preservation of traditional knowledge is not only part of

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[48] Ibid at 178.
[49] Ibid.
[50] Ibid.
[51] Ibid.
[52] Hassemer (note 14) at 161.
[53] Dutfield (note 32) at 100.
[54] Ibid at 99.
[55] Carlos Correa *Traditional Knowledge and Intellectual Property: Issues and Options Surrounding the Protection of Traditional Knowledge* (2001) 6. Available at http://www.quno.org/geneva/pdf/economic/Discussion/Traditional-Knowledge-IP-English.pdf [Accessed 1December 2009].

the right to self-identification; it is also considered a central element of the cultural heritage of humanity.[56]

An additional argument in the context of the protection of traditional knowledge is the promotion of the use of such knowledge, a foundation of which is laid down in the CBD.[57]

Morally, however, particular considerations of equity play an important role. Due to the value of traditional knowledge, the holders of such knowledge need to be compensated in an adequate way. In this context, the question becomes, who establishes the value inherent in traditional knowledge? Traditional knowledge holders themselves clearly do not only determine the value of their knowledge in terms of money, but rather in terms of cultural aspects and aspects of tradition. Nevertheless, companies, especially western biotechnological companies, focus on the commercial and economic value of traditional knowledge whereby value in monetary terms is influenced by demand of the market. Since this commercial interest in traditional knowledge exists, it is only logical that compensation of the original knowledge holders can, and should, be part of negotiations to establish the exchange value or worth of such knowledge in a case where someone is interested in acquiring that knowledge for its economic value. Yet, there is no automatic imperative for equity unless a free market analogy is evoked here. Free market is a 'summary term for an array of exchanges that take place in society. Each exchange is undertaken as a voluntary agreement between two people or groups of people represented by agents'.[58] Consequently, a free market is a market where property rights are voluntarily exchanged on mutually agreed terms.

Returning to the value of traditional knowledge, it can be stated that, to date, contractual agreements in the form of prior informed consent and benefit sharing arrangements between knowledge holders and biotech companies have seldom taken place. In most cases, mutually agreed terms have not been reached. Instead, biotech companies have taken samples from biological resources and relied upon traditional knowledge related to them without permission. Therefore, protection mechanisms

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[56] Ibid.
[57] The Convention of Biological Diversity requires in Article 8 (j) the promotion of the 'wider application' of traditional knowledge.
[58] Murray N. Rothbard *Free Market* The Concise Encyclopedia of Economics. Available at http://www.econlib.org/library/Enc/FreeMarket.html [Accessed 30 January 2010].

need to be established to bring fairness to unequal relations.[59] The urgency of this matter is due to the fact that the biotechnological industry is a fast-growing sector and the number of claimed biopiracy cases has increased during the last few years. At the moment, there is no clear and binding regulation regarding biopiracy at international level, or many national levels, and a lot of these practices fall within the so called 'grey zone'. Consequently, as long as there is no clear, binding guideline, both bioprospecting and biopiracy will continue.

To conclude, there are many different reasons for the protection of traditional knowledge. Nevertheless, for the purpose of this thesis, the concentration lies on the aspect of biopiracy.

F. Objections to the Protection of Traditional Knowledge

In spite of the existence of several reasons that support the need for the protection of traditional knowledge, there are still objections against the protection of such knowledge.

It is alleged that the protection of traditional knowledge results in the removal of a large amount of traditional knowledge about the biosphere including solutions to health and environmental problems out of the public domain.[60] Consequently, it is assumed that the removal may have a negative effect on the global community since everybody benefits from a large public domain. Therefore, the attempt to regulate traditional knowledge would have implications for the creation, management and free flow of information and as a result traditional knowledge should not be the subject of exclusive rights.[61]

Yet, it can be said that demands for the protection of traditional knowledge are not necessarily seeking the creation of new rights. In fact, these demands wish to achieve a wider recognition and enforceability of rights than already exists.[62] Also, not everything that is in the public domain should be in the public domain.[63] The public domain is often promoted in opposition to the privatisation of rights.[64] Nevertheless, this argumentation does not necessarily serve the interests of local

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[59] Correa (note 55) at 5.
[60] Dutfield and Suthersanen (note 22) at 335.
[61] WIPO *Report on Fact-Finding Missions on Intellectual Property and Traditional Knowledge 1998-1999 Intellectual Property Needs and Expectations of Traditional Knowledge Holders* (2001) 216.
[62] Dutfield and Suthersanen (note 22) at 336.
[63] Ibid.
[64] Ibid.

communities. Historically, once traditional knowledge had been disclosed, this knowledge had to be treated as belonging to no one, or in other words, as belonging to everyone.[65] Nowadays, numerous representatives of indigenous and local communities have expressed their concern that such a way of thinking threatens the rights of the knowledge holders. This concern is underlined by the fact that in many of these communities the traditional knowledge is assigned to tribal elders or others that have ongoing responsibilities regarding the use of the knowledge; this custodianship does not end just because the knowledge is placed in the public domain.[66] Time and again, the knowledge has been disclosed without the consent of its holders. Therefore, it can be concluded that traditional knowledge does need to be protected.

G. Patents and the North-South Debate

Much in the debate about patents, traditional knowledge and biopiracy has been shaped by different views in different countries. In this debate, the industrial countries are accused by developing nations of misappropriating their biological resources and knowledge related to these resources.

This allocation is due to the unequal distribution of biological resources around the world. The developing south is home to the majority of the Earth's biodiversity. Two-thirds of existing species can be found in the developing countries.[67] The North, on the contrary, is the owner of the capital and the technologies which are necessary to develop this natural wealth. It is these northern, industrialised nations that own the biotechnological equipment to exploit the genetic resources in the South.[68] Their biotechnology companies wish to freely "bio-prospect" the biodiversity that characterises the southern countries, hoping to develop useful and highly lucrative products. Yet, the question remains, why it is the expectation of these companies that they can exploit these resources for free when that is not a practice recognised or carried out elsewhere in the world? If this knowledge had no real value on the market, it would not be an (international) issue of determining whether or not a commercial relationship should be entered into between the concerned agents.

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[65] Ibid.
[66] Ibid.
[67] Suthersanen (note 19) at 47.
[68] Ibid.

One of the problems in this context is that the commercial value of biological resources and related knowledge is hard to estimate and may vary from case to case. The main reason, however, might be that, for a long time, biological resources have been regarded as the 'common heritage of mankind'.[69] This way of thinking led to the automatic assumption that the same had to be true for related traditional knowledge. Nevertheless, with the Convention on Biological Diversity in place, biological resources can no longer be regarded as the common heritage of mankind. Consequently, companies have to change their practices for the appropriation of genetic resources and knowledge, which in many cases has not yet taken place. This approach of acquiring biological resources and related knowledge for free, results in the south accusing foreign, private companies of stealing their genetic resources and local knowledge.[70]

III. Historical Overview of the Patent System

The debate about biopiracy cannot be fully understood outside the context of its historical origins and the philosophical foundations of the patent system. Therefore, it is important to understand what patents are, where the patent system originated and how the patent system has developed throughout time.

A. Origin of the Patent System

The concept of patents[71] originated in ancient Florence (Italy) when, in 1421, the Florentine architect and inventor Filippo Brunelleschi invented an ironclad sea craft.[72] Brunelleschi, however, refused to disclose the information of his invention, unless the city granted him the limited right to sole commercial exploitation of the sea craft.[73] The city agreed to his condition and granted Brunelleschi a public letter to that effect.

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[69] See Chapter 1.

[70] David Conforto 'Traditional and Modern Day Biopiracy: Redefining the Biopiracy Debate' (2004) *Journal of Environmental Law and Litigation* 358 at 360.

[71] The term patent derives from the Latin word 'patere' which means 'to be open. In relation with a document this term stood for an 'open letter addressed to the public.

[72] Craig Allen Nard and Andrew P. Morriss 'Constitutionalizing Patents: From Venice to Philadelphia' (2006) 2 2 *Review of Law and Economics* 224 at 233. Available at http://web.princeton.edu/sites/jmadison/calendar/documents/Nard-Constitutionalizing%20Patents.pdf [Accessed 10 December 2009].

[73] Christopher May and Susan K. Sell *Intellectual Property Rights: A Critical History* (2006) 54.

The concept of patents subsequently drifted to Venice[74] where it became known as what was most likely the first patent system in the world.[75] The Venetian Patent Statute was enacted on 19 March 1474 and included all the main components of modern patent law.[76] The Statute recognised the public interest in innovation and the benefits of public disclosure[77] and allowed for protection for a period of ten years to all inventions that have passed the examinations of the General Welfare Board.[78] Furthermore, the Statute did not discriminate between Venetians and foreign visitors[79] and also provided penalty for the unauthorised use or infringement of patents.[80]

The next significant step in the development of patent law took place in England, where the Parliament enacted its 'Statute of Monopolies' in 1624. This statute formed the basis for modern patent laws of countries whose laws had their roots in common law. One of the main parts of the statute was the general prohibition of monopoly.[81] Exceptions were made for 'new manufacture[s] within the Realm to the true and first inventors'.[82] Protection was then granted for a maximum period of 14 years. Meanwhile, the first piece of modern patent legislation in continental Europe was the French Law of 7 January 1791.

The concept of patents reached from Europe to other parts of the world via various means: namely, the European migration process and its colonisation of indigenous people, the free 'adaption' of the patent system by independent states, and external political pressure on states which ended in the creation of domestic patent systems.[83] The spread of the patent concept then resulted in international treaties that set standards for national patent protection legislation.[84]

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[74] Ikechi Mgbeoji *Global Biopiracy: Patents, Plants and Indigenous Knowledge* (2006) 16.
[75] Michael A. Gollin *Driving Innovation: Intellectual Property Strategies for a Dynamic World* (2008) 30.
[76] Ibid.
[77] Nard and Morriss (note 72) at 235.
[78] Mgbeoji (note 74).
[79] Gollin (note 75).
[80] Mgbeoji (note 74).
[81] Nard and Morriss (note 72) at 284.
[82] English Statute of Monopolies [1624], Section VI.
[83] Mgbeoji (note 74) at 28.
[84] Gollin (note 75) at 32.

In 1884, the Paris Convention entered into force, which was the first approach to a common intellectual property system.[85] Yet, in the context of patents, the Paris Convention only handles a small number of aspects. However, the Convention did provide the foundation for successful international cooperation in the field of patent rights, particularly for the European Patent Convention itself.[86] One of the most important principles of the Convention is located in Article 2 (1), where it states that foreigners and citizens have to be treated equally in matters of patent and trademark law.

In 1893, the United International Bureaux for the Protection of Intellectual Property was formed. Due to the growing importance of intellectual property, the structure and form of the organisation changed and the International Bureaux became the 'World Intellectual Property Organization' (WIPO).[87] In 1974, WIPO became a specialised agency of the United Nations' system of organisations, with a mandate to administer intellectual property matters recognised by the member States of the UN.[88]

Meanwhile, in 1995, probably the most important treaty in regards to patents entered into force: the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). The TRIPS Agreement is administered by the World Trade Organization and sets minimum standards for the protection of trade secrets, patents, copyrights and trademarks.[89] Chapter IV will examine this agreement in detail by analysing its relationship to the CBD.

The aforementioned has shown that there has been significant development in the history of (international) patent law. International treaties have come into force, regulating different aspects of patent law, demanding harmonisation, and requiring member states to comply. Yet, the internationalisation of patent law is still an ongoing process around the world. In fact, more than the above mentioned treaties have entered into force, regulating different aspects of patent law such as the International Union for the Protection of New Varieties of Plants, and the Patent

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[85] World Intellectual Property Organization *Treaties.* Available at http://www.wipo.int/treaties/en/general/ [Accessed 24 July 2009].
[86] Gerald Paterson *The European Patent System: The Law and Practice of the European Patent Convention* 2ed (2001) 13.
[87] World Intellectual Property Organization (note 85).
[88] Ibid.
[89] Gollin (note 75) at 33.

Cooperation Treaty. However, for the scope of this paper, a detailed analysis of each of these laws and treaties would be too much to consider.

B. Theories on Patents

Ever since the materialisation of the patent system in Europe, several theories have evolved in order to justify the existence of patents. This area of scholarship is important to consider because it highlights the historical basis on which the patent system has been justified in the European context. The theories reviewed below are the Reward Theory, the Natural Law Theory, the Contract or Disclosure Theory and the Incentive Theory.

1. Reward Theory

The first theory to be introduced in this context is the 'Reward Theory'. This theory argues that inventors should be rewarded for their inventions and that the law must be used to guarantee this reward.[90] This assumption, however, leads to the conclusion that the only reason for new inventions is the announced reward.

Consequently, without the reward there would be no inventions. However, the emphasis on monetary gain is generalised and monetary profit is misconceived as every inventor's motivation.[91] The commercialisation of inventions and inventiveness itself are rather different phenomena. However, merely the fact that some individuals wish to see no commercial value attached to traditional knowledge does not mean that such knowledge should not have one at all. In this context, the best solution may be a compromise that could be reached with regards to categories of traditional knowledge that can be viewed as non-commercial and commercial.

2. Natural Law Theory

The second theory to be introduced is the 'Natural Law Theory' by John Locke. According to this theory, an inventor has the 'natural right to his/her invention and society, represented by the state, has an obligation to recognise, protect, and enforce that right'.[92]

This theory, however, jumps to the misleading conclusion that patents are the 'inherent right of an inventor rather than privileges of governments'.[93] Meanwhile,

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[90] Mgbeoji (note 74) at 20; David I. Bainbridge Intellectual Property 7ed (2009) 368.
[91] Mgbeoji (note 74) at 20.
[92] Bainbridge (note 90) at 370; Mgbeoji (note 74) at 19; see also Gollin (note 75) at 38.
[93] Mgbeoji (note 74) at 19.

one should rather consider the limitations of patents, such as patentable subject matter or the duration of patents. These limitations leave such a suggestion unsustainable.

3. Contract or Disclosure Theory

According to the 'Contract or Disclosure Theory' the purpose of the patent system is to serve as a contract between the inventor and society.[94] By disclosing the invention, the inventor will then get a limited monopoly over its use.[95] Yet, this argument is misconceived. It does not take into account that even if an inventor does not disclose his invention, other inventors would sooner or later come up with similar or identical ideas, since 'inventions are called forth by the needs of society'[96] or by the randomness of finding things out.

4. Incentive Theory

After considering Contract Theory, a better approach to the justification of patents might be the 'Incentive Theory.' This theory argues that constructing a framework whereby invention is rewarded will act as an incentive for people to make new inventions and to invest the necessary time and capital in new ventures.[97] This leads to the conclusion that patents serve as a useful motivation for the commercialisation and industrialisation of inventions.

C. Practical Results of Patents

The aforementioned has shown that there are several existing theories to justify the concept of patents. However, one cannot generalise the motivation behind the inventions. In many cases, different forms of motivations are combined and interrelated.

Another point to bear in mind is the fact that intellectual property rights also facilitate investment in innovations by offering investors a way to obtain financial returns in the form of higher profits.[98] These financial returns are reminiscent of the reward theory because they acknowledge that inventions can be rather expensive. Therefore, the grant of patents, as a more or less guaranteed species of property

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[94] Ibid at 20.
[95] Bainbridge (note 90) at 369.
[96] Mgbeoji (note 74) at 20.
[97] Bainbridge (note 90) at 370.
[98] Gollin (note 75) at 39.

rights in that jurisdiction, also attracts foreign investment and the transfer of technology.

The justification of patents needs to be open to new approaches since times change and new factors appear that need to be considered. Yet, it is important to remember that the grant of patents also faces criticism. One concern is that intellectual property rights create unfair monopolies in the interests of big companies and block access to the use of valuable information. Another concern is that intellectual property rights raise the prices for essential goods and overrule ethical and environmental concerns. However, these points fail to acknowledge that patents are seldom absolute and unlimited and that mechanisms for the abuse of intellectual property rights already exist.

IV. Patent Legislation

As stated previously in Chapter II, the term biopiracy is understood as 'the deliberate and intentional commercialisation and patenting of biological resources without regard to the source of origin of the indigenous knowledge and most importantly the consent of its holders'.[99] Although the process of appropriation of plants and traditional knowledge is 'a multiple one involving international institutions and juridical mechanisms, the most controversial process of biopiracy therefore involves the interplay between different patent laws.'[100]

Consequently, biopiracy cannot be fully understood without reference to patent laws. For that reason, this chapter provides an overview of international, regional and national patent legislation, starting with the Agreement on Trade Related Aspects of Intellectual Property Rights, then moving on to the European Patent Convention and the United States Patent Act.

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[99] Koyama and Mayet (note 20).
[100] Mgbeoji (note 74) at 121.

A. Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)

The TRIPS Agreement was adopted in 1995 within the 'framework of the Uruguay Round of multi-lateral trade negotiations',[101] which resulted in the incorporation of intellectual property protection into the Agreement on Trade and Tariffs (GATT).

1. General Overview

Today, the TRIPS Agreement is the 'key international agreement' promoting the standardisation of national intellectual property right regimes.[102] According to Article 7 of TRIPS '*the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a matter conducive to social and economic welfare, and to a balance of rights and obligations'.*[103]

TRIPS does not define the term 'intellectual property', but rather gives an enumeration of the different types of intellectual property that are included within the treaty.[104] However, intellectual property can generally be referred to as 'creations of the human mind'.[105] Intellectual property rights, therefore, protect 'the interests of creators by giving them property rights over their creations'.[106] A patent, on the other hand, is the right granted to an inventor by a state, or by regional office acting for several states, which allows the inventor to exclude anyone else from the commercial exploitation of his invention for a limited period.[107] According to Article 33 of TRIPS, the protection term for a patent is 20 years from the filing date.

