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Traditional Knowledge and the Patent System – Irreconcilable differences or a simple case of mistaken identity?

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Contents

Summary

Traditional knowledge (TK) is in simple terms knowledge systems held by indigenous communities, often relating to their surrounding natural environment. Through globalisation and the increased availability of this knowledge as well as the implementation of intellectual property systems in the developing world TK and its relationship with the IPR-system has become a much debated and highly complicated issue. Patents have been granted with knowledge that stems from TK, some of these patents have been challenged and accused of being examples of "biopiracy". The task of attempting to better adjust the patent system to TK is being undertaken for the most part by working groups attached to the Convention on Biodiversity and the World Intellectual Property Organization's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. Due to amongst other things, the controversy of biopiracy much of the debate has been mired in what can be seen as post-colonial anger and guilt, it is highly politicised and often far removed from the legal issues at hand.

This thesis attempts at reclaiming the issue from the political arena and approach the imperfect interaction between the two knowledge systems as a legal problem instead of a political one. The questions posed are if there is an actual need for accommodating the current patent system for TK, and if so, what measures would be justified?

In chapter 2 TK is defined further and the case for and against protection is covered. It is divided up into looking at its role in aiding sustainable development, the biopiracy debate, use of TK as a means of levelling out the playing field between the North and the South and finally its role in protecting the validity of the patent system.

Chapter 3 is a run through of the structure of the patent system within the European Patent Convention as well as a brief look at its history and theoretical justifications.

In chapter 4 three case studies are presented; Turmeric, Neem and Ayhuasca. They have been chosen because they are both representative in regards to being some of the most well documented cases as well as illustrating different aspects of the problems that can arise when the patent system and TK come into contact. The cases reveal problems connected to judging the patent criteria of novelty and inventive step in relation to TK as well as the issue of the moral rights of indigenous communities in terms of protection from infringement of their religious identity. Finally, an overhanging difficulty that is shown in all cases is the problem for communities both legally and economically in challenging patents which they feel infringe upon their TK.

Chapter 5 deals with possible defensive measures to adjust the system as a means of preventing occurrences such as those shown in the case studies. Three proposed solutions are studied: creating TK-databases and adjusting prior art searches, disclosure of origin within the patent applications and moral rights as an exception to patentability.

Chapter 6, the analysis and the conclusion in chapter 7 suggest that TK and the patent system do not interact well but not as badly as one is brought to believe. The mistaken identity of the issue being that TK is important but so is the patent system, and the question should not be treated as only a question of adapting the patent system to TK but also of adapting TK to the patent system as I argue that the patent system in spite of its imperfections is worth keeping as strong and efficient as possible, and patents which reach the standards set by the patentability critera should be granted notwithstanding if their content originates from TK or not. The most important thing is driving innovation, especially in areas such ESTs. The case studies, with the exception of the Ayahuasca case, also show that the patents granted were in actuality neither classic cases of theft nor doing any real harm to the TK-holders even if they were incorrectly granted as they did not meet the standards of the patentability criteria. In conclusion four changes are suggested. Firstly a further expansion of TK-databases is required as well as improved routines for prior art searches. Secondly a voluntary disclosure requirement should be included into the patent system. Thirdly the moral rights of TK holders as regards the sanctity of their religious beliefs should be included into the concept of *ordre public* as an exception to patentability under certain circumstances. The final suggestion regards giving aid to help indigenous communties both acquire patent protection and fight incorrectly granted patents.

Preface

For support in writing this thesis I would like to extend my thanks to Professor Hans Henrik Lidgard for both inspiration and guidance and to Måns for being such good company during long hours in the library. I would also like to thank my parents for supporting my studies and being such excellent proofreaders.

Abbreviations and Acronyms

ABS	Access and Benefit Sharing
CBD	Convention on Biological Diversity
COP	Conference of the Parties to the Convention on Biological Diversity
CSO	Civil Society Organization
EPC	European Patent Convention
EPO	European Patent Office
EST	Environmentally Sound Technologies
ETC	ETC Group
EU	European Union
IGC	Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore
IPC	International Patent Classification
IPR	Intellectual Property Right
PCT	Patent Co-operation Treaty
PIC	Prior Informed Consent
RAFI	Rural Advancement Foundation International
R&D	Research and Development
TCE	Traditional Cultural Expression
TK	Traditional Knowledge
TKDL	The Traditional Knowledge Digital Library project
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
USPTO	United States Patent and Trademark Office
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

1 Introduction

The fixing of identity is a concept within the sociological study of the mechanisms of power. Whether it be fixing the identity of a group of people or a contested issue, they who fix identity are given the platform to control.[1] By taking control of an issue or problem and defining it one can more easily steer the debate as one is often forced to make use of that fixed identity in the debate. Traditional Knowledge (TK) - knowledge systems held by indigenous communities, often relating to their surrounding natural environment - and its relation to patents is an area where the identity has been securely fixed by the developing countries and the Civil Society Organisations (CSOs). They have defined the relationship as being one of theft under the concept of "biopiracy" and that the wealthy developed nations are enacting a second wave of colonisation by stealing the genetic resources and traditional knowledge of the developing world. As a result much of the debate has been mired in what can be seen as post-colonial anger and guilt, often far removed from the legal issues at hand.[2] For beyond the political struggle, the relationship between TK and the patent system is undoubtedly far from frictionless.

Examining the field of TK and its relationship with the patent system is truly a case of opening up a can of worms. Not only due to the biopiracy debate but because it has become enmeshed with so many other different issues of contention relating to intellectual property rights (IPRs), for example genetically modified organisms and "patents on life".[3] Important issues, but different from the TK issue, even though they are often mentioned in the same breath. Consequently, such a multitude of topics easily becomes held up in the international political arena as it turns into a bargaining chip in large-scale trade negotiations between the developing (South) and the developed (North) nations. This leaves a Gordian knot of several different problems and issues to which there is no one answer. One must therefore as the legend reads, like Alexander the Great disentangle TK by simply cutting it free and from that point deconstruct what the true legal problems relating to TK are, and by extension what is being done, what could be done and what should be done to solve them.

If one starts by looking at the interaction problems, they can, at the most fundamental level, be connected to the clash in the structures of the knowledge systems of the developed and developing world. Some hold this to be an oversimplification[4]; even so, it cannot be denied to be an important factor. In the North, knowledge has developed into one of the most highly

[1] Clegg, Stewart R. *Frameworks of Power*, Sage Publications, London, 1989. p. 188
[2] Olsson, Henry. *WIPO:s Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore (IGC),* Nordisk Immateriellt Rättsskydd (2004) p. 203-205
[3] Mutter, Karl. *Traditional Knowledge related to Genetic Resources and its Intellectual Property in Colombia*, 9 European Intellectual Property Review (2005) p. 333
[4] See for example Downes, David R, *How Intellectual Property Could Be a Tool to Protect Traditional Knowledge*, (2000) 25 Columbia Journal of Environmental Law, p. 258-259

valued commodities in the economy. Knowledge is owned, bought and sold. Through IPRs, rights are conveyed, protected and knowledge monopolized. A system intended to reward those who create and invent but also aimed at fuelling invention and development through the fact that discoveries are made public and later free to use, as they become part of the public domain after the expiration of protection.

In summary one can see it as the North having reified knowledge, in contrast to the indigenous communities of the South which often regard knowledge as a living thing, closely connected to their cultural heritage but constantly evolving as it is passed on from generation to generation. Knowledge that simultaneously belongs to no one and everyone. But the question is if this is a question of fundamental cultural differences or simply a question of being at different stages of societal development?

Patents have however been introduced to the South, firstly through the Paris Convention for the Protection of Industrial Property which was first enacted in 1883 and has 169 contracting parties.[5] The Convention covers a wide variety of IP-rights and has as its main focus national treatment, right of priority and establishing some common rules. Secondly and more importantly the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) has more forcefully introduced IPRs to the South. It was accepted by developing nations in exchange for trade privileges and is by many seen as a controversial and much resented piece of legislation.[6] It came into effect in 1995 and is binding for all 149 members of the World Trade Organization (WTO). It covers most IP-rights and has as its main purpose to establish standards for protection, enforcement and dispute settlement between members within its scope.[7] In terms of patents, article 27 of TRIPS is the most central. It states what is patentable subject matter as well as amongst other things the patentability criteria of novelty, inventive step and industrial application.[8]

Thus an IPR system has been imposed upon the South, much of their knowledge which is exemplified by TK, however, lies within the public domain, owned by no-one and "free". This has to a certain extent been exploited by companies who have patented TK, patents which did not in actuality meet the patentability criteria. The South has been made to conform to the Northern system by enacting IPR-legislation. This in combination with Northern companies seeking out genetic material and traditional knowledge in the South has created an imbalance in-between the two systems. Whilst the piracy of Northern IPR-protected products in the South is heavily condemned and a source of great political pressure from

[5] http://www.wipo.int/treaties/en/ShowResults.jsp?country_id=ALL&start_year=ANY&end_year=ANY&search_what=C&treaty_id=2, 05/01/07
[6] Dutfield, Graham. *Intellectual Property, Biogenetic Resources and Traditional Knowledge*, Earthscan, London, 2004. p. 25
[7] http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm, 05/01/07
[8] Agreement on Trade-Related Aspects of Intellectual Property Rights, article 27

especially the U.S.[9], the patenting of TK often falls between the cracks in the patent system. Even though the patentability criteria of novelty and inventive step in theory should prevent known TK from being patented, it does not in reality however always work that way, as case studies in this thesis will later show.

If one moves on to the question of why solving this issue is so important, claims have been made that with this imbalance, there is a real risk for a crisis of legitimacy developing within the IPR-system.[10] The problem as stated above is however in many aspects a political one and not a legal one. The real legal problem is in reality confined to the issue of "bad" patents being granted.