2. Patentability Criteria

In regards to patents, one of the most important articles of the Agreement is Article 27.1 TRIPS,[108] which states that 'patents shall be available for any invention,

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[101] Dutfield (note 32) at 25.
[102] Ibid.
[103] Agreement on Trade Related Aspects of Intellectual Property Rights, 33 ILM 81, Article 7.
[104] According to Article 1.2 of the TRIPS Agreement, the term 'intellectual property' refers to 'all categories of intellectual property that are subject of Section 1 through 7 of Part II.'
[105] World Intellectual Property Organization '*Understanding Industrial Property.*' Available at http://www.wipo.int/freepublications/en/intproperty/895/wipo_pub_895.pdf [Accessed 4 September 2009].
[106] Ibid.
[107] Ibid.
[108] Andreas Neef and Susanne Reyes-Knoche *Part II Standards Concerning the Availability, Scope and use of Intellectual Property Rights: Section 5 Patents* in Peter-Tobias Stoll et al. *WTO: Trade-related aspects of intellectual property rights* (2009) 470-1.

whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.' Article 27.1 TRIPS, therefore, sets the criteria for patentability, but does not define the term 'invention' itself.[109] However, the consensus, predominantly in the European view, is that an invention must solve a particular problem.[110] Consequently, an invention compliant to Article 27.1 TRIPS can be defined as 'any activity leading up to a systematic course of action, and resulting in a clear success, in terms of product or process to which a causal relationship can be established'.[111]

In order to be patentable, an invention must meet the three criteria of 'novelty', 'inventive step' and 'industrial application'. The member states are free to determine the way in which they want to interpret these three criteria. Furthermore, countries can consider 'inventive step' as synonymous to 'non-obvious', and 'industrial application' as synonymous to 'useful'.[112] This is consistent with the working definitions in the EU and US law respectively the fact, that the USA made use of these synonyms, which affects the scope of protection as it will be examined later during this chapter.

The first criterion for the patentability of an invention is 'novelty' which means that the 'information must not have been available to the public prior to the original application date (priority date)'.[113] This requirement is based on the assumption that the inventor is '*granted a patent for the disclosure of something new which means in reverse that if the invention has already been disclosed in literature available to the public, the inventor cannot disclose something new in return for the grant of the patent*'.[114]

The second criterion for patentability is the involvement of an 'inventive step.' Hence, the invention must not 'barely be something new, it must represent a development over prior art'.[115] The evaluation of whether an invention contains an

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[109] Carlos M. Correa *Patent Rights* in Carlos M. Correa& Abdulqawi A. Yusuf *Intellectual Property and International Trade: The TRIPS Agreement*, 2ed (2008) 235; Neef and Reyes-Knoche (note 108) at 473-9.
[110] Neef and Reyes-Knoche (note 108) at 473-9.
[111] Ibid at 473- 10.
[112] Footnote to Article 27.1 TRIPS; Correa (note 109) at 237.
[113] UNCTAD-ICTSD Project on IPRs and Sustainable Development *Resource Book on TRIPS and Development* (2005) 359.
[114] Ibid.
[115] Ibid.

inventive step is dependent upon the objective understanding of a person skilled in the art.[116] The person skilled in the art is 'the legal fiction depending on the invention in question and the technical field'[117] and 'it embodies all the knowledge and skills of an average person trained and continuously engaged in the relevant field of technology'.[118]

Finally, the invention must be capable of 'industrial application.' Article 27.1 TRIPS does not provide a definition of this concept.[119] Industry, in this sense, is 'any physical activity of a technical character',[120] which leads to the conclusion that it is quite a broad definition.

3. Anti-Discrimination Clause

Article 27.1 subparagraph 2 contains an anti-discrimination clause, stating that 'patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced'. This article applies to the availability of rights as well as to their exercise.[121] Consequently, traditional knowledge is patentable subject matter under the TRIPS Agreement as long as the criteria of novelty, inventive step and industrial application are met.[122]

4. Exceptions to Patentability

Article 27.2 and 27.3 of the TRIPS Agreement identify the exceptions from patentability that the member countries are free to establish in their domestic patent laws.[123]

Article 27.2 TRIPS states that inventions may be excluded from patentability for the protection of 'ordre public' and 'morality.' These exceptions mean that member states can deny a patent to protect higher public interests.[124] 'Ordre public' is not defined within the TRIPS Agreement and there is no commonly agreed

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[116] Neef and Reyes-Knoche (note 108) at 484- 44.
[117] Ibid.
[118] Ibid.
[119] Ibid at 485-48.
[120] UNCTAD-ICTSD (note 113) at 361.
[121] Correa (note 109) at 239.
[122] Matthias Leistner *Analysis of Different Areas of Indigenous Resources* in Silke von Lewinski *Indigenous Heritage and Intellectual Property: Genetic Resources, Traditional Knowledge and Folklore* (2004) 65.
[123] Correa (note 109) at 230.
[124] UNCTAD-ICTSD (note 113) at 375.

definition.[125] Therefore, there is a certain amount of flexibility regarding this matter. What hypotheses are covered is dependent upon the member countries' conceptions of the protection of public values.[126] However, Article 27.2 TRIPS itself indicates that the concept is not only bound by 'security reasons' as it also relates to the protection of human, animal or plant life and health.[127] Like 'ordre public', the exception of 'morality' is also dependent upon moral values reflected in a society. These values, however, can differ in different societies.[128]

According to Article 27.3 (a) TRIPS, member states may also exclude from patentability 'diagnostic, therapeutic and surgical methods for the treatment of humans and animals'. This Article refers specifically to methods for the treatment of humans and animals.[129] The latter reference makes clear that patentable products or processes need to be differentiated from the methods of the treatment.[130]

Article 27.3 (b) TRIPS covers some of the most controversial exceptions of the TRIPS Agreement.[131] It describes subject matters that are allowed to be excluded from patentability. These exceptions are all related to the biotechnology sector. Firstly, this article allows for the exclusion of plants and animals in general.[132] The phrase, however, does not refer to certain classifications (or varieties) thereof.[133] Therefore, this phrase can be considered a very broad exception.[134] Furthermore, Article 27.3 (b) TRIPS allows for the exclusion of 'plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. ' At the same time, however, Article 27.3 (b) TRIPS obliges the member states to protect plant varieties by using either patents, an effective sui generis regime or a combination of both.[135]

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[125] Susanne Reyes-Knoche *Part II Standards Concerning the Availability, Scope and use of Intellectual Property Rights: Section 5 Patents* in Peter-Tobias Stoll et al. *WTO: Trade-related aspects of intellectual property rights* (2009) 493-8.
[126] Correa (note 109) 230.
[127] Ibid.
[128] Ibid.
[129] Reyes-Knoche (note 125) at 499- 4.
[130] UNCTAD-ICTSD (note 113) at 384.
[131] UNCTAD-ICTSD note 113) at 388; Reyes-Knoche (note 125) at 502- 1.
[132] Dutfield (note 32) at 28.
[133] Correa (note 109) at 232.
[134] UNCTAD-ICTSD (note 113) at 392.
[135] Pedro Roffe *Bringing Minimum Global Intellectual Property Standards into Agriculture: The Agreement on Trade Related Aspects of Intellectual Property Rights* in Geoff Tansey and Tasmin Rajotte *The Future Control of Food: A Guide to International Negotiations and Rules on Intellectual Property, Biodiversity and Food Security* (2008) 59; Reyes-Knoche (note 125) at 507-12.

Meanwhile, the provision does not define what is meant by an 'effective' system, which, once again, leaves the member states with flexibility regarding the extent and content of the protective rights.[136] This room for flexibility is a result of the lack of consensus among countries during the TRIPS negotiations. In the United States of America, for example, a plant variety may be patented as such, whereas in Europe this is not possible.[137]

5. Effect on Domestic Law

The TRIPS Agreement only sets out minimum standards for the protection of intellectual property rights. The contracting parties keep a certain amount of flexibility by the implementation of rules in their national laws.[138] According to Article 1.1 and 1.3 TRIPS, the member states are free to determine the way in which they implement the TRIPS provisions in their national laws and to establish even more extensive protection than required by the agreement. TRIPS is, however, a binding agreement and non-compliance with the treaty will lead to trade sanctions.

6. Conflict between the Convention of Biological Diversity and the TRIPS Agreement

It has been alleged by some countries that the implementation of TRIPS violates other treaties. These countries claim that even though the scope of the TRIPS Agreement is limited to intellectual property rights, TRIPS must be viewed in the context of other laws.

Indeed, the grant of patents might have an impact on the sovereign rights of countries over their biological resources assigned by the Convention on Biological Diversity. For example, TRIPS does not require prior informed consent from the owner of knowledge related to these resources, but rather focuses on giving rewards and incentives for innovation. This, however, might violate Article 16.5 of the Convention on Biological Diversity which requires its members to ensure that intellectual property rights support the goals set out by the CBD.

In this regard, several different views have been expressed in respect of the relationship between the CBD and the TRIPS Agreement.[139] In order to understand this discussion it may be useful to have a short overview of the CBD first.

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[136] Reyes-Knoche (note 125) at 507-12.
[137] UNCTAD-ICTSD (note 113) at 394.
[138] Jan Busche *Agreement on Trade-Related Aspects of Intellectual Property Rights* in Peter-Tobias Stoll et al. *WTO: Trade-Related Aspects of Intellectual Property Rights* (2009)14- 7.
[139] Reyes-Knoche (note 125) at 512-20.

a) The Convention on Biological Diversity

The CBD entered into force in 1993. According to Article 1, the CBD has three objectives: the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of benefits[140] arising out of the utilisation of genetic resources.[141] In the context of the protection of traditional knowledge, Articles 8 and 15 of the CBD are particularly significant because they form the basis for the principle of access and benefit sharing.[142] Article 8(j) of the CBD requires the contracting parties to 'protect indigenous and local knowledge and innovations as well as encourage their use with the participation of and benefit-sharing for these communities'.[143] Article 15.1 of the CBD recognises state sovereignty over natural resources in the context of genetic resource accessability. This allows countries to control access to these resources by allowing for the possibility of profiting from providing access. Furthermore, Article 15 of the CBD requires that access to genetic resources is to be on mutually agreed terms subject to prior informed consent.[144]

b) Relationship between the TRIPS Agreement and the Convention of Biological Diversity

By analysing the CBD, one gets the impression that there is no conflict between the TRIPS and the CBD because the two treaties seem to have different and non-conflicting objectives and deal with different subject matters:[145] While the CBD addresses ownership over genetic resources and access to these genetic resources, the TRIPS Agreement establishes minimum standards for the protection of intellectual property.[146]

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[140] Peter-Tobias Stoll and Anja von Hahn Part *II Indigenous Peoples, Traditional Knowledge and Indigenous Resources in International Law* in Silke von Lewinski *Indigenous Heritage and Intellectual Property: Genetic Resources, Traditional Knowledge and Folklore* (2004) 27.

[141] Janak Rana Ghose *Access and Benefit Sharing Systems: An Overview of the Issues and Regulation* (2003) 8. Available at: http://ranaghose.com/research/abs.pdf [Accessed 3October 2009]

[142] Kathryn Garforth *A New Regime on Access to Genetic Resources and Benefit-Sharing?* (2003) 2. Available at http://www.cisdl.org/pdf/brief_biodiv.pdf [Accessed 3 October 2009].

[143] Article 8(j) of the CBD.

[144] Garforth (note 142).

[145] Daniel Gervais *The TRIPS Agreement: Drafting History and Analysis* 3ed (2008) 366 -2.254; International Chamber of Commerce *Policy Statement: TRIPS and the Biodiversity Convention: What Conflict?* (2002) 1. Available at http://www.wipo.int/export/sites/www/tk/en/igc/ngo/iccpolicystatement.pdf [Accessed 3 October 2009]; Carolina Lasen Diaz *Intellectual Property and Biological Resources: An Overview of Key Issues and Current Debate* (2005) 36. Available at http://www.wupperinst.org/en/info/entwd/index.html?beitrag_id=125&bid=43&searchart=publikationen_uebersicht [Accessed 3 October 2009].

[146] International Chamber of Commerce (note 145).

Indeed, the view is expressed that there is no conflict between the two treaties at all and that the agreements should be read in a 'mutually supportive manner'.[147] However, it is evident that the CBD assigns sovereignty over biological resources to the countries where these resources are located, whereas the TRIPS Agreement allows these resources to be patented by foreign companies.[148] Both treaties deal with economic aspects of intellectual property, but only the CBD includes provisions to protect biological diversity.[149]

TRIPS does not include any responsibilities pertaining to the conservation of biological resources, or to those who will benefit from ownership rights over these resources.[150] Moreover, by 'requiring that certain genetic material be patentable or protected by sui generis plant variety rights and by not preventing the patenting of other genetic material',[151] TRIPS allows for the appropriation of genetic resources by private parties.

A basic conflict between the TRIPS Agreement and the CBD is that TRIPS focuses on intellectual property rights as private rights, whereas the CBD gives countries the sovereign right to exploit their own resources. Consequently, traditional knowledge and genetic resources belong to the state and local communities.[152] Therefore, problems arise when the intellectual property holder is a foreign company. Hence, in cases where both treaties address similar subject matter, there might be inconsistencies between TRIPS and the CBD.[153]

As a consequence, developing countries in particular express the view that the CBD and TRIPS stand in conflict to each other.[154] These countries have made the

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[147] Lasen Diaz (note 145) at 37.
[148] Ibid.
[149] Michael J. Krieger *Intellectual Property Rights and Traditional Knowledge: Biopiracy or Bioprospecting?* (2008) 6. Available at http://www.bepress.com/cgi/viewcontent.cgi?article=1053&context=ndsip [Accessed 10 December 2009].
[150] Ibid.
[151] World Trade Organization Council for Trade Related Aspects of Intellectual Property Rights *The Relationship between the TRIPS Agreement and the Convention on Biological Diversity: Summary of Issues and Points made* (2006) 7. Available at http://www.wto.org/english/tratop_e/TRIPS_e/ipcw368r1c1.pdf [Accessed 16 December 2009].
[152] Krieger (note 149).
[153] Reyes-Knoche (note 125) at 512-20.
[154] World Trade Organization Council for Trade Related Aspects of Intellectual Property (note 151) at 4; Chee Yoke Ling Zugang zu genetischen Resources und Vorteilsausgleich unter dem Übereinkommen für biologische Vielfalt. Eine Perspektive des Südens in: Biopiraterie stoppen- Zugang und gerechter Vorteilsausgleich in der Konvention über die biologische Vielfalt (2008) 19.

suggestion that TRIPS needs to be amended to require disclosure of origin, prior informed consent and some kind of benefit sharing agreement.[155] They also recommend that this could be achieved by a reconciliation of TRIPS and the CBD as part of the review of Article 27.3 (b) TRIPS.[156]

Furthermore, it has been suggested that the regulations of the Patent Cooperation Treaty of the World Intellectual Property Organization are amended to enable countries to disclose the source of genetic origin and the traditional knowledge related to these sources in patent applications.[157] Meanwhile, the discussions about the relationship between the two treaties are ongoing and no consent has been reached as yet.[158] However, a more detailed discussion of this matter is beyond the scope of this thesis.

Meanwhile, members of the WTO have to comply with the rules set out by the TRIPS Agreement. Since it is mainly the diversity-rich, developing countries accusing the developed nations of biopiracy, this chapter will further provide an overview of the European Patent Convention as well as the United States Patent Act. Numerous patents are granted in each of these two jurisdictions and some of the most controversially discussed patent cases in relation to biopiracy have been decided by the European Patent Office and the United States Patent and Trademark Office.

B. The European Patent Convention

The Convention of the Grant of European Patents, generally known as the 'European Patent Convention', was formed in 1973 and entered into force in 1977. The European Patent Convention (EPC) provides the legal framework for the granting of European patents through a harmonised procedure before the European Patent Office and represents the most important regional framework for the harmonisation of patent law.[159] Nevertheless, the examination of the EPC can be seen as

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Available at http://www.eed.de/fix/files/doc/EED_Biopiraterie_stoppen_08_deu.pdf [Accessed 3 October 2009].

[155] Jayashree Watal WIPO/ESCAP *High-level Forum on Intellectual Property Rights and Trade Developing Countries and the TRIPS Agreement* (2007) 10. Available at: http://www.unescap.org/tid/projects/iptrade_s1watal.pdf [Accessed 3 October 2009].

[156] Ibid.

[157] Ibid.

[158] Ling (note 154).

[159] Leistner (note 122) at 73.

'representative of the continental European national patent laws,[160] more so because they do not differ a great deal from the EPC, especially not regarding traditional knowledge'.[161]

1. Patentability Requirements

The nature of patentable inventions is governed by Articles 52 and 53 EPC, whereby Article 52 EPC sets out the four criteria an invention must fulfil if a patent is to be granted.[162] It states that 'European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application'.[163] Besides being patentable subject matter, the invention must also be 'novel', involve an 'inventive step' and 'be capable of industrial application.'

a) Novelty

Article 54 EPC defines the term 'novelty.' According to this article, an invention is new 'if it does not form part of the state of the art'.[164] Furthermore, 'the state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application'.[165] [166]

Therefore, it becomes clear that the EPC follows the so called 'first to file' system.[167] The state of the art is 'constituted by all information which has been "made available to the public" (Article 54 (2) EPC) together with the contents of (unpublished) European patent applications as defined in Article 54 (3) EPC ("prior rights")'.[168]

The language in which the information is made available is irrelevant, as well as whether or not any particular member of the public actually received information

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[160] The European regulation represents the various European countries due to the fact that the European Patent Convention formed the basis for member states of the European Union to modify their laws accordingly; see Mgbeoji (note 74) at 125.
[161] Leistner (note 122) at 74.
[162] Paterson (note 86) at 404 9-02.
[163] Article 52 (1) EPC available at: http://www.epo.org/patents/law/legal-texts/html/epc/2000/e/ar52.html [Accessed 5 September2009].
[164] Article 54 (1) EPC.
[165] Article 54 (2) EPC.
[166] For the purpose of examination before the European Patent Office, the state of the art will mainly consist of the documents listed in the search report.
[167] Leistner (note 122) at 74.
[168] Paterson (note 86) at 484 11-05.

about an invention.[169] The relevance of Article 54 (1) EPC in conjunction with Article 52 (1) EPC is that everything that has already formed part of the state of the art cannot be patented.[170]

Therefore, in the context of 'novelty', there are two questions that need to be considered: 'what is the prior art that comprises the state of the art?'[171] And 'is the claimed invention novel over the state of the art'.[172]

b) Inventive Step

An invention shall be 'considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art'.[173] Therefore, in order to determine if the invention involves an inventive step, one has to consider the problem that the invention deals with, and what the person skilled in the art without knowledge of the patent application would have done in the face of such a problem. The person skilled in the art will be 'presumed to be an ordinary practitioner, aware of what was common general knowledge in the art at the relevant date'.[174] Just like the criterion of novelty, the inventive step is an objective concept.[175]

c) Industrial Application

An invention has to be capable of industrial application in order to be patentable in European patent law.[176] Industrial application means that the 'invention can be made or used in any kind industry, including agriculture'.[177] According to the Guidelines for Examination, 'industry is an activity which belongs to the useful or practical arts as distinct from the aesthetic arts' and 'does not necessarily imply the use of a machine or the manufacture of an article'.[178]

2. Exclusions and Exceptions from Patentability

Article 52 and 53 EPC identify several types of subject matter which are not patentable under the European Patent Convention. The non-patentability results

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[169] Ibid at 485 11-07ff.
[170] Ibid at 484 11-05.
[171] Ibid.
[172] Ibid.
[173] Article 56 EPC.
[174] Guy Tritton et al. *Intellectual Property in Europe* 3ed (2008) 103 2-074.
[175] Ibid at 99 2-068.
[176] Ibid at 110 2-088.
[177] Article 57 EPC.
[178] European Patent Office *Guidelines for Examination in the European Patent Office, Part C, Chapter IV, 4.1.* Available at http://www.epo.org/patents/law/legal-texts/html/guiex/e/c_iv_4_2.htm [Accessed 3 October 2009].

either from exclusion, as it happens in Article 52 EPC, or from exception, as in Article 53 EPC.[179]

a) Article 52 EPC

Article 52 (2) EPC specifically refers to what is not to be considered an 'invention' within the European Patent Convention. According to this Article, discoveries and scientific theories are not regarded as inventions and, therefore, are not patentable subject matter. Furthermore, according to Article 52 (4) EPC, certain methods for the treatment of the human and animal body are excluded from patentable subject matter.

b) Article 53 EPC

Article 53 EPC defines certain types of inventions, which by their nature cannot be patentable subject matter, under the EPC. These exceptions are called the 'morality' and the 'biological' exceptions.[180] Even though the exceptions under this Article may meet all the requirements for an invention to be patentable, as set out by Article 52 (1) EPC, they are still not patentable due to public policy reasons.[181]

According to Article 53 (a) EPC, '*European patents shall not be granted in respect of inventions the publication or exploitation of which would be contrary to "ordre public" or "morality" provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States'*. By adopting this phrase, the EPC made use of the possible exceptions to patentability as allowed and set out in the TRIPS Agreement.

However, the EPC adopted a rather narrow understanding of 'ordre public' and morality by only linking these terms to security reasons such as riots, public disorder, and inventions that lead to criminal or other offensive behaviour.[182]

According to Article 53 (b) EPC, European patents shall not be granted in respect of 'plant or animal varieties or essentially biological processes for the production of plants or animals'. Furthermore, 'this provision shall not apply to microbiological processes or the products thereof'. These adoptions make clear that, unlike in the TRIPS Agreement, this phrase only relates to plant varieties and not to

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[179] Paterson (note 86) at 405 9-03.
[180] Ibid at 405 9-05.
[181] Ibid.
[182] Carlos M. Correa *Oxford Commentaries on the GATT/WTO Agreements: Trade Related Aspects of Intellectual Property Rights, A Commentary on the TRIPS Agreement* (2007) 287.

animals and plants themselves, which then leads to the result that plants and animals can be patentable subject matter.

The protection of some biotechnological inventions raises difficulties in relation to exceptions of patentability under Article 53 (a) and (b) EPC.[183] As a result, a European Directive[184] was issued, in 1998, concerning the legal protection of biotechnological inventions. This Directive is binding for the member states of the European Union, but not for the European Patent Convention.[185] Consequently, under Article 33 (1) (b) EPC, a new Chapter VI[186] was inserted into Part II of the Implementing Regulations,[187] which entered into force in 1999. Rule 23b (1) states that 'for European patent applications and patents concerning biotechnological inventions, the relevant provisions of the Convention shall be applied and interpreted in accordance with the provisions of this chapter. Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions shall be used as a supplementary means of interpretation.'[188] This statement clarifies that the rules[189] correspond to the provisions of the EC Directive and have to be considered in relation to the provisions in Article 53 (a) and (b) of the European Patent Convention.[190]

C. U.S. Patent Act

The next legislation to be analysed is the United States Patent Act. The United States' patent law can be taken as representative of the countries with roots in the common law system. Furthermore, the United States of America is amongst the countries that receive the largest number of traditional knowledge related patent applications worldwide; and international patents granted by the United States Patent and Trade Office (USPTO) are routinely registered around the world.[191]

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[183] Paterson (note 86) at 407- 9.10a.
[184] European Directive 98/44. Available at http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1998:213:0013:0021:EN:PDF [Accessed 3 October 2009].
[185] Paterson (note 86) at 407-9.10a and 12- 1.26.
[186] This chapter was entitled 'Biotechnological inventions.'
[187] The Implementing Regulations of the European Patent Convention. Available at http://www.epo.org/patents/law/legaltexts/html/epc/1973/e/r23c.html [accessed: 13 September 2009].
[188] Rule 23b (1). Availabe at http://www.epo.org/patents/law/legal-texts/html/epc/1973/e/r23b.html [Accessed 13 September 2009].
[189] Namely 23b, 23c, 23d, 23e of the Rules.
[190] Paterson (note 86) at 407- 9.10a.
[191] Koyama and Mayet (note 20) at 43.

1. Background and Overview

Federal patent laws in the United States have existed since 1790.[192] Much of these patent laws were derived from English patent law.[193] The constitutional basis for federal patent and copyright systems, found in the Constitution of the United States Article 1, Section 8, Clause 8, states that 'Congress shall have power ... to promote the progress of science and useful arts by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries'. Today, the patent law is governed by the Patent Act of 1952, which can be found in Title 35 of the United States Code.[194]

The U.S. Patent Code is one of the few national laws that follows the 'first to invent' system by granting the patent to the person who was the first to invent a particular invention.[195] Patent applications in the U.S. are handled by the United States Patent and Trademark Office. The United States of America is also a member of the TRIPS Agreement and, therefore, has to comply with its rules.

2. Patentability Criteria

In the U.S., the patentable subject matter is regulated in 35 U.S.C. 101. According to this section, a patent can be granted for an 'invention or discovery of any new and useful process, machine, manufacture, a composition of matter, or any new and useful improvement thereof'. Patentable subject matter includes processes, manufactures and compositions of matter. This broad, statutory definition has allowed the United States to take a lead in widening the scope of patentable subject matter.[196]

An example is the decision in the famous Diamond v. Chakrabarty Case,[197] where a patent was granted for a newly designed bacterium that did not exist in nature.[198] The court concluded that 'anything under the sun made by man' can be

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[192] Ladas&Parry LLP *Intellectual Property Law: U.S. Patent History*. Available at: http://www.ladas.com/Patents/USPatentHistory.html [Accessed 6 September 2009].
[193] David Lange et al. *Intellectual Property: Cases and Materials* 2ed. (2003) 352.
[194] Roger E. Schechter and John R. *Thomas Intellectual Property: The Law of Copyrights, Patents and Trademarks* (2003) 282.
[195] Leistner (note 122) at 76.
[196] Ladas&Parry LLP *Patentable Subject Matter*. Available at http://www.ladas.com/Patents/Biotechnology/USPharmPatentLaw/USPhar03.html [Accessed 1 October 2009].
[197] Diamond v. Chakrabarty (1980) 447 US 303 available at http://supreme.justia.com/us/447/303/case.html [accessed 1 October 2009].
[198] Rajendra K. Bera 'Patentable Subject Matter under the U.S. Patent Act, 1952: Cases' (2008) 95 10 *Current Science* 1421 at 1422.

considered a 'manufacture.' However, abstract ideas, physical phenomena and laws of nature are no patentable subject matter under United States patent law.[199]

a) Usefulness

Section 101 of the Patent Act clarifies that 'patents can only be granted for useful inventions.' The United States describes the term 'useful' as synonymous with 'industrial application' as provided for in TRIPS. For an invention to be useful, the invention has to be capable of achieving a pragmatic result.[200] The more modern view is that 'so long as the invention may be put to a single lawful use, it possesses utility within the patent statute'.[201]

b) Novelty

The criterion, 'novelty', is explained in 35 U.S.C 102 and presents the 'core value'[202] of the patent system. A person is entitled to a patent unless 'the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent'[203], or the 'invention was patented or described in a printed 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'.[204]

Firstly, the inventor must create something new. (The novelty standard denies patents to already existing technology).[205] By analysing the aforementioned section, however, it becomes quite clear, that the United States is 'maintaining a double novelty standard depending on whether the disclosure of the invention has taken place within or outside the territory of the US'.[206] Public use or public knowledge only 'counts among prior art if "the invention was known or in use" in the United States, thereby ignoring use or knowledge in any other country in the world'.[207] This definition of the novelty requirement is called 'relative novelty'.[208]

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[199] Ladas&Parry LLP (note 196); Bera (note 198).
[200] Mitchell v. Tilghman, 86 U.S. (19 Wall.) 287, 396, 22 L.Ed. 125 (1873). Available at http://bulk.resource.org/courts.gov/c/US/86/86.US.287.html [Accessed 3 October 2009].
[201] Schechter and Thomas (note 194) at 316.
[202] Ibid at 323.
[203] 35 USC 102 (a).
[204] 35 USC 102 (b).
[205] Schechter and Thomas (note 194) at 323.
[206] Correa (note 182) at 275.
[207] Nuno de Carvalhos *The TRIPS Regime of Patent Rights* 2ed (2005) 192; Carlos M. Correa *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options* (2000) 58.

The relative novelty, however, does not violate Article 27 of the TRIPS Agreement since TRIPS does not provide a definition of 'novelty'.

c) Non-Obviousness

The next criterion an invention must meet in order to be patentable under U.S. law is 'non-obviousness.' By using this term, the U.S. deemed non-obviousness to be synonymous with the term 'inventive step', as allowed by the official footnote 5 to the Article 27 of the TRIPS Agreement.

According to 35 U.S.C. 103 (a) patentability is denied *'if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains'*. Therefore, this phrase requires jurists and PTO officers to decide 'whether an inventor's work product differs from the state of art enough to be patent-worthy'.[209]

Hereby, the group of technology important for the evaluation of obviousness has to be defined whereby the relevant prior art in this context is the same as for the criterion of novelty.[210] 35 U.S.C. 103 (a) thereby refers to an objective standard referring to the knowledge of an ordinary person skilled in the art.[211]

D. Comment

By the time the TRIPS Agreement was negotiated, the main focus for the developed countries had been the trade related aspects of intellectual property and the elimination of trade barriers.[212] Therefore, the TRIPS Agreement is seen rather as a response to requirements of trade than of issues of sustainable development.

During the Uruguay Round Negotiations, TRIPS was not the only treaty discussed. If countries were to join other treaties, they also had to accept TRIPS. Therefore, developing countries accepted the Agreement as part of a 'package deal'.[213] The TRIPS Agreement established 'minimum standards of intellectual property rights' protection that are rather consistent with the prevailing standards in

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[208] Ibid.
[209] Schechter and Thomas (note 194) at 370.
[210] Ibid.
[211] Ibid at 377.
[212] Dutfield (note 32) at 25.
[213] Daniel Gervais *Trips and Development* in Daniel Gervais *Intellectual Property, Trade and Development: Strategies to optimize Economic Development in a TRIPS-plus Era* (2007) 8.

most highly industrialized countries than with the developing nations'.[214] For this reason, the developing countries accuse the developed countries of unfair trade advantages without consideration of the developing nations' interests.

Nevertheless, by analysing TRIPS, it becomes evident that the treaty allows flexibility for the member states to implement the rules for patentability.[215] Article 27 of TRIPS specifies the requirements an invention must fulfill in order to be patentable, but does not define the term 'invention' itself.[216] Yet, neither the European Patent Convention nor the United States Patent Act has made use of these flexibilities regarding traditional knowledge. Neither the EU nor the USA adopted a definition of 'novelty' that is broad enough to include traditional knowledge. Hence, the question is, what should such a definition should look like? The definition should take into account that most traditional knowledge is passed down orally and does not exist in written form. Therefore, the definition of 'novelty' should not be limited to written information, but also include knowledge that has been made available orally. In addition, the United States should give up their standard of relative novelty, which would enable more knowledge to be included in the definition of 'novelty'.

However, it is important to bear in mind that traditional knowledge, per sé, is not patentable. Unless an invention fulfills the requirement of novelty and inventive step, i.e. modifies the knowledge, it cannot be patented in theory.

Yet, the fact that in the United States, unpublished traditional knowledge acquired from abroad, but not known in the United States, can be the subject of a patent application by a company that simply discovers this knowledge, seems unfair and disregards the rights of traditional communities. For that reason, the prior art definition in the EPC is more reasonable for two reasons: firstly, oral disclosure (or mere use) is sufficient for establishing prior art; and secondly, in cases of oral disclosure, there is no distinction made as to the geographical source of prior art knowledge relevant to the invention, unlike in a number of national patent laws.[217] When oral disclosure has been made, for examination and litigation purposes, it must be traceable in court. Hence, the problem of establishing traditional knowledge as

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[214] UNCTAD-ICTSD (note 113) at 35; Dutfield (note 32) at 25.
[215] Busche (note 138).
[216] Neef and Reyes-Knoche (note 108) at 472-6.
[217] Leistner (note 122) at 74.

prior art becomes a practical one. Patent offices are mainly bound to the sources that are available to them, which is basically literature related to patent law. Yet, the European Patent Office tries to cover as many sources as possible of non-patent literature, comprising commercial databases as well as an annual prescription to 1,400 journals screened for use in the classified collection.[218] Nevertheless, the patent examiner is 'limited to searchable sources and therefore ignoring a large part of existing traditional knowledge'.[219] Therefore, it can be concluded that although the European Patent Convention has a fairer approach, overall traditional knowledge has not been sufficiently dealt with in any of the examined patent legislations as yet.

V. Case Studies

The analysis of different patent legislation has shown that neither of the examined patent laws is able to adequately deal with the protection of traditional knowledge. So far, the principles of prior informed consent, disclosure of origin and benefit sharing are not a part of patent law.

Hence, it is important to have a closer look at the consequences for traditional knowledge accompanying the lack of protection under current patent law. Furthermore, the practical implications of decisions have to be examined. Therefore, this chapter will provide insight into three of the most discussed, controversial court cases dealing with patentability of inventions related to plant genetic resources and traditional knowledge.

Although the cases relate to different genetic resources and different companies, the underlying stories can be considered to be quite similar in the sense that their development and outcome are alike. Generally speaking, a biotechnology company sends scientists to biodiversity-rich countries to collect samples of biological resources and to research traditional knowledge related to these resources. Later on, the company seeks to develop a new product, based on their findings, which could result in a successful end product and be commercialised throughout the world. Patent protection is sought for these products, but no prior informed consent or benefit sharing has taken place with the local communities. In most cases, patents

[218] Ibid.
[219] Ibid.

are obtained, granting exclusive rights for a period of twenty years. At this point, the patents are usually challenged by non-profit organisations which try to help the local communities.

A. Neem Patent

The first case to be introduced in this chapter deals with the 'Neem Patent', a patent which was granted by the European Patent Office in 1994.[220]

1. Background

The Neem tree is a 'subtropical member of the mahogany which is native to the Indian subcontinent'.[221] Indian texts documented the Neem tree approximately 2000 years ago. Over the centuries, Indian farmers have been using the tree as an insect and pest repellent, as well as in human and veterinary medicine.[222] Nevertheless, these ingredients have not been given 'Latinized scientific names'.[223]

Not until recently, did Western countries start paying attention to the Neem tree and its properties. The change of mind is partly due to growing interest in 'natural products';[224] yet, neither the Neem tree itself, nor its parts, has been patented. However, several processes and products involving various principles of the Neem tree have been patented.[225] In most cases, traditional knowledge has stimulated the research and development that resulted in the patents. Meanwhile, the subject matters in question were still claimed to be new to Western science and technology and to involve an inventive step.

2. The Grant of the Patent

The patent analysed above had been granted to the U.S. Corporation W.R. Grace Company and U.S. Department of Agriculture by the European Patent Office in 1994.

The patent disclosure described a 'method for controlling fungi on plants using hydrophobic oil extracted from the seeds of the neem tree (Azadirachta

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[220] European Patent No. 0436257.
[221] Cormac Sheridan 'EPO Neem Patent Revocation revives Biopiracy Debate' (2005) 23 5 *Nature Biotechnology* 511 at 511.
[222] Linda Bullard *Freeing the Free Tree* (2005). Available at http://www.wloe.org/The-Neem-Case.276.0.html?&no_cache=1&sword_list%5b%5d=Neem [Accessed 30 October 2009].
[223] Vandana Shiva *Protect or Plunder? Understanding Intellectual Property Rights* (2001) 60.
[224] Vandana Shiva *Biopiracy: The Plunder of Nature and Knowledge* (1997) 71.
[225] Shiva (note 223).

indica)'.[226] With the application, the applicant also submitted paper acknowledging the 'century old traditional knowledge of the neem tree as a source of insecticides in tropical countries'.[227] Yet, the patentee contrasted the subject matter to existing prior art, stating that 'the insecticide and fungicidal activities of the neem oil is unique and unexpected in the view of the absence of any known active ingredients'.[228]

Originally, the claims of the patentee also included insect repellent and insecticide effect of the neem formulation. However, the first examination report, of September 1992, found evidence of prior art in regards to insect repellent or insecticide effects in neem formulations. Therefore, the patentee had been advised to limit the patent claim to its fungicidal effect.[229] The second examination report, in 1993, acknowledged the novelty and the inventive step of the subject matter and the grant of the patent was published on September 14 1994.[230]

3. Opposition

In 1995, an opposition was filed against the patent by an alliance of Indian and European non-governmental organisations along with the Green Group of the European Parliament. An opposition is a 'means to which any person may have recourse, of contesting a decision and causing the legal validity of a patent to be re-examined'.[231] The challenge to the Neem tree patent was based on various grounds. To analyse the outcome of the case it is, however, necessary to have closer look at the opponents' main arguments. The opposition was based on Articles 53 (a), 54, 56 EPC.