The problems outlined above, both legal and political have not gone unnoticed and are under debate in many different forums. The most important forums are those relating to the Convention on Biological Diversity (CBD) and the World Intellectual Property Organization's (WIPO) Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). The CBD was signed by some 150 world leaders and the Rio Earth Summit in 1992. Today it has 168 signatories, the U.S. however is a notable exception.[11] It sparked the initial focus on biodiversity issues to which TK can be counted. Although it has many signatories and has inspired much national legislation, the CBD is a soft law convention and thus legally toothless in terms of creating real substantive change by itself.[12]

The IGC was established in 2000.[13] Its main purpose is: *"an international forum for debate and dialogue concerning the interplay between intellectual property (IP), and traditional knowledge, genetic resources, and traditional cultural expressions (folklore)"*.[14] The work of the IGC has by Graham Dutfield been named the *"most promising place"* at the present time for achieving genuine solutions for problems related to TK and it is undoubtedly where the most progress is currently being made.[15] As of late however, the progress of the IGC has been hindered by a political standoff over a proposed implementation of the substantive articles of the IGC Draft

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[9] Iyengar, Jayanthi, *Intellectual property piracy rocks China boat,* Asia Times, 16 September 2004, available at: http://www.atimes.com/atimes/China/FI16Ad07.html, 06/01/07

[10] Coombe, Rosemary J, *The Recognition of Indigenous Peoples' and Community Traditional Knowledge in International Law*, (2001) 14 St Thomas Law Review, p. 275

[11] http://www.biodiv.org/world/parties.asp

[12] Konold, Birgitta. *Access to Genetic Resources, Benefit Sharing and Traditional Knowledge in the Light of the Convention on Biodiversity* in Lidgard, Hans Henrik (ed.) *Transferring Technology to Developing Countries*, Centrum För Europaforskning, Lund, 2004 p. 159

[13] MATTERS CONCERNING INTELLECTUAL PROPERTY AND GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE, WO/GA/26/6

[14] http://www.wipo.int/tk/en/igc/, 06/01/07

[15] Dutfield, Graham. *Protecting Traditional Knowledge: Pathways to the Future,* ICTSD Issue Paper No. 16, 2006. p. 35, available at: http://www.iprsonline.org/unctadictsd/docs/Graham%20final.pdf, 04/01/07

provisions.[16] This has brought the process more or less back to square one by a lack of consensus over whether to implement the substantive provisions of the IGC draft provisions or not; the provisions have as a result been tabled until further notice.[17]

With two international organisations, seemingly too entrenched or weakened by polarised politics to act the questions arise if there is a possible solution to be had and if it from a legal point of view actually is needed?

1.1 Purpose and Delimitations

The main purpose of this thesis is to explore if there is actual need for accommodating the current patent system for Traditional Knowledge, and if so, what measures would be justified. This thesis will also aim to redefine the issue of TK and the patent system by as much as possible circumventing the political quagmire that currently surrounds the issue of TK and the patent system and view it as a legal problem, and in extension attempt to find viable legal solutions within the current system.

This paper will only deal with TK that can lead to patents; it therefore excludes what is known as Traditional Cultural Expressions (TCE), which includes artistic expressions in the form of art, music and folklore as well as the plant breeders' rights of the UPOV-regime.

The paper is written from the perspective of the European Union (EU) on a regional level. The legal instruments that will be focused upon are thus the European Patent Convention (EPC), the TRIPS-agreement and to a lesser extent other international instruments. No possible solutions through national legislation will be discussed. Even if a European perspective is chosen, the Community Patent Convention and the ongoing work with introducing such a system will be left out of this paper.

In terms of possible protective measures for TK only what is known as defensive protection will be taken up. Particulars regarding Access and Benefit Sharing and Prior Informed Consent are also left out as they are measures that are currently outside of the patent system as well as representing a form of positive protection.

I have decided to not take up the issues relating to positive protection, such as possible sui generis protection for TK. Partly because it widens the focus of this thesis too much and partly because it is my personal opinion that there is no real future for such a system. Even though the work in the international forums strongly advocate a system of positive protection it is

[16] Roberts, Tim. *Intellectual Property: 9th Meeting of the Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore, Geneva, April 24-28 2006*, 28(8) European Intellectual Property Review (2006) N155
[17] *Decisions of the Tenth Session of the Committee*, WIPO/GRTKF/IC/10. p. 7

unlikely that anything will happen in the near future if indeed ever. A sui generis system of protection could not realistically be limited in time: there is no logic in saying to a tribe that might have held specific knowledge for hundreds of years that they now have exclusive rights for twenty years.. Logically such a sui generis system must grant an unlimited monopoly right on certain knowledge. A grant that would counteract the purposes and efficiency of the IPR-patent system completely. Even though suggestions have been made to counteract this problem it is in my mind still very far from being a realistic alternative. Although the knowledge gathered in TK-systems should be respected and admired a sui generis protection system is not justified. Positive sui generis protection raises far too many questions in relation to foreseeability and legal security. For more on the issue of a sui generis protection see Graham Dutfield.[18]

Another limitation in respect to protective measures will be that use of trademarks and geographical indications will not be considered.

1.2 Method and Material

This thesis has been written using traditional legal method, which involves studying traditional legal sources such as laws, international agreements, case law and legal doctrine. This method has been chosen as it serves as a natural basis for a legal study. It has however been complemented with a sociological, philosophical and historical approach in some cases to put some issues in a wider perspective than allowed by a purely legal method.

The legal framework will primarily be relevant articles of the EPC, TRIPS and the CBD, as well as materials from the ongoing work of the WTO, WIPO's IGC and the COP.

Furthermore, three case studies of opposition procedures against what are popularly referred to as the Turmeric, Neem and Ayhuasca patents will be made. As far as possible, these studies will be based upon of official documentation where available.

In terms of doctrine the focus is put upon articles from legal journals. Even though some literature is used most material have been collected from articles and the Internet as there are constant developments and literature on the subject very quickly becomes dated. Some more extensive studies will however be used, namely Graham Dutfield's *"Protecting Traditional Knowledge: Pathways to the Future"* which is both recent and reasonably objective. This is something of a rarity as authors often clearly chose sides in their writing in relation to this subject. Ultimately very few truly

[18] Dutfield, Graham. *Protecting Traditional Knowledge: Pathways to the Future*. ICTSD Issue Paper No. 16 (2006), available at: http://www.iprsonline.org/unctadictsd/docs/Graham%20final.pdf, 04/01/07

objective appraisals are made, and even those who attempt it are often caught up in complicated stepdance of political correctness. As a result, most texts must be approached with caution as they are often biased according to their political affiliation.

2 Traditional Knowledge

One of the main underlying causes for TK being such a complex issue can be found in simply trying to define what it is. In the introduction, TK was briefly defined as traditional knowledge systems held by indigenous communities, often relating to their surrounding natural environment. It is by no means incorrect but it does not truly answer the question of what TK is as much as it creates new ones: What should be regarded as traditional? Moreover, without wandering off into epistemology, what should be regarded as knowledge within the meaning of TK? Furthermore, it is of interest to determine its potential value and why it should be granted protection as a means of ascertaining that the protection granted is not out of proportion to its importance.

2.1 Definition

There is no one universally accepted definition of what constitutes TK. Sometimes it also encompasses TCEs as within the CBD where The Convention on Biodiversity's Working Group on Art. 8(j) present this definition of TK:

"Traditional knowledge refers to the knowledge, innovations and practices of indigenous and local communities around the world. Developed from experience gained over the centuries and adapted to the local culture and environment, traditional knowledge is transmitted orally from generation to generation. It tends to be collectively owned and takes the form of stories, songs, folklore, proverbs, cultural values, beliefs, rituals, community laws, local language, and agricultural practices, including the development of plant species and animal breeds. Traditional knowledge is mainly of a practical nature, particularly in such fields as agriculture, fisheries, health, horticulture, forestry and environmental management in general."[19]

Thus, sometimes TK can be used in a wider sense but whilst it can be held to be a wider definition, it is at the same time a sub-division of that. An example of this is the definition presented by the IGC:

"the content or substance of knowledge that is the result of intellectual activity and insight in a traditional context, and includes the know-how, skills, innovations, practices and learning that form part of traditional knowledge systems, and knowledge that is embodied in the traditional lifestyle of a community or people, or is contained in codified knowledge systems passed between generations. It is not limited to any specific

[19] http://www.biodiv.org/programmes/socio-eco/traditional/default.asp, 04/01/07

technical field, and may include agricultural, environmental and medicinal knowledge, and knowledge associated with genetic resources."[20]

The IGC definition is more specific and corresponds to the way TK is used within this thesis. It still leaves many questions unanswered however, such as, what specific knowledge held by whom does it apply to? One of many questions still searching for an answer and part of the work being undertaken by the IGC.[21]

2.2 The Case For and Against Protection

Even though TK is yet to be satisfactorily defined one thing is certain, and that is the fact that it is a source of knowledge, which is unprotected by IPRs and often freely available within the public domain.[22] That TK should be protected is often taken for granted and the question of why is often left aside.[23] However, the question of why TK should be granted better protection is still worth examining, as it not only justifies the actual protection, but also explores what the extent of the protection should be.

2.2.1 Aiding Sustainable Development

The value of TK in aiding sustainable development has been lauded by many commentators and intergovernmental bodies. This value can be seen both in terms of socio-economic value and the cultural value it holds for the TK-holders. This knowledge which often is more lenient on the environment can be a pivotal tool in developing Environmentally Sound Technologies (ESTs) and more sustainable ways of living.[24]

Sustainability is a central theme for the CBD, the objectives of the convention are found in its first article:

"The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of

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[20] http://www.wipo.int/tk/en/glossary/index.html#tk, 04/01/07
[21] http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_10/wipo_grtkf_ic_10_decisions.pdf, 04/01/07
[22] Gibson, Johanna. *Intellectual Property Systems, Traditional Knowledge and the Legal Authority of Community,* 7 European Intellectual Property Review (2004), p. 280
[23] Dutfield, Graham. *Protecting Traditional Knowledge: Pathways to the Future*. ICTSD Issue Paper No. 16 (2006), available at: http://www.iprsonline.org/unctadictsd/docs/Graham%20final.pdf, 04/01/07, p. 3
[24] Khor, Martin. *Intellectual Property, Biodiversity and Sustainable Development – Resolving the Difficult Issues*, Zed Books, London, 2002. p. 16

relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding."