The opponents first argued that, under the consideration of Article 53 (a) of the European Patent Convention, the grant of the patent resulted in a breach against the 'ordre public' and morality principle. They also argued that the grant of the patent 'deprived the Indian people of their cultural heritage and natural resources passed down for centuries'.[232] The opposition further claimed that the denial of prior

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[226] European Patent Specification for Patent 0436257 (1994) 1;Sheridan (note 221).
[227] Fritz Dolder 'Traditional Knowledge and Patenting: The Experience of the Neemfungicide and the Hoodia Cases: Analysis of European Patent Law' (2007) *Biotechnology Law Report* 583 at 584.
[228] Ibid.
[229] Ibid.
[230] Ibid.
[231] Albert Ballester Rodes et al. *Case Law of the Boards of Appeal of the European Patent Office* 5ed. (2005) 531.
[232] Dolder (note 227) at 586.

art, and the ensuing restrictions, violated the right of the local people to use the source.

Apart from that, it was alleged that the patent was directed at a plant variety, in the sense that the neem extract represented a part of the neem tree, which in practice leads to a partial monopoly of the plant variety Azadirachta indica.[233] They argued this to be true due to the fact that the process could only be performed by using seeds of the Neem tree.[234]

The opponents' central argument was that the Neem tree's properties had been used by Indian farmers for over centuries. The fungicidal effect of the hydrophobic extracts of Neem seeds was known and used by Indians in traditional agriculture to protect crops from being destroyed by fungal infections[235]and therefore constituted 'prior art.' Yet, if an opponent wants to '*rely upon prior use as being part of the state of the art for the purpose of Art. 54 (2) EPC and as part of the legal and factual framework within which the substantive examination of the opposition is to be conducted, the notice of opposition must indicate within the opposition period all the facts which make it possible to determine the date of prior use, what has been used, and the circumstances relating to the prior use'.*[236]

Consequently, the opponents supported their approach with documentary and oral evidence of field trials with hydrophobic extracts of Neem seeds. Furthermore, they brought forward the argument that even though the subject matter in question might be novel, the subject matter still constituted 'mere routine for a skilled person in the art' and therefore lacked an inventive step according to Article 56 EPC.[237]

4. The Outcome of the Opposition

The Opposition Division agreed with the opponents insofar as a patent should not be granted for anything that has been known before. Yet, they did not follow the 'ordre public' argument brought forward by the opposition. Rather, the Opposition Division argued that under the European Patent Convention, this was a question of novelty and not a matter of 'ordre public'. In respect to the argument that the patent would allow a monopoly over the whole plant variety, the Opposition division held

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[233] Christina Federle *Biopiraterie und Patentrecht* (2005) 70.
[234] Dolder (note 227) at 586.
[235] Bullard (note 222).
[236] Rodes et al. (note 231) at 561.
[237] Dolder (note 227) at 586.

that 'the exclusion of plant varieties in Article 53 (b) EPC could not be infringing by a method for controlling fungi that used an extract obtainable by using the seeds of a special tree and the tree itself'.[238]

After the testimony of the scientific director of an Indian biotechnology company on the field trials, who supplied detailed information on the technical aspects of the trials and stated that the trials had been open to the whole agricultural population in the area, the Opposition Division concluded, on the basis of the submitted evidence and the oral testimony,[239] that the subject matter involved in the case lacked novelty.[240]

In response to this, the patentee submitted an auxiliary claim, which amended the Neem formulation slightly. As a consequence, the concentration of Neem oil contained fell just outside the parameter described in any evidence of the submitted documents relevant for prior art. Yet, the Opposition Division ruled that, in the amended form, the subject matter lacked an inventive step[241], because a 'person skilled in the art would obviously have lowered the neem oil concentration while accepting that the effect might be less'.[242] As a result, the patent was revoked.

5. Appeal Procedure

The patentee filed an appeal against the revocation, requesting it be overturned. Within this request, the patentees again submitted a modified form of their original claim.[243] Yet, in 2005, the Board of Appeal came to the conclusion that the subject matter lacked an inventive step because it was 'obvious to try to use formulations, such as those defined in the claim, for controlling fungi on plants'.[244] Consequently, the subject matter lacked an inventive step.[245] As a result, the Board of Appeal

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[238] Ibid.
[239] Boards Of Appeal of the European Patent Office, Decision of 8 March 2005 Case Number T 0416/01-3.3.2 Application Number 90250319.2, Publication Number 0436257 ('Neem Tree Decision') p. 3. Available at http://www.tk.bioetica.org/biblioteca/neem.pdf [Accessed 1 December 2009].
[240] Kari Moyer-Henry 'Patenting Neem and Hoodia: Conflicting Decisions Issued by the Opposition Board of the European Patent Office' (2008) 1 *Biotechnology Law Report* 1 at 5.
[241] Bullard (note 222).
[242] Dolder (note 227) at 587.
[243] Boards Of Appeal of the European Patent Office (note 239) at 4; Bullard (note 222).
[244] Ibid at 20.
[245] Ibid.

dismissed the appeal of the patentee and, therefore, confirmed the decision made by the Opposition Division.[246] [247]

6. Comment

The outcome of the 'Neem Tree Case' is a great victory for traditional communities in general. The opposition successfully proved that the Neem tree properties, including the method of extracting oil out of seeds, had been used by farmers in India for centuries and, therefore, constituted prior art under European Patent Law. Yet, it is not surprising that the Opposition Division rather relied on the requirements of inventive step and novelty than on the aspect of 'ordre public' and morality.[248] This approach corresponds to the almost unanimous opinion of legal literature that the mere utilisation of traditional knowledge cannot render a patent immoral.[249] This follows from the wording of Article 53 (a) EPC, which has to be interpreted in a narrow way in the sense that 'the immorality exception can only apply in exceptional cases and that the immorality must follow from the publication or exploitation of the invention and not from the immoral use of the underlying material'.[250] Furthermore, the rules for the assessment of inventive step and novelty are well established and are easily applied, whereas hardly any established rules exist for the application of 'ordre public' or morality.[251]

The revocation of the Neem patent shows the possibility to defeat cases of biopiracy. Nevertheless, the procedure was costly and took many years and could have been avoided from the beginning if the patent office examiner had closely looked at the requirement of novelty and prior art. In fact, the examination process had been insufficient regarding the determination of prior art. The European patent officer ought to have found evidence for the Indian use of the Neem tree properties. Yet, the European Patent Office has recognised 'that traditional knowledge is a potential public prior use but evidence has to be provided of it'.[252] According to Julian Kinderlerer, the decision urges the 'EPO to widen its research in relation to

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[246] Ibid at 21.
[247] In this context it is interesting to note, that a quite similar Neem patent had been granted in the United States of America by the USPTO. Yet this patent had not been revoked by the USPTO but rather had been withdrawn by the patentee due to political and public pressure.
[248] Dolder (note 227) at 588.
[249] Leistner (note 122) at 75.
[250] Ibid.
[251] Dolder (note 227) at 588.
[252] Sheridan (note 221) at 511.

novelty'.[253] This conforms to the result from the previous chapter where the flaws in the patent office's research possibilities had been pointed out.[254]

To avoid confusion, it is important to realise that even if the patent had not been revoked, the patentee would only have had the monopoly over the commercial exploitation for 20 years for 'the method for controlling fungi by using a hydrophobic neem oil extract'. The patent neither covered the Neem tree itself, nor the Neem tree seeds. Moreover, the protection of the patent would have been limited to the country in which the patent had been issued, since patent rights are not enforceable worldwide, which in this case would have been the contracting parties to the EPC. Local communities in India could have used the same invention as long as there had not been a patent issued in India as well.

The problem, however, is of a broader scope. One has to bear in mind that this case only pertains to one specific patent on neem. Worldwide, there are quite a number of other patents on uses of the Neem tree, which are not affected by the decision of the European Board of Appeal. To challenge every single patent would be extremely expensive.

The revoked Neem Tree patent is just one case and shows the controversy surrounding the patenting of inventions related to traditional knowledge. One can, however, say that it was a revocation with a symbolic value. To show people and especially biotechnological companies that they cannot simply take away traditional knowledge related to genetic resources that have been available in the public for years.[255]

B. Pelargonium Patents

The second case to be analysed in respect of biopiracy, deals with the 'Pelargonium Patents'.

The pelargonium plants 'are part of the geranium plant family, which has a worldwide distribution'.[256] The two species of pelargonium that form the subject

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[253] Statement of Julian Kinderlerer in Cormac Sheridan 'EPO Neem Patent Revocation revives Biopiracy Debate' (2005) 23 5 *Nature Biotechnology* 511 at 511.
[254] Supra page 34.
[255] Sheridan (note 221) at 511.
[256] African Center for Biosafety *Frequently Asked Questions about the Pelargonium Patents* (2008)1. Available at http://www.biosafetyafrica.net/index.html/index.php/20090213201/Frequently-asked-questions-on-the-PELARGONIUM-PATENT-CHALLENGES/menu-id-100029.html [Accessed 1 December 2009].

matter of the patent challenges are Pelargonium sidoides and Pelargonium reniforme, which are indigenous to South Africa.[257] Both pelargonium species are well-known in South African communities for their medicinal properties, and are used to treat various illnesses. The plants have been used by 'local communities for respiratory tract infections, common coughs and colds, tuberculosis and stomach ailments, amongst many other illnesses'.[258] Written records of these pelargonium species date back to the 1800s. However, knowledge, and practical application of such knowledge, has 'a long ancestral lineage, going back to time immemorial, among local communities of South Africa'.[259]

1. The Patents

Two patents related to the described species of pelargonium have been granted to Schwabe in 2007 by the European Patent Office. The Dr. Willmar Schwabe Group was founded in 1866 and specialises in homeopathic remedies.[260] Today, Schwabe Pharmaceutical is among the 'leading phytomedicine companies in the world'.[261]

The first patent[262] was granted to Schwabe by the European Patent Office on 13 June 2007 and is titled 'Method for Producing Extracts of Pelargonium Sidoides and/or Pelargonium Reniforme'.[263] The patent relates to the extraction and production methods for the two pelargonium species, using various scientific methods. It grants Schwabe the right, for 20 years, to preclude all other persons from making, selling, or licensing the pelargoniums that have been extracted by water and alcohol in all European countries that are Parties to the European Patent Convention.[264]

The second patent was granted on 29 August in 2007.[265] The invention refers to the use of Pelargonium sidoides and/or Pelargonium reniforme root extracts for

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[257] Ibid.
[258] Ibid at 3; Koyama and Mayet (note 20) at 28.
[259] African Center for Biosafety (note 256).
[260] Schwabe Group *History*. Available at http://www.schwabepharma.com/international/about-us/history/index.php [Accessed 14 September 2009].
[261] Ibid.
[262] EP 1429795B1; Europäische Patentschrift. Available at https://data.epo.org/publication-server/getpdf.jsp?pn=1429795&ki=B1&cc=EP (Accessed 17 February 2010].
[263] Ibid.
[264] African Center for Biosafety *'Knowledge not for Sale'* Briefing Paper p 8. Available at http://www.biosafetyafrica.net/index.html/images/stories/dmdocuments/pelargonium-brief.pdf [Accessed 19 November 2009].
[265] EP 1651244 B1; Europäische Patentschrift. Available at https://data.epo.org/publication-server/getpdf.jsp?pn=1651244&ki=B1&cc=EP [accessed 17 February 2010].

the creation of a medication for the treatment of AIDS and AIDS related infections caused by other viruses, bacteria (especially mycobacteria), fungi and parasites.[266]

2. Challenging the Patents

a) First Patent

In 2008, the African Centre for Biosafety and the Berne Declaration, among others, filed a challenge to the patent and asked the European Patent Office to revoke the patent. The challenge is based on several grounds.

First of all, the opponents claim that the Convention on Biological Diversity requires prior informed consent, disclosure of origin and benefit sharing when accessing biological resources and traditional knowledge related to these resources.[267] The opponents, therefore, allege that Schwabe should have complied with these requirements in first place; however, they complain that there is no evidence provided that Schwabe fulfilled these criteria. Consequently, in the opposition's point of view, this misbehaviour leads to breach of Article 53 (a) EPC, which does not allow patents to be granted if they are against 'ordre public' or morality.[268]

The opposition further alleged that there is no inventive step involved in the extraction process of pelargonium. The opponents held that '*it is a standard textbook procedure in herbal chemistry and biology, which is also not novel, in that it duplicates extraction methods used by the Alice Community and other communities since time immemorial.*'[269]

b) Second Patent

The second Pelargonium patent has been challenged on similar grounds. The opposition claimed that the application of pelargonium for HIV and related diseases lacked novelty. Furthermore, they alleged that the claimed inventive step did not justify being called an invention, because it had been proven that, within the Alice Community, pelargonium species had been used for numerous viral and bacterial

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[266] The text of the German original version is 'Die Erfindung betrifft die Verwendung von Extrakten aus Wurzeln von Pelargonium sidoides und/oder Pelargonium reniforme zur Herstellung eines Arzneimittels zur Behandlung von AIDS und AIDS-assoziierten Infektionen verursacht durch andere Viren, Bakterien, insbesondere Mykobakterien, Pilze und Parasiten.'

[267] African Center for Biosafety (note 264).

[268] Ibid.

[269] Ibid at 9.

infections.[270] The opposition asserted this knowledge to be in the South African Public domain, and therefore not eligible for patent.[271]

c) Comment

The Pelargonium Patents are proof of ongoing misappropriation of traditional knowledge by western companies. Again, patents have been granted for an invention based on genetic resources and traditional knowledge related to these resources and again patents have been challenged on the grounds of lacking novelty and inventive step.

The outcome of these two cases[272] is not clear, but it is likely that the patents have to be revoked on the evidence of prior art provided by the opposition and the similarity to the previously discussed Neem Case decision. Hence it is also unlikely that the decision will be based on aspects of morality. For the same reasons provided in the Neem Decision, the exception of morality must follow from the immoral publication or exploitation of the invention and not from the immoral use of the underlying material.

Once more, this case shows the lack of ability to adequately deal with traditional knowledge as prior art. Much time will pass before this case will be decided; time, which allows Schwabe to continue with the commercialisation of the patent. Moreover, challenges to patents are a costly procedure. If it had not been for the help of non-governmental organisation, the challenge could not have been filed in first place, which again shows the flaws in existing patent law.

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[270] Ibid.

[271] Ibid at 8.

[272] Meanwhile, on 26 January 2010, at a hearing in opposition procedure, the EPO has revoked one of the two patents, namely EP 1429795B1, because the patent did not fulfil the inventive step requirement of the European Patent Convention. By the time this thesis has been completed; the reasons for the decision have not been published. Publication is however expected within a few weeks. Even though the outcome of the decision may be considered a success, the decision remains appealable at a second instance by an EPO technical Board of Appeals. See for more information the European Patent Office press release: *European Patent Office Revokes "Pelargonium Extract" Patent* (26 January 2010), which is available at http://www.epo.org/about-us/press/releases/archive/2010/20100126.html [accessed 17 February 2010].

C. Enola Bean Patent[273]

The last case to be discussed within this thesis is the so called 'Enola Bean Patent.'

1. The Grant of the Patent

The 'Enola Bean Case' goes back to 1994, when a man called Larry Proctor bought a bag of multicoloured beans on a market in Mexico. He brought these beans back to the United States of America, where he planted the yellow beans he had previously selected due to their colour. After further selection and cultivation he filed for a patent. He even admitted that the Enola bean is a descendant of the traditional Mexican bean from the Andes, but claimed the bean to have a 'better yellow color and a more consistent shape'.[274] Despite this, in 1999, Proctor was granted a patent in this regards which was later assigned to his Colorado based seed company POD-NERS. The scope of the exclusive monopoly covered 'all Phaseolus vulgaris (dry bean) with a seed colour of a particular shade of yellow'.[275]

Fifteen related claims had originally been granted by the United States Patent and Trademark Office. Four of these were 'directed to various aspects of the Enola Bean, three recite methods for crossing Enola with another field bean plant and the last eight claims encompass any bean variety with the recited characteristics, which includes but is not limited to the Enola variety'.[276] Furthermore, Proctor applied for a United States Plant Variety Protection certificate to further protect the bean.

2. The Bean

The yellow bean is an important basic food in Mexico and the source of income for small farmers.[277] Ninety-eight per cent of surveyed Mexicans in the Northwestern area of Mexico eat the yellow bean which is known in that region as 'Azufrado' or 'Mayacoba'. Yellow beans had been discovered many years ago in a cave in the Peruvian Andes and in 1978; Mexican agronomists crossed two yellow-tinted

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[273] U.S. Patent No. 5,894,079.
[274] Danielle B. Goldberg *Jack and the Enola Bean* (2003). Available at http://www1.american.edu/TED/enola-bean.htm [Accessed 9 November 2009].
[275] Sangeeta Shashikant and Asmeret Asghedom *The Enola Bean Dispute. Patent Failure&Lessons for Developing Countries* (2009).Available at http://www.twnside.org.sg/title2/intellectual_property/info.service/2009/twn.ipr.info.090801.htm [Accessed 1 November 2009].
[276] Carol Nottenburg *Enola Bean Controversy: Facts and Analysis* (2009) Harvest Choice 3. Available at http://cougarlaw.com/linked_files/enola_bean_fa_20090714.pdf [Accessed 16 December 2009].
[277] Neil Palmer 'A Patent Problem with Enola Bean' (2009) *New Agriculturist*. Available at http://www.new-ag.info/developments/devItem.php?a=964 [Accessed 1November 2009].

varieties and developed a modern version of the yellow bean which was called 'Mayacoba' after a nearby village in Sinaloa state.[278]

The Enola Bean patent allowed Proctor to claim royalties from Mexican companies that wished to export yellow beans to the United States of America.[279] Furthermore, U.S. American farmers had to pay for a licence from POD-NERS if they wanted to sell this type of bean within the United States.[280] They were most likely in danger of being sued for patent infringement if they did not comply.

3. Re-examination

In December 2000, the CIAT[281] sought a re-examination of the Enola Bean Patent. Under the rules of the United States Patent and Trademark Office, the grant of a patent can be reversed if published material before a patent application is found that had not been brought to the attention of the patent examiner before.[282]

The CIAT brought forward '*evidence of 260 yellow beans among the almost 28,000 samples of Phaseolus in its crop gene bank and claimed that 'at least six of the CIAT varieties were identical in respect of colour and genetic markers to the beans described in Proctor's patent claims'*.[283] It was further alleged, that Proctor's patent claims relied on research material which at the time of the claims had already been available in literature and, therefore, the claims regarding the breeding of the bean did not meet the criteria of 'non-obviousness' and 'novelty'.[284] Also, the opponents claimed that the misappropriation of the bean variety 'violated Mexico's sovereign rights over its genetic resources, as recognized by the Convention on Biological Diversity'.[285]

Noteworthy in this context is that the re-examination procedure has been delayed by Proctor's lawyers and their amendments of the original patent. In fact, during the re-examination, they filed 43 new claims. Even though a final rejection was released by the USPTO on 14 April 2005, Proctor was allowed another six

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[278] Goldberg (note 274).
[279] Palmer (note 277).
[280] Ibid.
[281] The CIAT is short for the Columbian based International Centre for Tropical Agriculture.
[282] International Centre for Tropical Agriculture *US Patent Office Rejects US Company's Patent Protection for Bean Commonly Grown by Latin American Farmers* (2008). Available at http://webapp.ciat.cgiar.org/newsroom/release_31.htm [Accessed 20 February 2010].
[283] Ibid.
[284] Ibid.
[285] Shashikant and Asghedom (note 275).

months to file a request for a further extension of the re-examination period. Consequently, Proctor filed the request which resulted in a three month reprieve.[286] On 21 December 2005, the USPTO issued another decision with the final rejection of the patent claims, but allowed Proctor to take the case to a higher board of appeals.[287]

4. Board of Patent Appeals and Interferences' Decision[288]

Proctor appealed, but the Board of Patent Appeals ruled the patent invalid in April 2008. However, it is noteworthy that the Board of Appeals and Interferences first reversed the decision by the re-examination by stating that the examiner did not provide sufficient evidence to support a prima facie case of unpatentability in the light of the seeds provided by the CIAT and documents by Kaplan, Hernandez-Xolocotzi and Voysest.[289]

Hence, in the opinion of the Board, the provided evidence did not qualify to deny novelty or to prevent non-obviousness. However, the Board accepted the Pallotini document in connection with the Azufrado Peruano 87 plant evidence, as brought forward by the CIAT, and stated that the Azufrado Peruano 87 plant reasonably appeared to be the substantially the same as Proctor's claimed Enola Bean.[290] Hence, the examiner provided sufficient prima facie case of anticipation to shift the burden to Appellant (Proctor) to show that the Enola cultivar, its propagating material and seeds are not the same as the Azufrado Peruano 87 cultivar, propagating material and seeds.[291] The Board concluded that Proctor had failed to provide this evidence. Therefore the rejection of the claims had been affirmed by the Board.

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[286] Ibid.
[287] Ibid.
[288] United States Patent and Trademark Office Board of Patent Appeals and Interferences Ex Parte POD-NERS L.L.C. Appeal 2007-3938 Re-examination Control 90/005,892 Reissue Application 09/773,303 Patent 5,894,079 Decided 29 April (2008).
[289] Ibid at 34/ 39.
[290] Ibid at 41.
[291] Ibid at 42.

5. United States Court of Appeals for the Federal Circuit[292]

Nevertheless, Proctor took the case to the United States Court of Appeal for the Federal Circuit. In July 2009, The U.S. Court of Appeals ruled Proctor's patent to be invalid due to lack of non-obviousness, but did not reach all the issues of the examiner's rejection. This decision came after many years of legal battle. The US Court of Appeals merely reaffirmed that the 'Enola Bean patent was erroneous, blatantly invalid since it has been grown and eaten in Mexico for centuries'.[293] Therefore, the case was decided on very limited grounds and did not refer to the major issues of patentability. The Court then stated that the disposition is non-precedential. By doing so, the Court has warned that it is not obligated to treat subsequent cases in the same way.

6. Comment

The 'Enola Bean Case' highlights the controversy surrounding the patenting of genetic material related to traditional knowledge. The yellow bean had been found in the Peruvian Andes, grown in Mexico for centuries, and further developed by Mexicans. Proctor, however, had been given the patent on the basis that the Enola bean was a distinct colour and was unlike any other bean produced in the United States of America.[294]

For developing countries, the dispute presents several key issues in the biopiracy debate and strengthens their argument that measures have to be developed to prevent cases of biopiracy. The opposition claimed the same reasons for the patent to be invalid as it had been claimed in the Neem Patent Case at the EPO. A supporter of the patent system could argue this example demonstrates a working system because the patent was eventually found to be invalid. However, once again, a patent has been issued that should have not been issued in the first place due to lack of novelty and inventive step.

Moreover, it is hard to believe that the re-examination process was delayed because lawyers amended the original claims by filing as many as 43 new claims. This delay allowed Proctor to enjoy the monopoly over the Enola bean. Hence, he was able to enforce a monopoly on the market and received royalties from other

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[292] United States Court of Appeals for the Federal Circuit 2008-1492 Re examination No. 90/005,892 IN RE POD NERS L.L.C. Appeal from the United States Patent and Trademark Office, Board of Appeals and Interferences, decided 10 July 2009.

[293] Shashikant and Asghedom (note 275).

[294] Ibid.

entities which resulted in economic losses for other farmers. The fact remains that if the Enola Bean seeds had been collected somewhere in the United States of America, they would have qualified as prior art and a patent would have been denied. Yet, due to the mixed standard of novelty, as laid out in Chapter IV, a patent based on the seeds was granted.

The ongoing grant of patents related to genetic resources and traditional knowledge offers reasons for concern, particularly in the developing world. Patent examiners do not seem capable of determining traditional knowledge as prior art. Yet, again the outcome of the case proved that biopiracy can be fought. However, as indicated previously in this chapter,[295] patent challenges are a costly procedure that should be avoided if possible. These procedures can only be avoided if measures are established that protect traditional knowledge from being exploited.

VI. Discussion and Analysis

The previous chapters have demonstrated the flaws in current patent law in respect of the protection of traditional knowledge. The analysis of the TRIPS Agreement, as well as the European Patent Convention and the United States Patent Act has shown that neither of these laws requires prior informed consent, disclosure of origin or benefit sharing agreements, even though these three criteria are obligatory under the Convention on Biological Diversity.

Generally speaking, it can be alleged that patent law is not 'applicable to the traditional knowledge stock itself, including the traditional knowledge systems, because it is limited to inventions adding an inventive step to a free knowledge stock and thus not protecting the public domain knowledge stock itself but only derivate products'.[296] As a result, defenders of strong patent laws claim that as long as the requirements of novelty, inventive step and industrial application are fulfilled, there is no need for traditional knowledge holders to be alerted and feel exploited.[297] In

[295] Supra page 43.
[296] Leistner (note 122) at 65.
[297] Dutfield (note 32) at 56.

their argument, it can be concluded that if traditional knowledge had simply been copied, there would be no patentable subject matter and, therefore, no valid patent.[298]

This sounds fine in theory. Yet, the case studies have revealed that patents have been granted to companies that should not have been granted to them because they either lacked novelty or inventive step or even both. The Enola Bean Patent, as well as the Neem Patent and the Pelargonium Patents, involved patentable subject matter related to traditional knowledge and prior art had existed in this context. Still, the patents had been granted. Consequently, it can be concluded that 'theory and practice of patenting differ'.[299] Patent law, therefore, does not hinder the misappropriation of traditional knowledge, but rather enables the misappropriation to an extent that is not tolerable anymore.

Nevertheless, with TRIPS in place, there is practically no possibility of excluding the subjects of traditional knowledge from patentability. Therefore, the most important question to be considered is how to protect the traditional knowledge adequately. The first question to consider is why traditional communities do not patent the products related to their traditional knowledge themselves.

It simply may not an option. Firstly, to obtain a patent is a highly costly procedure; and, secondly, cultural values play an important role. For indigenous communities, patents are tools of industrialised countries, companies and societies and reflect values of private ownership and wealth.[300] These values are non-existent in indigenous communities. Their traditional values and lifestyles are bound in communal living and the sharing of resources which leads to an interdependency in regards to all living things.[301]

Therefore, it should be asked whether or not patent law, despite its mentioned flaws, 'provides promising solutions'.[302] Indeed, the opinion exists that patent law cannot provide the necessary form of protection needed by traditional knowledge. Supporters of this view argue that intellectual property in general, and patent law

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[298] Ibid.
[299] Ibid.
[300] Global Exchange *Biopiracy: A new Threat to Indigenous Rights and Culture in Mexico* (2007). Available at http://www.globalexchange.org/countries/americas/mexico/biopiracyReport.html [Accessed 16 December 2009].
[301] Ibid.
[302] Dutfield (note 32) at 104.

specifically, has not been created to protect traditional knowledge, but much rather to give incentives and rewards for innovations.

Yet, there are other positions that suggest modifications to current patent systems in order to overcome the misappropriation of traditional knowledge. The next chapter will provide a profound analysis of the different approaches to overcome the issue of biopiracy.

VII. Ways to Prevent Cases of Biopiracy

This chapter will discuss possibilities and mechanisms, within and outside the patent system, for the protection of traditional knowledge and prevention of biopiracy. The chapter is divided into defensive and positive protection options. It is important to realise that the distinctions between the two different approaches are not always 'clear cut'.[303] In fact, 'positive protection measures can also be used to provide defensive protection and vice versa'.[304]

A. Defensive Protection Options

The chapter will start with the examination of different defensive protection options for protecting traditional knowledge through patent law. These options can be defined as 'enhancements to or modifications of existing intellectual property regimes'.[305] Several proposals have been made; however, focus will be on three of the most important suggestions developed from international negotiations.

1. Disclosure of Origin

The discussion about the relationship between TRIPS and the CBD in chapter IV has revealed the possible conflict between these two treaties. For that reason, the requirement of disclosure of origin in patent applications has been suggested.

Disclosure of origin requirements can fulfill several functions within the intellectual property system. More specifically, disclosure requirements can improve the 'substantive examination of patents, enhance determination of inventorship and other

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[303] Graham Dutfield *Protecting Traditional Knowledge: Pathways to the Future* (2006) 22. Available at http://www.iprsonline.org/unctadictsd/docs/Graham%20final.pdf [Accessed 3 November 2009].
[304] Ibid.
[305] Dutfield (note 31) at 506.

entitlements and facilitate or permit use of the subject matter'.[306] Also, disclosure of origin may promote compliance with the objectives laid out in the Convention on Biological Diversity[307] and, therefore, reduce possible misappropriation. In addition, such a requirement may 'assist in tracking the commercial exploitation of genetic resources and traditional knowledge in order to ensure equitable benefit sharing.[308]

a) General Considerations

Views in favour of disclosure requirements argue that the affirmation of sovereign rights over genetic resources under the CBD implies a 'subordination of private rights (including intellectual property rights) to public interest related measures'.[309] As a consequence, governments cannot be forced to grant private rights in cases where potential title holders are in conflict with national norms or principles of public interest. Yet, suggestions for disclosure of origin vary in regards to the 'weight and nature of the legal, administrative and informational burdens' imposed upon the patent holders and applicants.[310]

Therefore, it is necessary to have a closer look at three of the most important suggestions in this regard. The first suggestion is that disclosure should be encouraged and expected, but not legally required.[311] Consequently, omission would not hinder the patent from being granted. The second suggestion requires mandatory disclosure of origin; whereas the third suggestion goes further, requiring patent applicants to comply with the provisions on access and benefit sharing as laid out in the CBD.[312] Compliance could be ensured by establishing a certificate of origin system. Certificates of origin are used in trade as 'a way to guarantee that goods supposed to come from a country that enjoys a particular tariff privilege genuinely

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[306] Joshua D. Sarnoff and Carlos M. Correa *Analysis of Options for Implementing Disclosure of Origin Requirements in intellectual Property Applications: A Contribution to UNCTAD's Response to the Invitation of the Seventh Conference of the Parties of the Convention on Biological Diversity* (2006) 5. Available at http://www.unctad.org/en/docs/ditcted200514_en.pdf [Accessed 16 December 2009].

[307] Especially Article 15.1 CBD which addresses access to genetic resources.

[308] Sarnoff and Correa (note 306) at 6.

[309] David Vivas Eugui *Requiring the Disclosure of the Origin of Genetic Resources and Traditional Knowledge: The Current Debate and Possible Legal Alternatives* in Christophe Bellmann et al. Trading in Knowledge: Development Perspectives on TRIPS, Trade and Sustainability (2003) 200.

[310] Graham Dutfield *Thinking Aloud on Disclosure of Origin* (2005) 2. Available at http://www.quno.org/geneva/pdf/economic/Occassional/OP18-Dutfield.pdf [Accessed 30 November 2009].

[311] Dutfield (note 32) at 111.

[312] Ibid at 112.

originate there'.[313] The certificate, therefore, works as an 'official recognition of the legal origin (legal access) of a particular sample of a genetic resources or piece of information linked to traditional knowledge'.[314]

Several countries oppose the requirement of disclosure of origin. Their argument is based on Article 22 CBD which establishes that the provisions of the CBD shall not affect the rights and obligations of any contracting party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity.[315]

b) Compatibility with the TRIPS Agreement

As well as deciding between these views, the question remains whether or not the disclosure of origin requirement is compatible with the TRIPS Agreement.

One would assume the voluntary disclosure requirement would be unproblematic. However, several countries have expressed the view that a mandatory requirement is incompatible with TRIPS, because of its 'effects on the freedom of patent applicants and holders'. Different arguments have been brought forward by opponents of the disclosure of origin proposal. To date, these arguments are mainly based on Articles 27.1, 29, 32 and 62 TRIPS.

The first argument states that the requirement of disclosure violates Article 27.1 TRIPS. As described in chapter IV, Article 27.1 TRIPS lists the conditions of patentability, namely novelty, inventive step and industrial application. These criteria are absolute conditions in the sense that they refer to the 'invention per se, because they result from technical characteristics of the invention'.[316] The requirement of disclosure of origin would, therefore, establish another substantive condition among the three traditional ones. Yet, the way in which genetic material is obtained is much rather an external requirement, since the outcome of the inventive

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[313] Ibid.
[314] Ibid.
[315] Eugui (note 309).
[316] Nuno Pires de Carvalho *Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications without Infringing the TRIPS Agreement: The Problem and the Solution* (2000) 379. Available at http://law.wustl.edu/journal/2/p371carvalho.pdf [Accessed 16 December 2009].

activity is independent from the ways and means employed to reach it.[317] Therefore, the disclosure of origin is not compatible with Article 27.1 TRIPS.

The second argument brought forward in this context is the incompatibility with Article 29 TRIPS, which contains the formal requirements for the grant of a patent. More specifically, the Article requires the 'disclosure of the invention in a clear and complete manner so an expert in the field can replicate the invention'.[318] Yet, the indication of the origin of the genetic resources and of other circumstances related to their acquisition is not generally necessary for the invention to be carried out by a person skilled in the art. Therefore, the disclosure of origin cannot be interpreted as being contained in Article 29 TRIPS.

The third argument is based on an interlinked interpretation of Articles 27.1 and 32 TRIPS. According to this interlinked interpretation, a patent can only be revoked on failure 'to fulfill one or more of the elements of the patentability requirements, namely novelty, inventive step and industrial application'.[319]

Lastly, opponents claim that the disclosure requirement is not compatible with Article 62 TRIPS. Article 62 establishes the conditions for the acquisition or maintenance of IPRs.[320] The Article does not allow for other requirements besides the requirements related to the substantive conditions for the acquisition of the right or payment of certain tariffs. Consequently, the only substantive requirements of the patent are those contained in Article 27.1 TRIPS. However, the argument progresses further. Opponents to the disclosure of origin proposal rely on Article 62 TRIPS in the sense that the Article also requires the proceeding to be 'reasonable.' For that reason, opponents allege that the disclosure requirements will impose heavy and exaggerated administrative costs and therefore cannot be regarded as reasonable.[321]

Hence, it can be concluded that, based on the aforementioned arguments, the requirement of mandatory disclosure of origin is not compatible with the TRIPS Agreement in its current form.