Furthermore, the CBD in relation to TK more specifically in article 8(j) stipulates that each contracting party shall as far as possible and as appropriate:

"Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices;"

The CBD thus also identifies TK-holders as the true and rightful owners of their knowledge. A sentiment which is shared by the IGC within their draft provisions:

"The rights of traditional knowledge holders to the effective protection of their knowledge against misappropriation should be recognized and respected."[25]

2.2.2 The Biopiracy Debate

The most common reason given for why TK protection should be granted is the claim that Northern companies are exploiting the biodiverse South by patenting "their" knowledge. This claim has dominated as a reason for protection greatly due to the fact that developing nations and CSOs have defined it as a problem and as a concept and thus it steers much of the debate.

The concept of biopiracy arose as a counter definition to bioprospecting which is the collection of and search for biological material and associated TK with the aim of commercialisation.[26] It was coined by the Rural Advancement Foundation International.[27] They have since changed their name to the ETC Group (ETC). The ETC define biopiracy as:

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[25] *THE PROTECTION OF TRADITIONAL KNOWLEDGE: REVISED OBJECTIVES AND PRINCIPLES - Document prepared by the Secretariat*, WIPO/GRTKF/IC/9/5, Annex, page 9

[26] Lindeskog, Susanne. *Bioprospecting, Access and Benefit Sharing and Traditional Knowledge* in Lidgard, Hans Henrik (ed.) *Transferring Technology to Developing Countries*, 2004, Centrum För Europaforskning, Lund. p. 190

[27] Mooney, Pat. *Why We Call It Biopiracy,* in Svarstad and Dhillion (ed.) *Bioprospecting: From Biodiversity in the South to medicines in the North,* 2000, Spartacus, Oslo. p. 37

"the appropriation of the knowledge and genetic resources of farming and indigenous communities by individuals or institutions who seek exclusive monopoly control (patents or intellectual property) over these resources and knowledge. ETC group believes that intellectual property is predatory on the rights and knowledge of farming communities and indigenous peoples."[28]

ETC are like RAFI before them a CSO with an agenda. They are actively involved in lobbying and propaganda; they are for example involved in handing out the Captain Hook Awards for Biopiracy.[29] Agenda is a word that should be always kept in mind when traversing a subject that is as politically charged as the debate over biopiracy. ETC and the CSOs involved have a clear agenda and a propaganda apparatus and so do the lobbyists for the Biotech companies who themselves indulge in lobbying which is every bit as crude as the Captain Hook Awards.[30]

One of the most famous proponents of the biopiracy cause and to a certain extent the most extreme is Vandana Shiva. She equates patents and the GATT agreement to the colonial exploits of Columbus and states that the North is driven by a need to *"subdue, occupy, and possess"*.[31] Through her writing she expresses a view that the "biopiracy" of the west is an organised and intentional system of exploitation.[32]

If however one looks for actual proof of biopiracy there are a number of cases, three of which will later be discussed, which anti-biopiracy groups claim to be proof of biopiracy. The documented "biopiracy"-cases are not that many in relation to the power of the rhetoric however. An interesting study has been undertaken by the Peruvian Anti-Biopiracy commisson which conducted searches in U.S., EPO and Japanese databases in search of references to six plants which are found in Peru. The search showed a great number of references but they haven't been studied in greater detail yet and are thus labelled as "*potential cases of biopiracy*".[33]

A very interesting point is raised by The Council of Scientific and Industrial Research of India (CSIR) in relation to the Turmeric case, where they were the opponents in both the Turmeric and Basmati cases[34]:

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[28] http://www.etcgroup.org/en/issues/biopiracy.html, 04/01/07
[29] http://www.captainhookawards.org/coalition, 04/01/07
[30] Dutfield, Graham. *Protecting Traditional Knowledge: Pathways to the Future*. ICTSD Issue Paper No. 16 (2006): http://www.iprsonline.org/unctadictsd/docs/Graham%20final.pdf, p. 9-10, 04/01/07
[31] Shiva, Vandana. *Biopiracy*, 1998, Green Books, Totnes. p. 8-9
[32] Shiva, Vandana. *Protect or Plunder? – Understanding Intellectual Property Rights*, Zed Books, London, 2001. p. 49-53
[33] PATENT SYSTEM AND THE FIGHT AGAINST BIOPIRACY - THE PERUVIAN EXPERIENCE - Document submitted by Peru, WIPO/GRTKF/IC/8/12
[34] For more on the Turmeric case see section 4.1. For more on the Basmati case see: Subbiah, Sumathi, *Reaping what they sow: The Basmati rice controversy and strategies for protecting traditional knowledge*, 27 Boston College International & Comparative Law Review (2004) p. 529

"Amidst the loud protests against 'biopiracy' and 'theft' of India's biodiversity and traditional knowledge by foreign nationals, it is interesting to note here that the patentees were Indians (Das and Cohly), the re-examination in USPTO was done by an Indian (Kumar) and the re-examination was sought by an Indian institution (CSIR)."[35]

There are those who claim that biopiracy doesn't exist. A somewhat polemic contribution to the debate is provided by Jim Chen, professor of Law at the University of Minnesota. Chen refutes the Biopiracy argument and finds that it lacks content and claims that it is a perception of illicit appropriation which is grounded more in post-colonial theory on the obligations of the North toward the South than in actual reality.[36]

A more balanced view has been presented by Graham Dutfield who represents that the biggest problem with the biopiracy-rhetoric is that it is an imprecise term which may be helpful for certain reasons but in terms of aiding legal solutions is of no help. Dutfield puts forward the thesis that there is no agreement on what actually constitutes biopiracy and how much of it acutally goes on.[37]

The point raised by CSIR and the various sides of the debate over biopiracy show that the palette contains more colours than simply black and white. It is a confusing concept where it isn't unusual to see scholars deeming something to be an act of biopiracy and then later on question it as a concept within the confines of one text.[38]

Biopiracy isn't such a clear cut situation of the North plundering the South: it also shows that the issue of "Biopiracy" is not uncontroversial even in the developing world. Although debate to a certain degree is polarised between North and South one must keep in mind that there is no single position shared by all indigenous peoples in the same way as no such single position exists between the developed countries.[39]

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[35] Mashelkar, R. A., *Intellectual property rights and the Third World*, 81 Current Science (2001), p. 960, available at: http://www.ias.ac.in/currsci/oct252001/955.pdf, 04/01/07
[36] Chen, Jim. *There's No Such Thing as Biopiracy…and It's a Good Thing Too*, (2006) 37 McGeorge Law Review, p. 26
[37] Dutfield, Graham. *Protecting Traditional Knowledge: Pathways to the Future*. ICTSD Issue Paper No. 16 (2006): http://www.iprsonline.org/unctadictsd/docs/Graham%20final.pdf, p. 7, 04/01/07
[38] see for example: Arewa, Olufunmilayo B., *TRIPS and Traditional Knowledge: Local Communities, Local Knowledge, and Global Intellectual Property Frameworks*, 10 Marquette Intellectual Property Law Review (2006) p. 171 and 179-180
[39] Coombe, Rosemary J, The Recognition of Indigenous Peoples' and Community Traditional Knowledge in International Law, (2001) 14 St Thomas Law Review, p. 277

2.2.3 Levelling out the Playing field

Another reason for granting more protection could be defined as an attempt to level out the playing field. Both in terms of rewarding the South for adopting western IPR-legislation and also aiding them in building upon their own knowledge and resources as a means of boosting local industry and creating businesses with export potential.[40] Signs that this is starting slowly to happen can be seen by the fact that developing countries have increased their biotechnology patenting.[41] An ironic example of this is shown by the fact that the claims of the Neem patent, which will be discussed in great detail later, have been built upon by Indian scientists who themselves have been granted a patent for a storage stable pesticide which improves upon the earlier so heavily opposed patent.[42]

Article 66.2 in TRIPS states that developed countries have an obligation to transfer technology to the developing countries. A similar sentiment can be found in article 16 of the CBD. Technology and knowledge which could be put to use in developing domestic TK. One could therefore put forward the argument that TK is an opportunity for the South to help themselves by blending their traditional knowledge with the transferred technology from the North and as a result the ownership of this knowledge should lie with the countries of origin so that they can be given the opportunity to develop and profit from it. A theme that can be found in the CBD where fair and equitable sharing is a focal point.[43] These rights are also recognised in the policy objectives and general guiding principles of the draft provisions of the IGC.[44]

Another means of levelling the playing could be the use of Access and Benefit Sharing (ABS) and Prior Informed Consent (PIC). ABS is the monetary or non-monetary contribution from companies for being allowed to access and use genetic materials and/or TK.[45]

PIC as presented in Article 15(5) of the CBD is that any access must only be undertaken with the consent of the country where the resources are found.

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[40] *Intellectual Property Rights: Implications for Development*, ICTSD/UNCTAD Policy Discussion Paper, August 2003. p. 65-68
[41] Quach, Uyen et al. *Biotechnology patenting takes off in developing countries,* 8 International Journal of Biotechnology (2006) p. 43-59
[42] U.S. Patent 6,811,790
[43] See for example article 2 and 3 of The Convention of Biological Diversity
[44] *THE PROTECTION OF TRADITIONAL KNOWLEDGE: REVISED OBJECTIVES AND PRINCIPLES*, WIPO/GRTKF/IC/9/5
[45] Lindeskog, Susanne. *Bioprospecting, Access and Benefit Sharing and Traditional Knowledge* in Lidgard, Hans Henrik (ed.) *Transferring Technology to Developing Countries*, 2004, Centrum För Europaforskning, Lund. p. 191-194

2.2.4 Protecting the Validity of the Patent System

Novelty is often named the *sine qua non* ("without which it could not be") of the patent system. The indispensible condition without which it cannot function properly. If the patent system allows patents to be granted for inventions which lack novelty and inventive step it raises serious questions over the validity of the system if exclusive rights are granted solely because the prior art information is not accessible through the regular information sources used by patent examiners. The grant of a monopoly right depends upon the grant being bestowed on a product or process which is genuinely new and not because they are unheard of in the North. Bad patents blatantly lacking in novelty undermine the credibility of the patentsystem. An argument in favour of increasing protection for TK could thus be protecting the patent system itself as TK seemingly manages to more easily slip past the safeguards in the system.