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[317] Ibid.
[318] Eugui (note 309) at 201.
[319] Ibid.
[320] Ibid.
[321] Ibid.

c) Amendment of the TRIPS Agreement

For the above reason, the amendment of the TRIPS Agreement has been suggested. The most important proposals include the amendment of Article 27.1 TRIPS, the amendment of Article 27.3. (b) TRIPS and the amendment of Article 29 TRIPS.[322]

An amendment of Article 27.1 TRIPS is unlikely to have any success since such an amendment would require the introduction of a new patent criterion among the traditional ones of novelty, inventive step and industrial application.[323]

For that reason, the suggestion to include the disclosure requirement in Article 27.3 (b) TRIPS seems to be more promising. Article 27.3 (b) sub-clause 2 TRIPS is subject to a review clause anyway and the incorporation in this article would push the debate to the international level,[324] whereas an amendment of Article 27.1 TRIPS would have affected mainly national legislation. Nevertheless, Article 27.3 (b) TRIPS mainly addresses the responsibilities and influence of the WTO members in regards to the biological area. Therefore, the wording and the scope of this article do not offer the normative basis for the disclosure requirements.[325]

Hence, several developing countries have made suggestions at the Council for TRIPS to amend Article 29 of the Agreement in order to incorporate an obligation to disclose the origin of the invention in patent applications.[326] In this context, it is important to note that the TRIPS Agreement does not contain any clause that generally forbids the disclosure of origin of the invention. Such a requirement would also not infringe 'Article. 62.4 TRIPS read in conjunction with Article 42.2 TRIPS since disclosure of origin cannot be considered unnecessarily complicated or costly'.[327] Therefore, Article 29 TRIPS offers a good foundation for the disclosure of origin requirement.

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[322] Reyes-Knoche (note 125) at 532.
[323] Ibid.
[324] Ibid.
[325] Ibid.
[326] World Trade Organization *Doha Work Programme- The Outstanding implementation Issue on the Relationship between the TRIPS Agreement and the Convention on Biological Diversity* IP/C/W/474 (2006). Available at http://commerce.nic.in/wto_sub/TRIPS/sub_Trips-ipcw474.pdf [Accessed 31 January 2010].
[327] Reyes-Knoche (note 125) at 532.

d) Comment

The question remains, what difference would the incorporation of such a requirement make in practice? One problem arising in this context is the fact that patent applicants might simply not disclose the relevant information. Unless there is a particular reason, the patent examiner would not be suspicious that the invention is based on traditional knowledge and the patent would be granted.

Apart from this general problem, compulsory disclosure is expected to work well; especially regarding pharmaceutical patents. This is due to the fact that the pharmaceutical industry commonly bases its new drugs on single compounds.[328] To trace and declare the source of origin is normally an easy task. In the case of plant varieties, the situation is slightly different, since the genetic material may come from different sources, some of which 'may no longer be identifiable because of the lack of documentation and the length of time between its acquisition and its use in breeding programmes'.[329] Importantly, new plant varieties might be based on genetic material from different sources, and the value of each individual source, therefore, is relatively low.[330] In addition, the seed industry is much smaller than the pharmaceutical industry and will never generate as many benefits to share. Therefore, it can be concluded that, for plant varieties, the disclosure of origin might be an unworkable solution and might not benefit developing countries even if it did work.[331] In most cases, the patent applicant simply will not be able to comply with this requirement and the examiners will not verify whether or not the identities of the countries and local communities have been fully disclosed.[332] Yet, as a matter of fact, the protection of plant variety rights through patents only works in the United States of America. The most common case is that plant varieties are not protected within patent laws. Therefore, it is not necessary to make such an exception a requirement since the European system prefers the concept of UPOV.

Yet, proponents of mandatory disclosure of origin requirements should be aware that the disclosure of origin requirement made little difference in several

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[328] Dutfield (note 32) at 113.
[329] Ibid.
[330] Ibid.
[331] Dutfield (note 31) at 509.
[332] Ibid.

biopiracy cases.[333] In this context, it is important to take a closer look at the previously discussed 'Neem Tree Patent' and 'Enola Bean Patent'.

The Neem Tree Patent has been revoked due to lack of inventive step and novelty. In considering whether or not the disclosure of origin would have made a difference, one has to be aware that Neem trees are not only found in India, but also in situ conditions in several tropical countries.[334] For that reason, India does not have any special claim to the Neem tree in regards of being the country of origin.

For the same reason, it cannot be assumed that the Neem trees, from which the scientists had obtained the biological material used in the invention, were obtained directly from India.[335] A key point is that different uses of Neem properties have been published. As a consequence, if a patent related to Neem tree properties is granted, this is a result of the invention being disclosed as novel or a result of the fact that an inventive step has taken place beyond the published information available to patent examiners.[336] Yet, it is conceivable that a patent might also have been granted because of insufficient and inadequate access to relevant literature during the patent examination process. Therefore, doubts remain that disclosure of origin 'can adequately address the problems of undemanding inventive step thresholds and inadequate prior art searching'.[337]

Another example is the recently revoked Enola Bean Patent. As previously shown this patent was obvious and lacked an inventive step. Yet, the problem was, again, the quality of the patent examining process. As a matter of fact, Proctor himself had disclosed the source of the beans he used. Naturally, he did not consider that such honesty could be harmful to his legal claim in the future. It remains doubtful, that Proctor would have disclosed this information if he knew that the disclosure would lead to 'entailed certain legal obligations and consequences.'[338] Nevertheless, even though the origin of the invention had been disclosed, a patent had still been granted to Proctor for the Enola Bean.

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[333] Dolder (note 227) at 592.
[334] Dutfield (note 310) at 6.
[335] Ibid.
[336] Ibid.
[337] Ibid
[338] Dutfield (note 310) at 7.

There is also the concern that inventors may simply omit the disclosure of origin. Many inventors will be tempted not to disclose information of origin or, even worse, give false information regarding their inventions, if such behaviour is likely to save them from legal obligations.[339]

However, it is also important to bear in mind that companies interested in bioprospecting-related research and development might want to disclose the origin, because governments may decide to routinely screen their patent applications to find out whether or not a particular company has failed to declare legal acquisition.[340] Also, not every company wants to be connected to practices of bioprospecting or biopiracy and therefore voluntary complies with true disclosure of information requirement.[341]

Therefore, even if doubt about disclosure of origin exists, this doubt 'should not go so far as to discount all possibility of positive consequences in terms, for example, of improving business practices'.[342] It is likely that more cases of biopiracy occur than have been reported. There is the possibility that some of these cases can be prevented or at least brought to light by disclosure of origin requirements. Simultaneously, it must be noted that no requirement of origin proposal can prevent all cases of misappropriation of traditional knowledge and biological resources. Such a requirement can also not substitute for 'competent substantive examinations of patent applications'.[343]

2. Prior Informed Consent in Patent Applications

Another suggestion for the protection of traditional knowledge is the requirement of prior informed consent (PIC) in patent applications. This proposal is intended to seek compliance with the Convention on Biological Diversity. The CBD addresses PIC in Article 15, but does not provide a definition of this term.[344] However, PIC is commonly interpreted in the following way: 'that permission from the competent

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[339] Ibid.
[340] Ibid.
[341] Ibid.
[342] Ibid.
[343] Ibid.
[344] Preston Hardison 'Prior Informed Consent (PIC) and Prior Informed Approval (PIA)' 2007 *The Monthly Bulletin of the Canadian Indigenous Caucus on the Convention on Biological Diversity at* 3.

national authority or authorities of the provider country is to be obtained prior to accessing genetic resources, in accordance with national legislation'.[345]

Yet, the requirement of PIC faces the same problems as the suggestion of origin disclosure in terms of violating the TRIPS Agreement.[346] The requirement of PIC would establish another substantive condition for patentability among the three traditional criteria. Yet, these conditions are absolute in the sense that if they are fulfilled, a patent has to be granted. Hence, PIC would also violate TRIPS and, therefore, cannot be included under current patent law.

The amendment of TRIPS in this regard is conceivable, but has not been accomplished as yet. Nevertheless, the PIC requirement is a subject in the ongoing debate about the review of Article 27.3 (b) TRIPS.

3. Documentation of Traditional Knowledge

There has been considerable concern that patents have been granted for inventions that did not meet the criteria of novelty, inventive step and industrial application when 'compared to traditional knowledge from which these inventions might have been directly or indirectly derived'.[347] As highlighted in the case study, if this knowledge had been known to patent officers at the time of the examination, the invention may have been considered as prior art. As a consequence, a patent would have been denied.

Therefore, the problem arising out of the current standard of prior art and its relation to traditional knowledge, is that although there is traditional knowledge kept and used by traditional communities, 'such knowledge is rarely recognised as forming part of the state of art for the purpose of the patent system in general'.[348]

Documentation can protect traditional knowledge by serving as prior art in regards to the novelty requirement established in international patent law. Problems in the acceptance of traditional knowledge as prior art have existed because such knowledge is mostly passed down orally and, therefore, does not meet the criterion of novelty as laid out in most Western patent laws. Additionally, chapters IV and V

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[345]Convention on Biological Diversity *ABS Factsheet Frequently Asked Questions*. Available at http://www.cbd.int/doc/programmes/abs/factsheets/ABS-factsheet-faqs-en.pdf [Accessed 2 December 2009].

[346] See previous pages.

[347] Riuz (note 40) at 5.

[348] Ibid.

have revealed that patent examiners rely on 'available' resources for the determination of novelty and inventive step. While most patent literature is easily accessible because it is contained in numerous databases, non-patent literature referring to traditional knowledge is scattered diversely in many cases.[349] The case study has proven the insufficient access to traditional knowledge information in journals outside patent literature, and the ineffectiveness of research tools tasked with retrieving such knowledge.[350]

Therefore, documentation of traditional knowledge serves as 'a more easily accessible non-patent literature database that deals with traditional knowledge subject matter'.[351] Consequently, the documentation of traditional knowledge could be a useful tool to qualify this knowledge as prior art and, therefore, prevent patents from being granted. Hence, documentation can be regarded as a precautionary measure to target biopiracy in its initial stages. Such documentation could be used to verify the patent applicant's information regarding the origin of biological resources and knowledge related to these resources.[352]

When considering the documentation of traditional knowledge, a distinction between registers and databases must be made. The registration of information in a register is linked to the granting of rights.[353] However, even though the registration of rights 'serves to secure the recognition of the relevant rights, the register does not itself grant rights but rather records such rights'.[354] As a consequence, registers are normally open to the public to provide a record for rights that have been registered.[355]

Databases, on the other hand, are not necessarily freely presented to the public.[356] They are 'systematized collections of information, developed for private or public use, that do not confer any legal right on the originator of the relevant

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[349] V.K. Gupta *Documentation of Traditional Medicine Knowledge: Digital Library of India* (2005) 2. Available at http://www.searo.who.int/linkfiles/meetings_document16.pdf [accessed 16December 2009].
[350] Riuz (note 40) at 6.
[351] Gupta (note 349).
[352] Ibid.
[353] Merle Alexander et al. *The Role of Registers and Databases in the Protection of Traditional Knowledge: A Comparative Analysis* (2003) 11. Available at http://www.ias.unu.edu/binaries/UNUIAS_TKRegistersReport.pdf [Accessed 16 December 2009].
[354] Ibid.
[355] Ibid at 12.
[356] Ibid.

information as a result of its inclusion in the database'.[357] For the purpose of this thesis, emphasis will be placed on documentation of traditional knowledge in databases. This emphasis has been chosen due to the fact that databases can be proprietary.

d) General Considerations

When developing a database for prior art purposes, several issues need to be considered. Firstly, it is important that as much information as possible is collected. The information should also include knowledge already in the public domain. Knowledge that is not intended to leave local communities should not be recorded. The collection of knowledge should either be by local communities themselves or at least with the consent of the knowledge holders and ideally, representatives of local communities should be involved in the design and management of such databases.[358]

Also, it is vital to use certain standards regarding structure, organisation of content, certification and language.[359] It might also be useful to develop official databases, which can connect to an international database in order to be available for patent examination worldwide.[360] The grant of access to such databases should be divided into different categories such as 'intend for commercial use' and 'intend only for scientific research'. Depending on these categories, different prices could be charged directly from people interested in the knowledge by different methods of payments. This system is commonly used for many websites which operate the pay per view system.

Any database including traditional knowledge should not as far as possible place constraints on the rights that local communities might have over the information.[361] Intellectual property rights should not be claimed over these databases as questions of who should pay for these databases and how the money should be collected are problematic in any case. One possibility is government funding or funding by different national or regional institutes since local communities themselves will not have the monetary and technological capacities to build such databases themselves. Once the database is established, special fees could

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[357] Ibid.
[358] Riuz (note 40) at 20.
[359] Ibid.
[360] Ibid.
[361] Ibid at 21.

be put into place just for being able to sign up and search the database. This fee, however, is not to be confused with the benefit sharing arrangements that would have to be made with a community once knowledge is being used by companies.

e) The Special Case of India

India is among the countries that have implemented such a database by establishing the 'Traditional Knowledge Digital Library' (TKDL) in 2001. The database is a collaborative project between the National Institute of Science Communication and Information Resources and the Department of Indian System of Medicine and Homeopathy and the Ministry of Health and Family Welfare.[362]

The compilation of the TKDL was a response to India's attempts to overturn two patents based on traditional knowledge that were granted in the United States of America and Europe.[363] As outlined before, challenging patents is an extremely costly procedure. For that reason, India decided to establish mechanisms to prevent the grant of 'inappropriate patents, rather than to rely on expensive and lengthy challenges to patents once granted'.[364]

The TKDL serves two objectives. First of all, the database attempts to prevent the grant of patents for products that are based on traditional knowledge, where there has been only little inventive step.[365] The library is, therefore, intended to be made available to patent offices around the world, so that patent examiners can be 'aware of the prior art relating to a particular medicinal plant.'[366] Hence the TKDL is established to ensure the efficiency of prior art searches.[367] Secondly, the database seeks to 'act as a bridge between modern science, modern medicines and traditional knowledge and moreover can be used for international advanced research based on information on traditional knowledge'.[368] Hence, the database also aims to translate Indian traditional knowledge which is only available in native languages to

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[362] Alexander et al. (note 353) at 17.
[363] Namely the 'Tumeric Patent' [U.S. Patent No.: 5,401,504] and the Neem Tree patent [EP Patent No. 436257]. Both patens have been revoked due to lack of novelty and/or inventive step.
[364] Alexander et al. (note 353) at 17.
[365] Ibid.
[366] Suman Sabai *Indigenous Knowledge and Its Protection in India in Christophe Bellmann et al Trading in Knowledge: Development Perspectives on TRIPS, Trade and Sustainability* (2003) 172.
[367] Dutfield (note 32) at 114.
[368] Gupta (note 349) at 2.

international languages.[369] Most of the knowledge contained in the library is 'based upon Ayurvedic texts which codify traditional knowledge in widely published volumes freely available in many Indian libraries'.[370]

The TKDL is a proprietary database available for patent offices around the world to prevent the misappropriation of traditional knowledge. Nevertheless, the database contains several user obligations. Even though access for patent offices will be free,[371] access will be based on an Access Agreement on non-disclosure. Hence, there will be no disclosure of the knowledge to any third party unless it is essential for research purposes.[372] Also the user has to notify the provider of the database in cases when the TKDL has been used for prior art searches.[373]

Despite these user obligations, the database also contains rules of access for collaborative research. In cases of collaborative research, access to the database will be provided on the basis of bilateral agreements. At the core of these agreements are non-disclosure clauses and principles for access and benefit sharing.[374]

f) Data Base Rights

To further strengthen the position of databases, it has been suggested they be protected under a special database right.[375] As set out previously in this section, there have been several attempts to document traditional knowledge. Yet, it is important to notice that in most cases, the traditional knowledge holders are not the ones responsible for the creation and holding of such databases. Nevertheless, copyright might provide a solution for this since one presumes that traditional communities 'would wish to control access to and use of the information held in the databases'.[376] However, in many cases this is simply not true under current practices. Therefore, a copyright approach might not be an adequate solution.

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[369] IPpro Services*Traditional Knowledge* (2008) 9. Available at http://www.ipproinc.com/admin/uploads/Traditional_Knowledge_-_Jan_30,_2009_54.pdf [Accessed 3 November 2009].
[370] Alexander et al. (note 353) at 17.
[371] Gupta (note 349) at 5.
[372] Ibid.
[373] Ibid.
[374] Ibid.
[375] Nuno Carvalho cited in Graham Dutfield *Legal and Economic Aspects of Traditional Knowledge* in Keith E. Maskus and Jerome H. Reichmann *International Public Goods and Transfer of Technology: Under a globalized Intellectual Property Regime* (2005) 516.
[376] Dutfield (note 31) at 516.

The basis for the suggestion of database rights can be found in Article 39.3 TRIPS, which deals with test data, or other, data that must be submitted to government authorities as a condition of approving the marketing of pharmaceutical or agrochemical products where the origination of such data involves considerable effort.[377] According to this article, governments are required to protect data against disclosure except where necessary to protect the public.

According to Carvalho's suggestion, this approach should be taken further and extended to traditional knowledge in the form of a legal framework for a database system. Such a database should contain: (1) the establishment of rights in data; (2) the enforceability of rights in the data against their use by unauthorised third parties; and (3) the absence of a predetermined term of protection.[378] Additionally, the database in question should be made available and registered with national patent offices; and, 'to avoid the appropriation of public domain knowledge, enforcement rights should be confined to knowledge that complies with a certain definition of novelty'.

g) Comment

The question is, how successful can such a database be for the protection of traditional knowledge? One difficulty can certainly arise out of the immense amount of existing traditional knowledge. As a consequence, it might be problematic to ensure that all traditional knowledge is successfully recorded. To further complicate documentation, the knowledge is in many cases widespread and people might have different names for plants in different regions.[379] Additionally, old text might be difficult to translate.[380] The terminology used in traditional knowledge practices also tends to be more generalised and is not on par with modern medical terminology.[381]

It is, however, essential to define the conditions of such a database, since access to it does not necessarily have to be free. Consequently, any person who wishes to access such a database should have to comply with certain conditions.[382] If such safeguard measures are implemented, the documentation of traditional

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[377] Ibid.
[378] Ibid at 516 and 517.
[379] Sangeeta Udgaonkar 'The Recording of Traditional Knowledge: Will it Prevent Biopiracy?' (2002) 82 4 *Current Science* 413 at 416.
[380] Ibid.
[381] Ibid.
[382] Ibid.

knowledge might play an essential role in its protection and preservation. Even though fears of misuse and practicability of such databases exist,[383] the documentation of traditional knowledge could be an important tool for patent examining authorities around the world. Although countries and local communities may want to develop their own sort of databases, standardisation has to be reached to be effective at an international level. It may be quite difficult to protect traditional knowledge that already exists in the public domain, since this knowledge might already have 'surpassed the physical and geographical boundaries of communities'.[384]

Nevertheless, the Indian example has demonstrated how to successfully implement a traditional knowledge database. However, it is important to bear in mind that access to such databases has to be regulated carefully per national legal requirements and policies.[385]

4. Use of Unfair Competition Law

Another possibility may be the protection of traditional knowledge under unfair competition law. Unfair competition law *'protects the outcome of a person's intellectual activity not by creating a private property title over the knowledge but by defining acts of unfair competition which are prohibited in relation to those outcomes'*.[386] Therefore, unfair competition could deal with situations in which 'traditional knowledge holders engaged in commercial activities pertaining, had their trade affected by certain unfair commercial practices committed by others'.[387]

History has shown the possibility to expand the list of unfair competition acts to suit new circumstances and needs of knowledge holders. Consequently, unfair competition law provides flexible grounds for the creation of protection for new forms of subject matter.[388] This flexibility within unfair competition law is derived

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[383] It has been feared that companies would use such databases as an information source for so far unknown traditional knowledge and therefore such databases facilitate the concept of biopiracy. However, this fear could generally be overcome if access to such databases is only allowed for patent offices.

[384] Riuz (note 40) at 21.

[385] Gupta (note 349) at 8.

[386] Shakeel Bhatti *New Forms of Sui Generis Protection Relevant for the International Regime (GR and/or TK)* 6. Available at http://www.canmexworkshop.com/documents/papers/III.3d.pdf [Accessed 16 December 2009].

[387] Dutfield (note 36) at 512.

[388] Bhatti (note 386).

from the way in which the Paris Convention for the Protection of Intellectual Property sets out international standards of unfair competition law.[389]

More specifically, Article 10bis of the Paris Convention establishes the key elements of unfair competition law. Within this article, a basic norm for the suppression of acts of unfair competition is established.[390] The act of unfair competition is defined as 'any act contrary to honest practices in industrial or commercial matters'.[391] However, the meaning of 'honest practices' is subject to national interpretation, which allows for flexibility. Moreover, the Paris Convention sets out a list of prohibited acts of unfair competition. The TRIPS Agreement explicitly mentions Article 10bis in its section dealing with geographical indications and undisclosed information.[392]

In this context, the 'Misappropriation Doctrine' which is a part of unfair competition law, may play an important role. The doctrine applies to those scenarios in which the acts complained of are not protected against by other specific legal instruments. In its conception the doctrine was based on the tort law principle which prohibits one from diverting another's business by the fraudulent misrepresentation that such goods are those of the other.[393] However, later developments of the doctrine have led to the expansion of the concept beyond the limits of misrepresentation to also include misappropriation.[394] Consequently, the doctrine can be used to prevent imitators from appropriation of an inventor's work, in other words, to prevent 'free riding'.[395]

It is conceivable that this doctrine could be extended to the protection of traditional knowledge. This could be achieved by interpretation of misappropriation as 'any act of acquisition or appropriation of traditional knowledge by unfair means'[396] As a consequence, the term 'unfair means' needs to be interpreted as

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[389] Ibid.
[390] Ibid.
[391] Ibid.
[392] Articles 22.2 (b) and 39.1 TRIPS; see also Dutfield (note 36) at 513.
[393] Restatement Torts, §760 (1939) cited in: W. Edward Sell 'The Doctrine of Misappropriation in Unfair Competition' (1957-1958) 11 *Vanderbilt Law Review* 483at 484.
[394] W. Edward Sell 'The Doctrine of Misappropriation in Unfair Competition' (1957-1958) 11 *Vanderbilt Law Review 483at* 493.
[395] C. Owen Paepke 'An Economic Interpretation of the Misappropriation Doctrine: Common Law Protection for Investments in Innovation' (1987) *High Technology Law Journal.* Available at http://www.law.berkeley.edu/journals/btlj/articles/vol2/paepke.pdf [Accessed 31 January 2010].
[396] Bhatti (note 386) at 7.

including the violation of any or all the policy tools chosen in the relevant national legislation.[397]

This approach towards the protection of traditional knowledge takes into account that traditional knowledge holders, in many cases, want recognition and benefit sharing rather than to generally prevent others from accessing their knowledge. As a consequence, 'the fact that something valuable yet incorporeal in nature created by one person or group is used without authorization or compensation by another is perceived to be unfair'.[398] Therefore, for some cases, the use of unfair competition law may provide promising alternatives for the protection of traditional knowledge.

5. Analysis

The aforementioned has shown the existing possibilities for defensive options for the protection of traditional knowledge. Each of the presented options, namely requirement of disclosure of origin, databases, and unfair competition law, may help to prevent the misappropriation of traditional knowledge and biological resources to some extent. Yet, it is important to note that defensive options might not be enough to address this issue. Different defensive protection options should be combined to provide sufficient protection of traditional knowledge. Yet, it has to be kept in mind that limiting the impact of patent law alone, does not necessarily serve as sufficient protection of traditional knowledge. As stated previously, patent law has not been designed to protect traditional knowledge, but much rather to lose trade barriers.

Therefore, in order to sufficiently protect traditional knowledge, positive protection options that are tailored to the needs of traditional knowledge holders have to be taken in consideration.

B. Positive Protection Options

Positive protection of traditional knowledge is likely to require 'a completely new system whose development requires the collaboration of different authorities and governments'.[399] Ideally, any form of traditional knowledge protection would defer the protection to its customary normative context, to 'apply globally what one

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[397] Ibid.

[398] Daniel J Gervais *Traditional Knowledge: A Challenge to the International Intellectual Property System* (2001). Available at http://www.cra-adc.ca/en/documents/traditional-knowledge [Accessed 16 December 2009].

[399] Dutfield (note 31) at 507.

commentator terms the principle of locality'.[400] This principle means 'to resolve any disputes over the acquisition and use of indigenous people's heritage according to the customary laws of the indigenous people concerned.'[401] Yet, if traditional conceptions of ownership and responsibility over traditional knowledge are to be recognised in a wider legal expression, this needs to be underpinned by legal and practical tools that provide a realistic prospect of defending traditional knowledge related interests through the full range of intellectual property rights and other rights.[402]

For that reason, there have been different approaches towards positive protection of traditional knowledge. This section will have a closer look at some of the most important proposals in this regard.

1. General Considerations

Even though these suggestions seem to be quite different from one another, they do have something in common. In fact, all the options for the positive protection of traditional knowledge are dependent upon two major factors.[403]

The first factor is the desired objectives. The second factor is the relative importance assigned to these objectives.[404] Despite these important factors, there are several other difficult choices to be made in any legal framework that seeks for the protection of traditional knowledge.

a) Knowledge to be Protected

Firstly, the kind of knowledge should be protected within such a framework has to be considered. The general reference to traditional knowledge is too broad a term to be sufficiently effective. In addition, no legal framework protects knowledge, per se, but rather different aspects of knowledge.[405] As a result, only different aspects of knowledge can, for example, be protected by patent law or copyrights. Consequently, the protection scope of traditional knowledge should be carefully

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[400] Antony Taubmann *Saving the Village: Conserving Jurisprudential Diversity* in Keith E. Maskus and Jerome H. Reichmann *International Public Goods and Transfer of Technology: Under a Globalized Intellectual Property Regime* (2005) 528.

[401] Ibid.

[402] Ibid.

[403] Commission on Intellectual Property Rights *Protecting Traditional Knowledge* (2006) 3. Available at http://www.iccwbo.org/uploadedFiles/ICC/policy/intellectual_property/Statements/Protecting_Traditional_Knowledge.pdf [Accessed 25 November 2009].

[404] Ibid.

[405] Ibid.

defined and divided into different areas such as medicine, food and agriculture for different purposes.[406]

b) Use of Knowledge and Nature of Rights Conferred

Another aspect is the kind of utilisation of knowledge being protected. Uses such as publication, possession or commercial exploitation are conceivable.[407] Interrelation of different uses is also possible in this context. Closely linked to this point is the aspect of what kind of rights such traditional knowledge will give. Various possibilities such as exclusion rights and compensation rights or even a combination of both exist.[408]

c) Ownership

Another issue to be solved is the question of ownership. Who owns the traditional knowledge within a community and what happens if traditional knowledge is not bound to a region? Questions like these, defy easy answers. Nevertheless, in order to access genetic resources and the traditional knowledge related to them, it is necessary to know whom to approach when asking for permission. There are quite a few possibilities that are imaginable within this context. These options include the creator, an individual holder, the leader of the community, or the community itself.[409]

One characteristic of traditional knowledge is, however, that this knowledge has been passed on for many years if not for centuries. Thus the owner of the knowledge can most certainly not be the original creator of the knowledge. Importantly, even though many communities have a strong sharing ethos, this does not necessarily lead to the conclusion that 'everything has to be shared with everybody'.[410] In fact, several communities have tribal elders who often have permanent duties related to the use of traditional knowledge 'irrespective of whether it is a secret, known to just a few people or known to thousands of people throughout the world'.[411] In addition, some communities have even set up their own 'custom based intellectual property system',[412] which can further complicate the question of ownership.

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[406] Ibid.
[407] Ibid.
[408] Ibid.
[409] Dutfield (note 31) at 501.
[410] Ibid.
[411] Ibid at 502.
[412] Ibid.

In conclusion, one cannot generalise the issue of ownership for every community. The best solution might be the installation of a trust fund for the whole community, whose people can divide the money as their tribal council, elders, or community leaders demand.[413] Furthermore, the trust fund could be overseen by neutral trustees, which would help to settle conflicts that may arise from various parties. A trust fund can be described as the 'amount of capital which a person places in custody of a trustee to be administered for the benefit of another (the beneficiary)'.[414]

There are different ways to install a trust fund. The first decision to be made is whether the trust fund should be operated at a national level or at a community level. The second decision to be made is how the money is put in the trust fund. There are different ways for this to take place: the money could either be paid as one single payment at the beginning of the research or as ongoing payments throughout the research period. Conceivably, the money could also be paid as an ongoing royalty from the sale of the final product.

d) Models of Benefits

Additionally, the type of benefits for local communities has to be considered. Any positive protection of traditional knowledge is likely to require some sort of compensation for the access to such knowledge. This conforms to the previously explained Reward Theory, which seeks to reward the inventor for their invention. If the invention is based on traditional knowledge, it is only consequent that these knowledge holders also get rewarded; in other words get compensated for sharing their knowledge.

However, the question remains, what type of compensation serves the interests of traditional knowledge holders best. In this context, there are mainly three different approaches worth being considered: namely, monetary benefits, non-monetary benefits or a combination of both.

The first approach to be introduced is the model of monetary benefit. This model implies that a certain amount of money has to be paid to the community of traditional people in order to gain access to their genetic resources. However, it has

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[413] This solution is desirably at least in cases of monetary benefits.

[414] Teach me Finance *Explain Trust Funds*. Available at http://www.teachmefinance.com/Financial_Terms/trust_fund.html [Accessed 29 October 2009].

to be kept in mind that in many cases traditional communities do not pursue monetary gains, but rather want their knowledge to be protected and respected because it is part of their culture, tradition and customary beliefs. These people separate themselves from the monetary way of thinking in the western world. Also, it is important to realise that in many cases it is better to provide assistance and empowerment rather than simply giving money. Hence, monetary compensation may not always provide the best form of compensation.[415]

Therefore, a second approach has emerged; the model of non-monetary benefits. This model implies that for the granted access, the contracting party has to provide the traditional people with benefits beyond money calculations. This type of benefit includes social benefits, which could be in the form of food security, an improved quality of life, or market opportunities.[416] Furthermore, these benefits could include increased access to technologies and information arising from the use of exchanged material; they could be in the form of environmental benefits, such as the protection of habitats and ecosystems and the reduction of genetic vulnerability.[417] In international exchange, further 'access to more germ plasma and improved material than can be found in any one country'[418] could be part of a benefit. Additionally, international collaboration allows for increased opportunities for developing joint strategies for conserving and using genetic resources, as well as for sharing responsibilities and costs.[419]

The third model to be introduced is a combination of both monetary and non-monetary benefits. Even though cases are different and generalisation should be avoided, this last model seems to be of great advantage for many cases where access is granted. This model combines the advantages of the other two models by allowing the traditional people to get money on the one hand, and access to training opportunities, new technologies and information arising from the use of exchanged

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[415] Darrell A. Posey and Graham Dutfield *Beyond Intellectual Property: Towards Traditional Resource Rights for Indigenous People and Local Communities* (1996) 38.
[416] Ruth Raymond and Cary Fowler *Sharing the Non-Monetary Benefits of Agricultural Biodiversity* (2001) 6. Available at http://oregonstate.edu/instruct/css/330/three/IPGRINo5.pdf [Accessed 1 December 2009].
[417] Ibid.
[418] Ibid.
[419] Ibid at 1.

material on the other hand. In this way, traditional people could further advance their own knowledge, which could be considered as 'self-sustaining help'.

e) How much Compensation?

Closely linked to the considerations regarding the form of benefit is the question of how much compensation the original knowledge holder should receive. In this context there are several factors influencing the answer to this question.

First of all, different biotechnological industries, such as the pharmaceutical or agricultural sector, rely on biological resources in different ways.[420] As a consequence, a product can either be quite similar to the resource or it may be the result of a process which makes it different from the original resource. A product derived and developed from various biological resources is possible.[421] If traditional knowledge and biological resources only contribute to the development of a new product during the early stages of research, compensation in the form of royalties will be quite low. Yet, if the knowledge and the resources identify an actual product, royalties will be higher.[422] In any case, the compensation for local communities has to be weighed against the risks and investment during the process of developing a final product.[423]

f) Duration and Effect of Rights

Another issue for any regime protecting traditional knowledge is the duration of rights. Rights might only be granted for a limited term. However, in that case, an exact starting point has to be considered.

Nevertheless, it is also possible to grant rights that are indefinite. The question is whether or not such rights would be retrospective; and consequently whether information already in the public domain would also become potential subject matter. Allowing rights to last indefinitely or retrospectively could 'create insurmountable problems regarding rights based on existing legal instruments'.[424] Therefore, this approach should not be followed.

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[420] Posey and Dutfield (note 415) at 37.
[421] Ibid.
[422] Ibid.
[423] Ibid at 38.
[424] Commission on Intellectual Property Rights *Protecting Traditional Knowledge* (2006) 4. Available at http://www.iccwbo.org/uploadedFiles/ICC/policy/intellectual_property/Statements/Protecting_Traditional_Knowledge.pdf [Accessed 25 November 2009].

Considerations also have to be taken into account regarding the effect of the rights. Possibilities include the creation of an international framework, as well as regional or national legislation. Also conceivable, is a regime on community level.

The aforementioned aspects have revealed the various possibilities for the protection of traditional knowledge. Some of these aspects are clearly more problematic than others. Nevertheless, each scheme would have to be judged as a whole. For any scheme there will be a difficult decision as to 'whether its benefits to society as a whole outweigh its drawbacks for specific sectors'.[425] The following section will provide a more detailed analysis of some of the options proposed for the positive protection of traditional knowledge.

2. Sui Generis Regimes

One of the most well-known suggestions is the creation of sui generis regimes for the protection of biological resources and traditional knowledge related to these resources. Sui generis is a Latin phrase meaning 'of its own kind'.[426] Consequently, a sui generis regime is a system 'specifically designed to address the needs and concerns of a particular issue'.[427]

The overall purpose of sui generis protection systems for traditional knowledge can be described as a set of measures '*that would respect, preserve and promote the knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity including biological and related genetic resources and to ensure that they derive fair and equitable benefits from its utilization and that such utilization is based on their prior informed consent*'.[428]

Most sui generis protection measures for traditional knowledge interlink two basic legal concepts to govern the use of traditional knowledge. These two concepts

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[425] Ibid.
[426] WIPO Report (note 61) at 24.
[427] Ibid.
[428] Convention on Biological Diversity Executive Secretary *Development of Elements of Sui Generis Systems for the Protection of Traditional Knowledge, Innovation and Practices to Indentify Priority Elements* UNEP/CBD/WG8J/5/6 (2007) 2. Available at https://69.90.183.227/doc/meetings/tk/wg8j-05/official/wg8j-05-06-en.pdf [Accessed 31 January 2010].

are regulations of access to traditional knowledge and the grant of exclusive rights over traditional knowledge.[429]

The combination of these two concepts reflects the 'two major legal frameworks within which most measures are adopted and implemented: intellectual property frameworks and access and benefit sharing arrangements'.[430] Nevertheless, sui generis measures also combine diverse 'conceptual and policy tools to customize legal protection for traditional knowledge'.[431] Such measures include the regulation of access to traditional knowledge, the grant of exclusive rights for traditional knowledge, concepts from the law on the repression of unfair competition and references to customary laws of indigenous and local communities.[432]

Nothing prevents governments from developing sui generis systems for the protection of traditional knowledge at the national level. During the past years several countries have implemented sui generis regimes, combining offensive and defensive protection possibilities.[433] What these regimes have in common is that they regulate access to genetic resources and conditions such access upon the fulfilment of certain requirements.

Nevertheless, sui generis regimes at the national level only create territorial rights.[434] Consequently, these rights cannot be claimed and enforced outside the territory in question. Yet, in many cases, appropriation of biological resources and traditional knowledge related to these resources is made by foreign companies, which eventually attempt to obtain patent protection abroad. For cases like this, national sui generis regimes for the protection of traditional knowledge may not provide an adequate solution.[435]

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[429] World Intellectual Property Organization *WIPO//GRTKF/IC/7/6 Annex II* (2004) 1. Available at http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_7/wipo_grtkf_ic_7_6-annex1.pdf [Accessed 31 January 2010].
[430] Ibid.
[431] Ibid.
[432] Ibid.
[433] Countries that have implemented sui generis regimes include among others Costa Rica, Brazil, Panama and Thailand.
[434] Carlos Correa *Traditional Knowledge and Intellectual Property: Issues and Options Surrounding the Protection of Traditional Knowledge* (2001) 17. Available at http://www.quno.org/geneva/pdf/economic/Discussion/Traditional-Knowledge-IP-English.pdf [accessed 31 January 2010].
[435] Ibid.