3 Patents

A patent is a monopoly right, which is granted to a patentee for a limited period of time during which he is given the exclusive right to hinder anyone else from using her invention without consent. Thus it is a negative right as it doesn't grant anyone the right to produce or do anything, simply the right to hinder others from doing or producing what is covered by the patent. Patents as a legal institution have evolved over hundreds of years. The scope, length and purpose for protection has changed many times and it is of value to this paper to examine the developments in relation to the developments occurring in the Southern countries but at a much more accelerated pace as a means of mirroring the development.

3.1 History of Patents

The roots of IPRs can be traced back far through history almost to the beginning of modern civilisation.[46] Patents akin to their current manifestation didn't develop until much later however. Historically patents were initially in practice no more than grants of monopoly over certain fields of commerce. Patents relating to invention however started to appear in Europe during the 16th century.[47] A lot of the historical development of patents took place in the United Kingdom. In 1614 the Clothworkers of Ipswich Case was decided; it is recognised as the first British legal ruling on patents relating to invention.[48] The following statement from the case shows a foundation and reasoning that albeit nearly 400 years old is very similar to that of the present day patent system:

" if a man hath brought in a new invention and a new trade within the kingdom in peril of his life and consumption of his estate or stock, etc, or if a man hath made a new discovery of anything, in such as cases the King of his grace and favour in recompense of his costs and travail may grant by charter unto him that he shall only use such a trade or trafique for a certain time, because at first people of the kingdom are ignorant, and have not the knowledge and skill to use it. But when the patent is expired the King cannot make a new grant thereof" [49]

Even though the patent system has evolved over centuries most knowledge was part of the public domain and society as a whole was more communitarian. A great change in this attitude however took place during

[46] May, Christopher and Sell, Susan K. *Intellectual Property Rights – A Critical History*, 2006. Lynne Rienner, London. p. 44
[47] Baker, J.H. An Introduction to English Legal History (3rd ed.), 1990. Butterworths, London. p. 511-512
[48] Thorley, Simon et al. *Terrell on the Law of Patents* (16th ed.), 2006, Sweet & Maxwell, London. p. 2-3
[49] Ibid. p. 3

the industrial revolution of the 19th century. Industrial pioneers in Europe and the United States built upon knowledge available in the public domain and created new products and processes for which they sought exclusive rights.[50]. An example of this explosive development can be seen by the fact that in 1750 only seven patents were registered in the United Kingdom, but by 1851 this number hade increased to 455.[51] H.I. Dutton, the author of "*The Patent System and Incentive Activity During the Industrial Revolution, 1750-1852",* acknowledges that although there is doubt over the use of the number of patents as an index of incentive activity during the industrial revolution, the majority of inventors did protect their inventions. This was done because in an era that marked the beginning of truly cutthroat competition the patent system provided security for inventors, which not only protected them against infringement but also granted them protection in dealing with potential industrial investors.[52]

3.2 The Theoretical Justifications for the Patent System

Although the philosophical debate over the patent system and IPRs is not the focus of this thesis there is value in understanding its theoretical building blocks when one potentially views altering how the system functions.

The two main justifications for the patent system are the deontological and the consequential (or utilitarian) theories.

The deontological approach which is also known as natural rights theory emphasizes that the product of invention belongs to the inventor. She has no obligation to disclose her invention and is therefore entitled to be compensated for doing so. The government thus grants an exclusive right as a means of bringing the knowledge into to the open so that other inventors can also benefit from the discovery.[53] Although this is put forward by some as a legitimate theory, Dutton argues that is has been abandoned and in reality hasn't been taken seriously since the early part of the 19th century.[54]

The consequential justification is also known as contract theory and sees use of patents as an incentive system, which works for the greater good of humankind. Contract theory is based upon the view that invention will be encouraged if there are rewards to be had. Patents are thus through this view

[50] Cottier, Thomas. The Protection of Genetic Resources and Traditional Knowledge, (1998) 1 Journal of International Economic Law, p. 561
[51] Dutton, H.I., *The Patent System and Incentive Activity During the Industrial Revolution, 1750-1852*, (1986) Manchester University Press, Manchester. p. 1
[52] Ibid. p. 202-203
[53] Miller, Arthur R. and Davis, Michael H., *Intellectual Property – Patents, Trademarks and Copyright* (3rd ed.) 2000, West Group St. Paul. p. 16-17
[54] Dutton, H.I., *The Patent System and Incentive Activity During the Industrial Revolution, 1750-1852*, (1986) Manchester University Press, Manchester. p. 18

seen as incentives.[55] An extension of this is the Monopoly Profit Incentive Theory which is linked to consequential approach but with the difference that the incentive is linked to the idea that patents are a great generator of economic growth as new inventions lead to more industry.[56]

The patent system has under its entire existence always stood under fire. As a monopolistic institution, it naturally attracts critics. This was true under the industrial revolution and is still true today when globalisation opponents view it as an oppressive tool and legal scholars question its efficiency.[57] Vandana Shiva is an avid part of the movement to protect TK and to abandon the IPR-system. In *"Protect or Plunder? – Understanding Intellectual Property Rights*" she presents arguments against the IPR system. Although Shiva's argumentation is deeply flawed and lacks credible support it is interesting to study as an opposing view. Shiva recounts that a central fallacy in connection with the ideology of IPRs is that creativity is dependent on the ability to be able to make profits, which are guaranteed by IP-protection. Shiva claims that this is disproved by the fact that creativity exists which is not profit driven, for example within universities and public research systems.[58] Shiva has within her argumentation missed the mark: IPRs do not in theory claim to be the sole driving force behind invention but quite simply they provide an added incentive for someone to create something, whether we may like it or not, money is a motivational force in society. Secondly, R&D on a large-scale would probably not take place if some protection was not granted. Support for this is provided by Bengt Domeij who states that the pharmaceutical industry and patents are linked in such a way that they couldn't exist if they weren't able to recoup the cost of developing a new product through the protection granted by patents and that at least for many pharmaceuticals patents are an essential incentive.[59] A study published in 2003 estimated development costs for a new pharmaceutical and bringing it onto the market at on average 403 million dollars, and although some question whether this high figure is a result of over investment in the pharmaceutical industry costs are nevertheless staggering.[60]

3.3 European Patent Convention

As this thesis is written from a European perspective, the main focal point for changes in actual patent legislation and guiding principles will be the

[55] Miller, Arthur R. and Davis, Michael H., *Intellectual Property – Patents, Trademarks and Copyright* (3rd ed.) 2000, West Group St. Paul. p. 16-17
[56] Dutton, H.I., *The Patent System and Incentive Activity During the Industrial Revolution, 1750-1852*, (1986) Manchester University Press, Manchester. p. 20-21
[57] May, Christopher and Sell, Susan K. Intellectual Property Rights – A Critical History, 2006. Lynne Rienner, London. p. 37-42
[58] Shiva, Vandana. *Protect or Plunder – Understanding Intellectual Property Rights*, (2001), Zed Books, London. p. 25
[59] Domeij, Bengt. *Pharmaceutical Patents in Europe,* 2000. Kluwer Law International & Norstedts Juridik AB, Stockholm, 2000. p. 9-10
[60] The Lancet, Volume 363, Issue 9404 , 17 January 2004. p. 184

European Patent Convention (EPC). The EPC was signed in 1973 and came into force in 1977.[61] There are currently 31 contracting states, as well as 5 extension states that recognise European patents.[62] The EPC has undergone a modernisation process, which resulted in EPC 2000, which is currently being ratified and will come into force on the 13th of December 2007 at the latest. The EPC 2000 however doesn't contain any substantive changes that directly relate to TK issues.[63]

The EPC doesn't provide applicants with a European patent per se, the system isn't separated from the national patents in the contracting states. What it does do however is present a cost efficient system for centrally applying for patents in several European countries at once as it permits a single regional examination of patent applications and subsequent national grants based on that examination.[64]

The basic contents of a patent are the claims, detailing the nature of the inventions. The disclosure is another vital aspect. In terms of European patents, the disclosure requirements are according to article 83 EPC that

"The European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art."[65]

Disclosure is thus a very central aspect of the patent application as the dissemination of knowledge therein is the patentee's part of the bargain, by allowing the knowledge to become public the exclusive right is granted by the state. The COP have outlined the disclosure requirement within the EPO as thus: "*Rule 27.1(b) of the European Patent Convention, for instance, requires that the content of the description of the patent should indicate the background art which, as far as known to the applicant, can be regarded as useful for understanding the invention, for drawing up the European search report and for the examination, and, preferably, cite the documents reflecting such art"*[66]

Once a patent application is filed with the European Patent Office (EPO) an examination of the claims of the patent is carried out and examined against the patentability criteria.[67] This involves the creation of a European search report.[68] This search is primarily carried out by use of patent documents and

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[61] http://annual-report.european-patent-office.org/facts_figures/_pdf/facts_figures_05.pdf, 03/01/07
[62] http://www.european-patent-office.org/epo/members.htm, 03/01/07
[63] http://patlaw-reform.european-patent-office.org/epc2000/status/index.en.php, 03/01/07
[64] Paterson, Gerald. *The European Patent System – The Law and Practice of the European Patent Convention*, (2001) Sweet & Maxwell, London. p. ix
[65] European Patent Convention, Article 83
[66] THE CONVENTION ON BIOLOGICAL DIVERSITY AND THE AGREEMENT ON TRADE-RELATED INTELLECTUAL PROPERTY RIGHTS (TRIPS): RELATIONSHIPS AND SYNERGIES, UNEP/CBD/COP/3/23, p. 20
[67] Guidelines for Examination in the EPO, June 2005 edition, p. III-1
[68] European Patent Convention, Article 92

"non-patent literature", namely periodicals and other technical publications.[69]

3.3.1 Exceptions to Patentability

The exceptions to patentability as defined by article 53 EPC are:

"European patents shall not be granted in respect of:

(a) 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;

(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof."[70]

Of these exceptions ordre public is the most interesting in the context of this thesis, it can rougly be translated as matters relating to public order. Accordning to the Guidelines for Examination in the European Patent Office it is to be understood as:

"Any invention the publication or exploitation of which would be contrary to "ordre public" or morality is specifically excluded from patentability. The purpose of this is to exclude from protection inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour (see also II, 7.2). Obvious examples of subject-matter which should be excluded under this provision are letter-bombs and anti-personnel mines. In general, this provision is likely to be invoked only in rare and extreme cases. A fair test to apply is to consider whether it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable. If it is clear that this is the case, objection should be raised under Art. 53(a); otherwise not. If difficult legal questions arise in this context, then refer to VI, 7.8." [71]

The reference to VI, 7.8 indicates the possibility to enlarge the examining division by addition of a legally qualified examiner.[72]. The case law of the EPO has further defined the concept of ordre public within the EPC, in T 356/93 the board reached this conclusion:

"The board defined the concept of "ordre public" as covering the protection of public security and the physical integrity of individuals as part of society. It also encompassed the protection of the environment. Accordingly,

[69] Guidelines for Examination in the EPO, June 2005 edition, p. IX-1
[70] European Patent Convention, Article 53
[71] http://www.european-patent-office.org/legal/gui_lines/e/c_iv_3_1.htm, 03/01/07
[72] http://www.european-patent-office.org/legal/gui_lines/e/c_vi_7_8.htm, 03/01/07

inventions the exploitation of which was likely to seriously prejudice the environment were to be excluded from patentability as being contrary to "ordre public". The concept of morality was related to the belief that some behaviour was right and acceptable whereas other behaviour was wrong, this belief being founded on the totality of the accepted norms which were deeply rooted in a particular culture. For the purposes of the EPC, the culture in question was the culture inherent in European society and civilisation. Accordingly, inventions the exploitation of which was not in conformity with the conventionally accepted standards of conduct pertaining to this culture were to be excluded from Exceptions to patentability as being contrary to morality."[73]

3.3.2 Patentability Criteria

For a patent to be granted, three criteria must be met; novelty, inventive step and industrial application. These criteria are more or less universally accepted and can also be found in art. 27.1 of TRIPS. The third criteria, industrial application is not of great relevance to TK issues and is quite self-explanatory, it simply requires that the invention can be used in any kind of industry including agriculture as is presented in Article 56 EPC.

3.3.2.1 Novelty

Article 54 of the European Patent Convention (EPC) defines novelty as:

"(1) An invention shall be considered to be new if it does not form part of the state of the art.

(2) 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."[74]

Thus anything, which is already known and part of the public domain cannot be patented, at least in theory.[75] The reality is however somewhat different as all available knowledge in the world isn't indexed and easily searchable.

[73] T 0356/93 as cited in *Case Law of the Boards of Appeal of the European Patent Office* Fourth Edition, December 2001. p.33, available at: http://www.european-patent-office.org/legal/case_law/pdf/clr_all_en.pdf, 04/01/07

[74] European Patent Convention, Article 54

[75] The patent law of the U.S. by comparison do not recognize oral description that is made outside of its borders for more on this see for example: Bagley, Margo A., *Patently Unconstitutional: The Geographical Limitation on Prior Art in a Small World*, (2003) 87 Minnesota Law Review, p. 679

The EPO however have through their case law displayed at least a generous definition of what is considered publicly available:

"In the opinion of the board the information is publicly available where it was made available to a limited circle of people"[76]

3.3.2.2 Inventive step

The EPC definition of inventive step (or non-obviousness as it is also known) can be found in article 56:

"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…"[77]

A person skilled in the art is according to the EPO guidelines an:

"ordinary practitioner aware of what was common general knowledge in the art at the relevant date. He should also be presumed to have had access to everything in the "state of the art", in particular the documents cited in the search report, and to have had at his disposal the normal means and capacity for routine work and experimentation."[78]

Thus if an invention is judged to be novel, the state of the art as defined in Article 54(2) EPC is judged against the claimed invention and whether or not it "provides a solution to an objective technical problem in a non-obvious way". The most common approach to be used is "problem-and-solution" approach in assessing inventive step, its basis can be found in 27(1) (d) EPC and in effect it means that the assessment is made on the basis of the patent being a step from the technical problem to the solution.[79]

The inventive step criterion is crucial in judging patentability. Especially in terms of patents which incorporate TK as they risk being granted when there is no real inventive step save the combination of Northern and Southern common knowledge.

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[76] T 0877/90 as cited in *Case Law of the Boards of Appeal of the European Patent Office* Fourth Edition, December 2001. p.46, available at: http://www.european-patent-office.org/legal/case_law/pdf/clr_all_en.pdf, 04/01/07

[77] European Patent Convention, Article 56

[78] Guidelines for Examination in the EPO, June 2005 edition, p. IV-22

[79] Paterson, Gerald. *The European Patent System – The Law and Practice of the European Patent Convention*, (2001) Sweet & Maxwell, London. p. 536-538

4 Three case studies of TK/IP conflicts

Many tall tales are told about the horrors of biopiracy, and separating fact from fiction can sometimes be hard for the casual observer. Both in terms of its existence, relative prevalence and supposed sinister intentions. In an attempt to discern the legal reality of what has been labelled as biopiracy, three well-publicised cases will be studied. They have been chosen because they are both representative in regards to being some of the most well documented as well as illustrating different aspects of the problems that can arise through the interaction of the patent system and TK. The Turmeric case was the first high profile case where a patent was rejected on the grounds of TK as prior art, the Neem case was the first major case that was decided within the EPO system and therefore extra focus will be given to that case. Finally, the Ayahuasca case is something of an odd bird as it covers plant patents, which are beyond the focus of this thesis. It does however breach the interesting subject of the moral rights of indigenous peoples.

4.1 Turmeric

Turmeric (Curcuma longa) is a perennial plant, which is native to the tropical regions of Southern Asia. It is a plant that is frequently used in regional cooking as well as having a central place in Ayurvedic and Chinese medicine to treat various ailments. Its use within the medicinal field has been found to help against among other things inflammations, digestive disorders, liver diseases and cancer. [80]

4.1.1 The Patent

In 1995 two Indian scientists working in the U.S. were granted a patent for a method of: "*promoting healing of a wound by administering Turmeric to a patient afflicted with the wound.*" [81] The patent was assigned to the University of Mississippi Medical Center.

[80] http://www.umm.edu/altmed/ConsHerbs/Turmericch.html, 04/01/07
[81] U.S. Patent 5,401,504

4.1.2 The Opposition

The Council of Scientific and Industrial Research (CSIR) of India challenged the patent in 1996.[82] CSIR claimed that the patent lacked novelty as the use of Turmeric as a method for healing wounds was age old in India and therefore a part of the prior art. CSIR presented 32 references, some of them over a hundred years old, to support that the claims of the patent were well known and part of the prior art. In 1997, the USPTO rejected all six claims of the patent as anticipated by the submissions of CSIR. The patent was thus declared invalid.[83]

The University of Mississippi Medical Center decided after this initial blow to abandon the patent and the patent was re-assigned to the inventors. The inventors chose to pursue the case further on the grounds that *"the powder and paste had different physical properties, i.e. bio-availability and absorbability, and therefore, one of ordinary skill in the art would not expect, with any reasonable degree of certainty, that a powdered material would be useful in the same application as a paste of the same material. The inventors, further, mentioned that oral administration was available only with honey and honey itself was considered to have wound healing properties."* [84]

The USPTO however rejected this objection and stated that both paste and powder were equivalent in relation the references submitted by CSIR. In 1997 the claims were rejected a second time, and in 1998 the re-examination certificate was issued which signified the end of the case.[85]

4.1.3 Summary

The Turmeric case is widely hailed as the first patent re-examination case where the rejection was based on the presentation of TK. It is thus considered a landmark ruling. What the Turmeric case clearly shows is that even though something is not actually new it can still slip through the cracks within the patent system. Ensuring that patents such as the Turmeric patent which lacked novelty are not granted is therefore of the utmost importance.

The cost of the case is another interesting issue; according to CSIR, the entire process cost them 500,000 rupees[86], nearly 14,000 dollars using the average exchange rate during 1997.[87] Not an awful lot in the light of what

[82] USPTO Reexam. No. 90/004,433, Oct. 28, 1996
[83] Mashelkar, R. A., *Intellectual property rights and the Third World*, 81 Current Science (2001), p. 960, available at: http://www.ias.ac.in/currsci/oct252001/955.pdf, 04/01/07
[84] Ibid.
[85] Ibid.
[86] Ibid. p. 959
[87] Calculated using: http://www.oanda.com/convert/fxaverage

patent cases can cost but still sufficiently expensive to exclude many poor indigenous communities from initiating an opposition procedure.

4.2 Neem

The Neem tree (Azadirachta Indica) is a large tropical evergreen that can grow up to 30 meters tall and 2.5 meters in girth. The tree carries a yellow or greenish yellow fruit, which holds a seed. The exact origin of the tree is unknown, it is found in many different countries but it is in India that the tree is most widely spread; the subcontinent is estimated to contain approximately 18 million Neem trees.