3. Regimes on Access and Benefit Sharing (ABS)

a) General Considerations

The protection of traditional knowledge under access and benefit sharing regimes has been suggested. The Convention on Biological Diversity addresses the issue of access and benefit sharing through Articles 8 (j), 15 (4), 15 (5), 15 (7), 16 (3), 19 (1), and 19 (2) of the CBD text.[436] In this context, one of the most important Articles is Article 15 which provides guidance when benefits arise from different kinds of utilisation of genetic resources and principles of mutually agreed terms.[437]

Parties to the Convention of Biological Diversity have formalised ABS through the above mentioned Articles of the Convention, and through the 'Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of their Utilization'. These Guidelines were adopted in 2002 and set out the practical procedures for implementing access and benefit sharing as required by Article 15 of the CBD.[438] The Bonn Guidelines address prior informed consent to genetic resources, and they address mutually agreed terms for the 'access and use of genetic resources and benefit sharing from the utilization of the genetic resources'.[439] Even though they are voluntary,[440] they are the most widely accepted guidelines for implementing ABS.

Countries are free to establish ABS regimes in their national legislation. TRIPS itself does not have any regulations regarding the access to biological resources and traditional knowledge. Consequently, such an implementation would not violate TRIPS as long as these regulations only intend to accompany patent law. In fact, several countries[441] have incorporated ABS measures into their sui generis regime for the protection of traditional knowledge.[442]

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[436] MS Suneetha and Balakrishna Pisupati *Benefitsharing in ABS: Options and Elaborations* (2009) 12. Available at http://www.unep.org/environmentalgovernance/LinkClick.aspx?fileticket=rve59ttnofo%3D&tabid=383&language=en-US [Accessed 16 December 2009].

[437] Ibid; see also page 22 where the relationship between TRIPS and the CBD has been examined.

[438] Susan Bragdon et al. *Safeguarding Biodiversity: The Convention on Biological Diversity (CBD)* in Geoff Tansey&Tasmin Rajotte *The Future Control of Food: A Guide to International Negotiations and Rules on Intellectual Property, Biodiversity and Food Security* (2008) 100.

[439] Ibid.

[440] Ghose (note 141) at 8.

[441] According to the Secretariat to the CBD, more than 50 countries have adopted or are in process of adopting ABS policies and legislation [see http://www.cisdl.org/pdf/brief_biodiv.pdf].

[442] Supra page 72.

Such legislation may enable traditional knowledge holders to effectively enforce the requirements if the principles of prior informed consent and benefit sharing are put into legislation. The connecting factor for this form of protection is, however, not the patent system itself, since the requirement of prior informed consent is not compatible with TRIPS in its current form. Local communities can much rather intervene earlier, right at the point where access to biological resources is sought. In cases where local communities are in possession of the biological resources, this right also enables them to regulate access to these resources.

Consequently, if access to biological resources is denied, the knowledge related to these resources cannot be exploited and patented. In conclusion, carefully designed regimes on access and benefit sharing may provide an effective measure to prevent biopiracy.

b) International Regime on Access and Benefit Sharing

Closely linked to the implementation of such national regimes are efforts at the CBD to create an international regime on access and benefit sharing.

In order to further implement the principles by the CBD and its related provisions for access and benefit sharing, the World Summit for Sustainable Development held in Johannesburg in 2002, called for actions to 'negotiate within the framework of the Convention on Biological Development an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources'.[443]

As a response to this demand, the Conference to the Parties in 2004 mandated the Working Group on Access and Benefit Sharing to elaborate and negotiate the international regime on access and benefit sharing. These negotiations are expected to be completed by the 10th meeting of the Conference to the Parties in Nagoya in 2010.[444]

At first, the attempt to create an international sui generis regime for the protection of traditional knowledge may seem paradoxical. This is due to the tension created by giving 'broader and even global meaning and effect to norms and knowledge systems that are intrinsically and irreducibly local in character and that

[443] Convention on Biological Diversity *Access and Benefitsharing* p.2. Available at http://www.cbd.int/doc/programmes/abs/factsheets/ABS-factsheet-general-en.pdf [Accessed 1 December 2009].
[444] Ibid.

rely on the original community context for their full significance, without eliminating the essential qualities of traditional knowledge'.[445]

Yet, an international regime can help to ensure that biodiversity-rich countries obtain a fair and equitable share of benefits arising out of the use of genetic resources that have their origin in these countries. This can be achieved by setting out a 'clear and transparent framework for access and benefit sharing'.[446] Furthermore, such a framework can contribute to sustainable development through technology transfer and training of human resources in biodiversity-rich countries.[447]

Nevertheless, in the ABS negotiations towards the development of an international regime, a lot needs to be considered, since there is much more on trial than the influence between sovereign states. The Convention of Biological Diversity was mostly responsible for the implementation of access and benefit sharing requirements. However, the ABS provisions in the CBD are very general and leave the detailed elaboration open to the convention's parties for further development.[448]

Consequently, the question has become, how does one implement international ABS? The Bonn Guidelines have 'proven useful for countries developing national systems to govern ABS; however they make little to no mention of obligations on users of genetic resources or issues of enforcement'.[449]

The ongoing discussion regarding the detailed elaboration of an international ABS regime has highlighted the difficulties of establishing a regime that satisfies all parties. The international regime needs to provide guidance to already existing national ABS regimes as well as integrate other international agreements and international organisations that touch upon mentioned issues. Most significant among them are: International Treaty on Plant and Genetic Resources for Food and Agriculture, the International Union for the Protection of New Varieties of Plants, and the World Intellectual Property Organization and the World Trade Organization. Since the international regime is to be negotiated within the context of the CBD,[450]

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[445] Taubmann (note 400) at 525.
[446] Convention on Biological Diversity (note 443) at 2.
[447] Ibid.
[448] Bragdon et al. (note 438) at 100.
[449] Ibid.
[450] Convention on Biological Diversity *International Regime on Access and Benefitsharing*. Available at http://www.cbd.int/abs/regime.shtml [Accessed 1 December 2009].

its goals should first of all follow those of the CBD.[451] Whatever the negotiating parties decide should be further goals of the international regime, "they must be clear, consistent and attainable".[452]

c) Contractual Agreements

ABS can also be achieved through contractual agreements at national, regional or international level. As mentioned previously in this section, several countries have enacted sui generis laws or regulations to control the access to their genetic resources and traditional knowledge.

In many of these national legislations, contractual access and benefit sharing arrangements are the main legal mechanism to control access to these resources. Such arrangements bolster the principle of benefit sharing while establishing a link between the 'access and the current or future payment of compensation and the transfer of technology to the providing country'.[453]

Agreements can be conceived in various different forms. Among other possibilities, memoranda of understanding or detailed and formal contracts can be created. Therefore, it is important to bear in mind that such terms can only serve as a 'role model' since there are numerous forms of agreement.[454] However, there are a number of important issues that every contractual access and benefit sharing agreement should incorporate.

First of all, the contracting parties need to be clearly defined as well as the purpose of the research and the intended final product. The agreement should provide the detailed rights and obligations of the contracting parties including the method for fair and equitable sharing of benefits. Additionally, the agreement should contain 'the community/scientific name for the sample and a list of uses that the community has used the plant for'.[455] In this context, the elements and quantifications of the uses of the samples need to be exactly identified. Also an

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[451] Garforth (note 142) at 12.
[452] Ibid.
[453] Hassemer (note 14) at 205.
[454] Ibid.
[455] International Intellectual Property Institute *Is a Sui Generis System Necessary?-Benefit Sharing Agreements* (2004) 5. Available at http://www.iipi.org/speeches/newyork011404.pdf [Accessed 1 December 2009].

authority should be named to bind the parties.[456] Lastly, provisions need to be established for cases where the research does not result in a 'saleable product'.[457]

4. Compensatory Liability Regime

Another proposal is the creation of a compensatory liability regime. As the name already indicates, the basis of such a regime is made of liability rules rather than intellectual property rights.[458] The idea is that a right to compensation will be granted for commercial follow-on uses, but not a right to prevent such follow-on uses.[459] Consequently, such rules can be regarded as a 'use now, pay later system'.[460] According to such a regime, the utilisation of traditional knowledge is allowed without the permission of the traditional knowledge holder, but an ex post compensation is required for commercial and industrial uses in cases where the traditional knowledge provides a technology based advantage to the user.[461]

5. Global Bio-collecting Society

Peter Drahos has suggested the creation of a global bio-collecting society (GBS) for the protection of traditional knowledge. This is 'a property rights-based institution that would reduce transaction costs while improving the international enforcement of rights over traditional knowledge associated with biodiversity'.[462] The GBS would operate as an international institution and should be established outside the context of any treaty negotiations.[463]

According to Drahos, the GBS's mandate would be to implement the goals set out by the CBD and membership would be open to companies as well as indigenous people.[464] The idea of the GBS is 'to stimulate a process of private ordering among companies and indigenous groups and local communities'.[465] Furthermore, the GBS would constitute a repository of community knowledge registers which would be submitted voluntarily by communities.[466] However, such

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[456] Ibid.
[457] Ibid.
[458] Dutfield (note 31) at 518.
[459] Jerome Reichmann 'Of Green Tulips and Legal Kudzu: Repackaging Right's in Subpatentable Innovation' (2002) 53 6 *Vanderbilt Law Review* 1743.
[460] Bhatti (note 386) at 5.
[461] Ibid.
[462] Dutfield (note 36) at 517. L
[463] Peter Drahos 'Indigenous Knowledge, Intellectual Property and Biopiracy: Is a Global Biocollecting Society the Answer?' (2000) *European Intellectual Property Review* 245 at 247.
[464] Ibid.
[465] Ibid.
[466] Dutfield (note 31) at 517.

knowledge would be kept confidential and the only information available will be the name of group that submitted knowledge.[467]

The GBS could also provide a wide range of services besides being a repository of traditional knowledge registers. It could also serve as an assistant in contractual negotiations between local communities and companies.[468] Furthermore, the GBS could offer an independent dispute settlement function, even though its recommendations would not be legally binding.[469] The question remaining in this context is what the incentive would be for developed nations or companies to join. This is not easy to answer and may be the reason why the GBS would not work in practice, especially since funding would be problematic. Yet there is a chance that companies would join particularly because the GBS would provide assistance in negotiations with local stakeholders. One problem with prior informed consent and benefit sharing is that companies often do not know whom to address for permission and how to handle this matter in general. For them, the GBS could provide an opportunity to solve these issues. Also the companies could benefit from the neutral position of the GBS, which might enable contacts for companies with local communities which would not have negotiated with the companies themselves due to lack of trust. Hence, this mechanism could provide companies with opportunities they would not have had if they negotiated on their own.

C. Comment

The analysis of different approaches towards the efficient protection of traditional knowledge has revealed the complexity of this issue. Different forms of different approaches should be combined to provide an adequate solution for the protection of such knowledge. For short-term protection, defensive options should be implemented, since the implementation of new regimes would take too long to establish. In any case, a 'one size fits all' approach has to be carefully avoided. Therefore, a regime has to be designed that leaves enough flexibility to deal with different (cultural) aspects of traditional knowledge and allows for tailored measures that suit traditional knowledge from different parts of the world.

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[467] Drahos (note 463).
[468] Ibid.
[469] Dutfield (note 31) at 518.

VIII. Conclusion

This thesis has examined the interrelation between patents and biological and traditional knowledge. Reasons for and against the protection of traditional knowledge have been brought forward and the concepts of bioprospecting and biopiracy have been questioned.

The last decade has led to numerous technological advancements and developments especially in the sector of biotechnology. Advanced industrial processes allow companies to make extensive use of biological resources.[470] For that reason, biotechnological companies target biological resources as an important tool for the development of new products, especially in the area of pharmaceutical and agricultural products. These potential consumer markets are attracting profits and further investment and need intellectual property rights, particularly patents, to ensure maximum returns and prevent others from freely using their inventions.[471] Consequently, the benefit that arises from granting intellectual property rights is innovation, whereas the reward for innovating is the opportunity to collect, for a time, the monopoly rents available from devising a successful innovation.

The current patent legislation, deplorably, seems to favour bigger industrial and economic states, granting patents that allow them to exploit traditional peoples by capitalising on their knowledge in order to develop it further. Particularly international intellectual property law, which is based on novelty, inventiveness and industrial application is not sufficiently sensitised to deal with cases of traditional knowledge. The difficulty faced by patent examiners, in a large part, arises from the lack of written prior art due to undocumented records of traditional use of biological resources. Neither the TRIPS Agreement nor the European Patent Convention and the U.S. Patent Act require disclosure of origin, prior informed consent or any form of benefit sharing for traditional knowledge holders and therefore violate the principles of the Convention on Biological Diversity.

The case studies of the Neem Patent, the Enola Bean Patent and the Pelargonium Patents have revealed that patents have been granted that should not have been granted in the first place, mainly because they lacked novelty, an inventive

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[470] Lasen Diaz (note 145) at 49.
[471] Ibid.

step or even both. For that reason it has been concluded, that neither of the analysed patent systems is adequately able to protect traditional knowledge and therefore favours the concept of biopiracy.

At the same time, it has been argued that patent law, per sé, does not create biopiracy, but rather biopiracy is a form of misappropriation, unfair acquisition, and inequitable sharing of benefits with respect to biological resources. Consequently, the grant of a patent is not necessarily negative. The injustice of such behaviour arises out of the fact that there is no prior informed consent with traditional knowledge holders and no compensation for local communities even though an invention is based on grounds related to traditional knowledge.

Consequently, there is a need to rethink global attitudes and patent systems. The position of traditional knowledge holders has improved slightly since the implementation of the CBD. In many countries, national and regional legislation has been implemented, requiring certain criteria such as prior informed consent and benefit sharing arrangements before access to knowledge will be granted. Nevertheless, most of the legal measures for the protection of traditional knowledge have yet to be enacted.[472] It is also important to bear in mind that when national and regional legislation becomes too restrictive on access, benefit sharing and intellectual property rights, the legal conditions for biological research seem to have the effect of hindering foreign and even domestic access to biological resources rather than promoting it.[473]

Generally speaking, the protection of traditional knowledge raises numerous policy related issues such as the objectives and modalities of such a protection framework. This thesis has outlined the complexities and points to be considered within each approach towards adequate protection of traditional knowledge. Overall, it can be concluded that the best protection can be achieved through a combination of different options. Defensive options alone cannot provide satisfying solutions for the long-term. Yet, they are essential, especially for the short–term, since the negotiations of completely new systems will require time. In the meantime, however, traditional knowledge should not be left unprotected. The creation of databases is something that every country should consider as an intermediate

[472] Hassemer (note 14) at 215.
[473] Ibid.

measure. Countries should also consider targeting the misappropriation of biological resources and knowledge through a system of fines and penalties, which can be included in national sui generis regimes.

It lies in the hands of governments, countries and international organisations to articulate what should be achieved through patent law and other juridical concepts.[474] Nevertheless, it remains doubtful that the overall solution for targeting biopiracy lies in the patent system. After all, patent law and especially TRIPS is not designed to suit the needs of indigenous and local communities. The TRIPS Agreement has established excessively high standards of protection and the criteria are difficult to satisfy by innovations generated at the community level. Consequently, for the effective protection of traditional knowledge, a different set of questions has to be raised separate from issues of trade and commercialisation.

It is inappropriate for countries to come up with a 'one size fits all' international sui generis regime. Any new international norms will have to be flexible enough to accommodate jurisprudential diversity and take into account customary laws and structures.[475] For the present, the most important tools to establish a link between access to biological resources, benefit sharing and intellectual property rights remain contractual agreements and national legislation.[476] Such a contractual position of strength is what developing countries have lacked in the past, but their position has improved to some extent due to the implementation of the CBD.

The fact that traditional knowledge is being discussed in different forums means both opportunity and challenges. Opportunities can arise from the fact that protection of traditional knowledge is now subject to ongoing debate and proposals in several forums, most notably the World Intellectual Property Organization[477] and

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[474] Mgbeoji (note 74) at 192.
[475] Dutfield (note 32) at 124.
[476] Graham Dutfield ICTSD-UNCTAD Project on IPRs and Sustainable Development *Protecting Traditional Knowledge and Folklore A review of progress in diplomacy and policy formulation* (2003) 47. Available at http://www.iprsonline.org/resources/docs/Dutfield%20-%20Protecting%20TK%20and%20Folklore%20-%20Blue%201.pdf [Accessed 16 December 2009].
[477] The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (the IGC)'is discussing a draft for the enhanced protection of TK and traditional cultural expressions against misappropriation and misuse.' See World Intellectual Property Organization *Traditional Knowledge, Genetic Resources and Traditional Cultural Expressions/Folklore.* Available at http://www.wipo.int/tk/en [Accessed 31 January 2010].However

the Convention on Biological Diversity.[478] Nevertheless, the management of traditional knowledge is complicated, even more so because of the number of varying forums in which the issues are discussed and the need to be consistent, farsighted and aware of the stakes involved.[479] Consistency is important because 'government representatives sometimes express contradictory positions on the same subject in different forums'.[480]

Therefore, the goal is to adopt a long-term vision. When it comes to traditional knowledge, precise and realistic goals have to be formulated based 'on an informed calculation of what is necessary and feasible'.[481]

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the Committee has faced difficulties which in July 2009 have led to a standstill of the negotiations since no consensus could be reached between developing and developed nations. In the meantime the Committee has managed to develop its mandate for 2010.

[478] Dutfield (note 476).

[479] Ibid.

[480] Ibid.

[481] Ibid.

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