The tree has been shown to be useful in many different areas including contraception, dental hygiene and pesticides, as well as being part of many traditional Indian medicines and cures. The widespread growth of the Neem tree and its many practical uses has made the Neem tree very dear to the Indian people to whom it represents an integral part of their traditional and even religious heritage.[88]

Indian scientists have been researching the Neem tree as a natural pesticide since the 1920's but Western awareness of its qualities wasn't raised until 1959 when German entomologist Heinrich Schmutterer witnessed a locust plague in the Sudan and noticed that the Neem trees were the only ones that had withstood the onslaught. He immediately started studying the Neem tree and his work in turn generated a great deal of western scientific interest in its pesticidal qualities.[89]

That the Neem tree could withstand locust infestations had been common knowledge among Indian farmers for centuries. Both the seeds and to a lesser extent the leaves contain the active substance azadirachtin, which is a powerful insecticide that is not harmful to human beings.[90] Even before the discovery of the active substance in the later half of the 20th century, Neem seeds had been used by Indian farmers as a natural pesticide. The most common practice was to break up the seeds, soak them in water or alcohol, and then apply the resulting emulsion on their crops. The efficiency of this practice was however limited by the rapid degradation of the chemical solution which usually only lasted a couple of days. [91]

[88] *Neem: A Tree for Solving Global Problems*, Office of International Affairs (1992), p.1-5, 23-25, available at: http://darwin.nap.edu/books/0309046866/html, 05/01/07
[89] Ibid. p. 3
[90] Ibid.
[91] Marden, Emily, The Neem Tree Patent: International Conflict over the Commodification of Life, 22 Boston College International and Comparative Law Review (1999) p. 283.

4.2.1 The Patent

The first U.S. patent on a storage stable composition for Neem seed extract was issued in 1985 to inventor Robert O. Larsson.[92] The patent was improved upon by The U.S. company W.R. Grace who built upon this knowledge and developed a storage stable azadirachtin formulation which increased the shelf-life of the pesticide to up to two years. For this they were granted two co-dependent US patents in 1991 and 1992 respectively.[93]

W.R. Grace in partnership with The United States of America as represented by The Secretary of Agriculture jointly filed a Patent Application for the formulation with the EPO, who after a long drawn out examination process granted the applicants the patent in 1994[94]. The main claim of the patent had however been restricted by the EPO in relation to the patent granted in the U.S.[95]

4.2.2 The Opposition

The patents granted to W.R. Grace in Europe and the U.S. stirred up a lot of feelings in India and amongst many CSOs who felt that W.R. Grace had claimed for their own, knowledge, which belonged to the people of India. The storage stable formulation was regarded as at best obvious and thus lacking any inventive step. Another great fear was that the traditional use in India would eventually be seen as patent infringement if they were to gain a patent in the country as well as fears over W.R. Grace driving up the price of Neem seed.[96]

The US based Foundation on Economic Trends organised and filed a petition for re-examination on the grounds that the invention lacked non-obviousness in the light of prior art which was represented by the prior use in India.[97] The petition was turned down due to the geographical limitation in U.S. patent legislation concerning prior use.

In 1995 European parliament member and representative of the Greens in the European Parliament, Magda Aelvoet, filed an opposition with the EPO with regard to the patent in cooperation with two CSOs. The opponents filed for revocation of the patent in its entirety on the grounds that the patent lacked novelty in accordance with Article 54(1) and (2) EPC and lack of inventive step pursuant to Article 56 EPC. They also claimed that the patent

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[92] United States Patent 4,556,562
[93] United States Patent no. *5,001,146 and 5,124,349*
[94] EPO Patent no. 436257
[95] Bullard, Linda, *Freeing the Free Tree – A Briefing Paper on the paper on the first legal defeat of a biopiracy patent*, March 2005, available at: http://www.patentinglives.org/NeemBriefingfinalaugust.doc, 05/01/07
[96] Kadidal, Shayana, *Subject-matter imperialism? Biodiversity, foreign prior art and the Neem patent controversy,* 37 *IDEA: The Journal of Law and Technology* (1996-97) p. 371
[97] USPTO Reexam. No. 90/004,050, Dec. 8, 1995

was contrary to morality (Article 53(a) EPC) and pursuant to Article 100 (b) EPC that there was insufficiency of disclosure.[98]

The opposition division found the requirements for sufficiency of disclosure to have been met and that Article 53(a) EPC was not applicable to the present case. They found inter alia that the question of TK was related to novelty and not morality *"since the patent did not give its proprietor any right to prohibit acts in India"*.[99]

When it came to the question of novelty however, the opposition division ruled in favour of the opponents.[100] The opposition division found that the "when" and "where" of alleged prior use as having taken place in 1985/1986 in the Pune and Sangli Districts of Maharashtra, Western India. The opposition division based this on the affidavit and testimony of Mr A.D. Phadke.[101] Mr Phadke who was a witness on behalf of the opponents, is an Indian agronomist who had without claiming patent protection developed a commercial Neem product in India and who had during the course of this work conducted extensive field trials in collaboration with Indian farmers.[102]

During the oral proceedings, the patentee filed an auxiliary request, which amended the Neem formulation of the patent. The Opposition division dismissed this auxiliary request nonetheless, because it lacked an inventive step in comparison to the prior art that was represented by the Indian TK. [103] Consequently the EPO fully revoked the patent.

The patentees appealed against this decision and the Boards of Appeal of the European Patent Office delivered its final decision on March 8th 2005. Ownership of the patent had during this time been transferred from W.R. Grace to another US company, Thermo Trilogy Corporation. The US government remained co-proprietor of the patent throughout however.[104] The grounds for the appeal rested mainly on the assertion that Mr Phadke's affidavit and testimony were insufficient proof of prior use as their credibility could be put into doubt as they relied on precise testimonies of what had taken place between 10 and 14 years ago. Instead of deciding this question however, and in consequence the case on the grounds of prior use, which had been the basis for the decision by the Opposition division, the

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[98] Boards of Appeal of the European Patent Office, Case Number: T 0416/01, p. 1-2
[99] Ibid. s.2
[100] *"Neem tree oil" case: European patent No. 0436 257 revoked*, available at: http://www.european-patent-office.org/news/pressrel/2000_05_11_e.htm, 05/01/07
[101] Boards of Appeal of the European Patent Office, Case Number: T 0416/01, p. 3
[102] Bullard, Linda, *Freeing the Free Tree – A Briefing Paper on the paper on the first legal defeat of a biopiracy patent*, March 2005, available at: http://www.patentinglives.org/NeemBriefingfinalaugust.doc, 05/01/07
[103] Boards of Appeal of the European Patent Office, Case Number: T 0416/01, p. 4
[104] Bullard, Linda, *Freeing the Free Tree – A Briefing Paper on the paper on the first legal defeat of a biopiracy patent*, March 2005, available at: http://www.patentinglives.org/NeemBriefingfinalaugust.doc, 05/01/07

board chose not to tackle this contended issue and relied instead on a far less controversial piece of evidence:

"The appellant's main argument was that the recollection of dates and numerals was uncertain for most people and hence some supporting documents, such as laboratory books or notebooks, were required. However, there is no dispute between the parties concerning the existence of the prior art document (8) as a part of the state of the art within the meaning of Article 54(2) EPC. In the board's view, document (8) is highly relevant for the ruling of the present case. Thus, it can be left open whether or not prior use is proven as the case can be decided on the basis on document (8) alone."[105]

Document (8), which the board refers to, is a scientific article published by H.B. Singh and U.P. Singh in Australian Plant Pathology in 1981. The title of the article is "Effect of Volatiles of Some Plant Extracts and their Oils on Conidia of Erysiphe polygoni DC". One of the plant extracts discussed in the article was Neem oil, it also discusses the antifungal effect of the Neem extract, as well as different concentrations of Neem oil used in the study.[106]

The board found that the document disclosed the use of an extract of Neem oil as fungicidal on plants, but it did not according to their view: *"disclose which is the solvent employed. Moreover, document does not disclose the presence of an emulsifying surfactant in the formulations employed"*. The board therefore found that the claims of the patent were to be regarded as novel over the contents of the article.[107]

The next step for the board was to review the inventive step. After examining the process outlined in the article and in the patent claim the board reached the conclusion that the patent should be revoked for lack of inventive step. The board of appeal also failed the auxiliary request because it did not meet the requirements of article 123 (2) EPC as the amendments extended beyond the content of the original application. Thus the patent was finally revoked.[108]

4.2.3 Summary

In a press release on March 8th 2005 the Greens in the European Parliament cabled out to the world that the decision to uphold the revocation of a patent on the Indian Neem tree was *"a killer blow to biopiracy in Europe and around the world"*.[109] For the Greens this represented an end to a ten year

[105] Boards of Appeal of the European Patent Office, Case Number: T 0416/01, p. 15
[106] Ibid. p. 1 and 16-17
[107] Ibid. p. 16
[108] Ibid. p. 20-22
[109] "EPO upholds decision to withdraw 'free tree' patent: Greens celebrate Neem biopiracy victory", available at: http://www.greens-

struggle, which they had fought alongside a number of CSOs to have the patent revoked. The rhetoric used by the Greens in the press release clearly displays how the Neem case has become the anti-biopiracy movement's symbolic champion.

The aim of the opponents was to revoke the patent, and more specifically on the grounds of prior use and TK so as to gain an important case law precedent in their battle against biopiracy.[110] The decision of the opposition division followed along the lines of what they were after. The claim was rejected on the grounds of lacking novelty and the evidence upon which this decision was taken was the testimony of a witness who had worked with the process himself and who could verify its use among Indian farmers. The decision of the Board of appeal to leave open whether prior art had been proven or not changed the whole focus of the case. In choosing the article as the closest prior art they relied on a scientific study published in a Western journal. Thereby the question of novelty and inventive step wasn't truly judged on the grounds of TK. The decision was taken on the basis of comparing two scientific documents, the lack of inventive step wasn't judged against Indian traditional practices but the scientific studies of two scholars. The board shied away from dealing with the issue of prior use and decided the case on materials with which they were more comfortable. Another interesting aspect of the change is that the patentees who had declined an oral hearing provided no defence against the article on the grounds of inventive step and only a fleeting remark regarding the article in relation to novelty. Even if the significance of the inadequate defence presented by the patentees is hard to discern, it cannot be ignored as a potential factor in the decision.[111]

4.3 Ayahuasca

Ayahuasca (Banisteriopsis caapi) is a vine that is indigenous to the northwestern regions of the Amazon rainforest in South America.[112] The bark of Ayahuasca is a natural hallucinogen and is used in shamanistic rituals by indigenous tribes in both Peru and Ecuador. The Shamans process the vine into a beverage in order to see spirit visions, a sacred and integral part of their animistic religion. It is also used in healing sessions wherein the "mother spirit of the vine" sometimes is believed to enter into the visions of the ill and instruct them through special Ayahuasca songs. [113]

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efa.org/cms/default/dok/101/101492.epo_upholds_decision_to_withdraw_free_tr@en.htm, 05/01/07

[110] Bullard, Linda, *Freeing the Free Tree – A Briefing Paper on the paper on the first legal defeat of a biopiracy patent*, March 2005, available at: http://www.patentinglives.org/NeemBriefingfinalaugust.doc, 05/01/07

[111] Boards of Appeal of the European Patent Office, Case Number: T 0416/01, p. 21

[112] Bennett, Bradley C. *Hallucinogenic plants of the Shuar and related indigenous groups in Amazonian Ecuador and Peru,* 44(4) Brittonia (1992) p. 483

[113] Dorkin De Rios, Marlene. *A Note on the Use of Ayahuasca Among Urban Mestizo Populations in the Peruvian Amazon,* 72 American Anthropologist (1970) p. 1419-1421

4.3.1 The Patent

In 1984, an American citizen, Loren Miller, filed a request with the USPTO for a plant patent on a variation of Ayahuasca that she had named "Da Vine". U.S. Plant patent 5,751 was granted in 1986. [114]

4.3.2 The Opposition

The indigenous communities of the region learnt about the patent and were upset by the fact that a private citizen had claimed for their own, a plant which was an integral part of many sacred ceremonies. The Center for International Environmental Law (CIEL), a CSO that works toward using international institutions and laws as a means for protecting the environment, filed a re-examination request with the USPTO on behalf of the Coordinating Body of Indigenous Organizations of the Amazon Basin and the Coalition for Amazonian Peoples and Their Environment.[115] The re-examination request was based upon the fact that "Da Vine" was not new and distinct but had been documented even within the United States. Secondly CIEL claimed that "Prior Art Reveals that Issuance of the Da Vine Patent Does not Meet the Public Policy and Morality Aspects of the Patent Act's Utility Requirement" as found in 15 U.S.C. § 101 that permits the USPTO to deny patentability to inventions deemed "injurious to the well being, good policy, or good morals of society."[116]

The patent was revoked in 1999 due to it being "known and available" prior to filing.[117] The issue of the moral rights of the indigenous tribes was not considered. In 2001 however, the USPTO reversed its rejection and allowed the patent to stand for the remainder of its term which at this time was two years.[118]

4.3.3 Summary

Even if the material content of the Ayahuasca case is outside the scope of this thesis, its underlying theme is highly relevant. Namely the respect for the religious beliefs of indigenous populations. Even though novelty and inventive step, if they work effectively, provide protection there are still situations where another defensive line may be justified. Protecting what is a central part of indigenous peoples' religious identity is essential if one is to fully respect TK. The animistic beliefs of certain groups may be hard to grasp from a western perspective but in reality it can be likened to any religious symbol of importance in for example Islam or Christianity. A

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[114] U.S. Plant patent 5,751
[115] http://www.ciel.org/reciel.html, 05/01/07
[116] http://www.ciel.org/Publications/ReexaminationofUSPlantPatent5751.pdf, 05/01/07
[117] http://www.ciel.org/Biodiversity/AyahuascaRejectionPR.html, 05/01/07
[118] http://www.ciel.org/Publications/PTODecisionAnalysis.pdf, 05/01/07

safety guard that ensures respect for such matters is therefore an issue that should be considered in the light of showing respect for the belief systems of indigenous populations.

4.4 Summary of Problems

The cases display actual problems in the interaction between TK and the patent system. Many accusations about present problems or those arising in the future are made, but these are steadfast examples of TK having collided badly with the patent system. The issues that are shown are foremost of course the issue of novelty. The Neem case also displays the problems of inventive step wherein Southern and Northern common knowledge mixed together initially can be enough for a patent grant. The Neem case also outlines the problems within the EPO in handling a case that deals with TK. Thirdly the issue of the moral rights of indigenous communities can be seen. Moral rights could be seen to include PIC and ABS, i.e. ownership, but in this case the moral rights are refined to only the infringement of their religious identity.

Finally, an overhanging issue that is shown in all cases is the problem for communities both legally and economically in challenging patents which they feel infringe upon their TK.

5 Possible Defensive Measures

Patent laws are not internationally homogenous. There is no completely harmonized substantive international regulation although progress is being made and has been made through for example TRIPS and the Patent Law Treaty[119]. Even though no detailed multinational substantive agreements exist there are several conventions and treaties which combined with the nature of patents requires there to be international consensus both in terms of ensuring largely harmonious legislation as well as the binding obligations that some of the international agreements impose. The problems exposed by the case studies in the previous chapter require resolutions which need to be in harmony and potentially enforced through the skeletal substantive and procedural framework that exists. Along with major treaties the CBD is found, a convention relating specifically to issues related to biodiversity such as genetic resources and TK. Even though this thesis is mainly focused upon the EPC, the other international legal tools are essential in crafting a long-lasting solution.

As shown by the previous chapter one can subdivide the problems between the patent system and TK into three separate issues, the problem with prior art searches and procedural handling, the problem of disclosure and the problem with moral rights.

5.1 Traditional Knowledge-Databases and Improved Prior Art Searches

One of the most basic and straightforward ways to protect TK from being patented is organising TK in such a way that it more easily can be found during prior art searches. It is also the defensive measure where the most progress already has been made, greatly due to the work of the IGC.[120]

On the international level the International Patent Classification (IPC) has been modified. The IPC is a WIPO administered agreement that is used in more than 100 countries for classifying patent documents and is a near essential tool for searching patent-related databases.[121] In 2003 the IPC was updated to include a new category which covers TK, and thus will hopefully be an aid in discovering possible prior art in patent applications which relate to TK.[122]

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[119] for more on the Patent Law Treaty see:
http://www.wipo.int/treaties/en/ip/plt/summary_plt.html, 05/01/07

[120] *DEFENSIVE PROTECTION MEASURES RELATING TO INTELLECTUAL PROPERTY, GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE: AN UPDATE*, WIPO/GRTKF/IC/6/8

[121] http://www.wipo.int/classifications/ipc/en/faq/ipcfaq-ver01.htm#G9, 03/01/07

[122] http://listbox.wipo.int/wilma/pressinfo-en/2003/msg00034.html, 03/01/07

Another international instrument and WIPO administered treaty which has been amended is the The Patent Co-operation Treaty (PCT). It is open to signatories of the Paris convention and has 133 contracting parties.[123] The PCT enables filing for patent protection in a number of countries at the same time. The filing is subjected to an international search as regards prior art and a non-binding written opinion that judges the patentability.[124] The minimum documentation that is required that is taken into account during a PCT search has been expanded to include eleven new TK-related databases.[125]

Several national projects aimed at improving TK accessibility have also been instigated. In India the Traditional Knowledge Digital Library project (TKDL) was created through a collaboration between several Indian Government agencies and aims to document disclosed traditional medicinal knowledge in the public domain, which relates to Ayurvedic and other traditional Indian medicine. The TKDL is digitalised and available in English, German, French, Japanese and Spanish.[126] Access to the TKDL is however only granted to IPR-offices on the grounds that they sign an agreement of non-disclosure to any third party.[127] This measure accentuates the major problem with TK-databases from the compilers point of view, namely that open access to the data would aid others in using the knowledge instead of preventing use. A danger therefore exists in collecting data in this way, especially if the TK is not openly available in the public domain. The EPO have signed a non-disclosure agreement with India and the TKDL is therefore a part of available databases for prior art searches within the EPO.[128]

A similar database to the TKDL but covering traditional Chinese medicine has also been developed.[129] Other international databases that cover TK are NAPRALERT[130], which is kept up by the University of Illinois, and the World Bank's Indigenous Knowledge Database.[131] The EPO are themselves also compiling a TK-database.[132]

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[123] http://www.wipo.int/treaties/en/ShowResults.jsp?country_id=ALL&start_year=ANY&end_year=ANY&search_what=C&treaty_id=6, 03/01/07
[124] http://www.wipo.int/treaties/en/registration/pct/summary_pct.html, 03/01/07
[125] WIPO Intellectual Property and Traditional Knowledge Booklet no 2, p. 29
[126] http://203.200.90.6/tkdl/langdefault/common/Abouttkdl.asp?GL=, 03/01/07
[127] http://www.wipo.int/edocs/mdocs/classifications/en/ipc_ce_35/ipc_ce_35_9.pdf, p. 7 03/01/07
[128] http://economictimes.indiatimes.com/articleshow/1111159.cms, 03/01/07
[129] http://211.157.104.69/englishversion/help/help.html, 03/01/07
[130] http://www.napralert.org/, 03/01/07
[131] http://www4.worldbank.org/afr/ikdb/search.cfm, 03/01/07
[132] http://www.european-patent-office.org/news/pressrel/2005_06_15_e.htm, 03/01/07

5.2 Disclosure

One of the main suggestions that it is being put forward both through the CBD and the IGC, is that there should exist a mandatory requirement to disclose the origin of any genetic material or TK used in a patent. Mandatory disclosure can be seen as both a defensive and positive measure as it can be a way to prevent a flawed patent based on TK from being granted as well as ensuring that the patentees have sought and been granted PIC or have committed to ABS.

The most significant development regarding the disclosure requirement can be found in the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization. It was adopted by the CBD's Conference of the Parties to the Convention (COP) in 2002. It represents the first attempt to truly operationalize the provisions of the CBD and in part deals with the issue of mandatory disclosure[133]:

"C. Responsibilities
...
16. Recognizing that Parties and stakeholders may be both users and providers, the following balanced list of roles and responsibilities provides key elements to be acted upon:
...
d. Contracting Parties with users of genetic resources under their jurisdiction should take appropriate legal, administrative, or policy measures, as appropriate, to support compliance with prior informed consent of the Contracting Party providing such resources and mutually agreed terms on which access was granted. These countries could consider, inter alia, the following measures:
...
ii. Measures to encourage the disclosure of the country of origin of the genetic resources and of the origin of traditional knowledge, innovations and practices of indigenous and local communities in applications for intellectual property rights"[134]

Although the Bonn Guidelines are voluntary, as is basically all of the CBD, efforts have been made to implement them and the European Commission has discussed an implementation within the EU.[135] The EU has also within the IGC put forth a proposal for a disclosure system.[136] This proposal

[133] http://www.biodiv.org/programmes/socio-eco/benefit/bonn.asp, 03/01/07
[134] http://www.biodiv.org/decisions/default.aspx?m=cop-06&d=24, 03/01/07
[135] *Communication from the Commission to the European Parliament and the Council - The implementation by the EC of the "Bonn Guidelines" on access to genetic resources and benefit-sharing under the Convention on Biological Diversity*, COM/2003/821/F
[136] *DISCLOSURE OF ORIGIN OR SOURCE OF GENETIC RESOURCES AND ASSOCIATED TRADITIONAL KNOWLEDGE IN PATENT APPLICATIONS - Document submitted by the European Community and Its Member States*, WIPO/GRTKF/IC/8/11

however marks out TK as problematic due to its unclear scope and states that *"a further in-depth discussion of the concept of TK is necessary"* in order to ensure legal certainty.[137]

So far, however, no substantive international agreement concerning mandatory disclosure has been made even if the issue is at the forefront of discussions. Although it may seem a quite innocuous requirement, which would provide tremendous aid in the struggle to prevent patenting of TK and add more transparency to the patent system it is by no means uncontroversial.

The supporters of a mandatory disclosure can be found among primarily the developing nations and CSO's. The following submission from India to the WTO Committee on Trade and the environment in 1997 presents the basic initial standpoint:

"The first important contradiction between the TRIPS Agreement and the CBD is the lack of any conditions on patent application (in Article 29 of the TRIPS Agreement) to mention the origin of biological/genetic resources and indigenous/traditional knowledge used in the biotechnological invention. The present mandatory conditions are confined to disclosure of the invention in a manner sufficiently clear and complete for inventions to be carried out by a person skilled in the art. In addition, Members may require the applicant to indicate the best mode of carrying out the inventions known to the inventor at the filing date. These conditions were developed in the patent laws of different countries basically with respect to mechanical and chemical inventions. Biotechnological inventions need to be governed by a set of additional specification requirements. It could be considered whether the objectives of the CBD could be incorporated through inclusion in Article 29 of provisions requiring a clear mention of the biological source material by indigenous communities in the country of origin. This part of the patent application should be open to full public scrutiny immediately after filing of the application. Such a reconciliation would permit countries with possible opposition claims to examine the application and stake their claims well in time."[138]

Dr N.S. Gopalakrishnan at the Centre for Intellectual Property at Cochin University, India, supports the use of disclosure requirements. He represents that the lack of documentation for TK, or more often than that the documentation is sometimes only conserved in an ancient language makes searching for TK difficult even when documentation is available. A disclosure requirement would in his view make the process a lot easier than it currently is. He also balks at the idea that is put forth by some that this would put yet another burden on the patentee and that it doesn't present any

[137] Ibid. Annex p. 3
[138] *ITEM 8: THE RELATIONSHIP BETWEEN THE TRIPS AGREEMENT AND THE CONVENTION ON BIODIVERSITY - Communication from India*, WT/CTE/W/65

real new burden upon the inventor who probably already has this information anyway.[139]

Gopalakrishnan continues to cite the fact that no disclosure requirements existed during the earlier period of the patent system, and that the need for disclosure evolved naturally as a means to maintain a credible system to keep pace with industrial development. From that context the changes that now are occurring are a natural continuation of that development through presenting TK and genetic disclosure requirements, or else the credibility of the system again will be threatened once more.[140]

Another point raised by Gopalakrishnan is that the knowledge developed by the indigenous societies has aided scientists and they should therefore be acknowledged and accordingly rewarded.[141]

The main opponents of a disclosure requirement are, not surprisingly, the Biotech Companies. BIO, the Biotechnology Industry Organization, a US lobby group, have stated several problems with the suggested requirement from their subjective point of view. The most central claims are that firstly the proposal ignores the practical realities of genetic resources. Namely, that they are often not exclusively found within just one territory but have multiple origins.[142] Something that often also can be said to be true for TK as well. Secondly patent disclosure requirements will according to BIO frustrate the goal of the CBD to promote use of genetic resources that may create benefits that can be shared, as companies will be discouraged from bioprospecting by the risk of having a patent annulled and thus losing the considerable investment connected to it through a non-disclosure made unknowingly. The result will according to BIO be that there will be no benefits for the South to share in.[143] Although BIO are opposed to disclosure they express support for use of national PIC and ABS regimes instead.[144]

In addition, Patent authorities and those working there have also displayed their opposition toward the suggested requirements. The Swedish Patent and Registration office (PRV) have declared that they are principally opposed to patentees being required to submit information which isn't motivated from a patent law point of view. PRV put forth that there is an ongoing process in international patent law wherein formal requirements are being minimised so as to make patent applications easier. Secondly a decision to grant a patent does not imply a positive right to use the invention but simply a

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[139] Gopalakrishnan, N.S. *TRIPs and Protection of Traditional Knowledge of Genetic Resources: New Challenges to the Patent System* , European Intellectual Property Review Issue 1 (2005) p. 13
[140] Ibid. p. 14
[141] Ibid. s. 15
[142] BIO letter opposing amendments to the TRIPs agreement to the Honorable Robert Portman, U.S. Trade Representative (Dec. 6, 2005) available at: http://www.bio.org/ip/letters/20051206.pdf, p. 6, 04/01/07
[143] Ibid. p. 8-9
[144] Ibid. p. 12-13

negative right to prevent others from using the invention. The patentlegislation is neutral and should in the opinion of PRV remain thus in terms of the inventions and the possible resources that are needed in terms of industrially realising the patent. Their concluding view is that the patent system shouldn't be used as a system for controlling other legal structures. If sanctions must be instigated PRV feel it is more appropriate that they should lie outside of the patent system. For example through a civil suit wherein an injunction can be made which forces the patentee to settle PIC and ABS issues if they haven't followed the CBD guidelines or possibly a criminal sanction for purposely omitting or recklessly submitting false information in their patent application. A patent should however never be declared void due to insufficient disclosure in terms of origin.[145]

Dominic Keating, a USPTO patent attorney, raises the point that the fast changing world of biotechnology has already made the genetic resources of the South less important in R&D, as lead molecules are nowadays more and more frequently being produced in laboratories rather than as before by finding genetic samples. [146] A view that is also expressed by Biotech companies.[147]

Keating also predicts that new disclosure requirements simply would discourage companies from using the genetic resources of the South in their research as well as questioning whether the disclosure actually would aid tracking the use of genetic resources and the difficulties connected to invention.[148]

The EU have touched upon the issue of disclosure in the Biotech-directive. In the 27th point of the preamble the following statement is made:

"(27) Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents"[149]

It of course holds no substantive legal importance but can be seen as a policy indication, but another possible bar to already implementing

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[145] Yttrande AD 2004/3491-50, *Svensk ståndpunkt om ursprungsangivelser m.m. i samband med genomförandet av Bonn-riktlinjerna om tillträde till och rättvis fördelning av avkastningen från användningen av genetiska resurser,* available at: http://www.prv.se/om_prv/remissvar/bonn_prv_pa_ph_040830.doc, 04/01/07

[146] Keating, Dominic. *Access to Genetic Resources and Equitable Benefit Sharing Through a New Disclosure Requirement in the Patent System: An Issue in Search of a Forum.* 87 Journal of Patent & Trademark Office Society (2005) p. 544

[147] Nash, Robert J. *Editorial Comment: Who Benefits from biopiracy?*, 56 Phytochemistry (2001) p. 403-405

[148] Keating, Dominic. *Access to Genetic Resources and Equitable Benefit Sharing Through a New Disclosure Requirement in the Patent System: An Issue in Search of a Forum,* 87 Journal of Patent & Trademark Office Society (2005) p. 544

[149] DIRECTIVE 98/44/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 July 1998 on the legal protection of biotechnological inventions

disclosure requirements is the fact that opinions vary on whether or not it is in accordance with TRIPS to sanction disclosure.[150] WIPO have carried out an extensive Technical Study on disclosure requirements but chose to avoid interpreting the obligations of TRIPS in comparison to mandatory disclosure.[151]

The preamble of the Biotech-directive has however inspired some voluntary disclosure requirements. An example of this is the the Swedish Patentkungörelsen 5a§:

"If an invention concerns genetic material from the plant- or animal kingdom, or if such material is used in an invention, the patent application shall include a disclosure of the geographical origin, if this is known. If the origin is not known, this shall be stated.

Insufficient disclosure of the geographical origin or the applicant's knowledge of the origin does not affect the assessment of the application or the rights that follow a granted patent." [152]

As stated in the paragraph a patentee that does not disclose does not run the risk of actually being punished for omitting such information. The Swedish government decided to leave the disclosure requirement unsanctioned partly due to the fact that they believed it to be inconsistent with the TRIPS-agreement.[153]

If one finally looks to the disclosure currently being made the results are possibly somewhat surprising. A study carried out on behalf of the Secretariat for the Convention on Biological Diversity reviewed over five hundred patent applications from amongst others The US, The EPO, Germany and France, which made use of biological materials. The study found that:

"Of the applications involving plants, the country of origin was invariably mentioned unless the plant was widely distributed or well known (such as the lemon or rosemary" [154]

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[150] Sarnoff, Joshua. *Memorandum Re: Compatibility With Existing International Intellectual Property Agreements of Requirements for Patent Applicants to Disclose Origins of Genetic Resources and Traditional Knowledge and Evidence of Legal Access and Benefit Sharing*, p. 35-37, available at: http://www.piipa.org/DOO_memo.doc, 05/01/07

[151] WIPO Technical Study on Disclosure Requirements in Patent Systems Related to Genetic Resources and Traditional Knowledge, p.16, available at: http://www.wipo.int/tk/en/publications/technical_study.pdf, 04/01/07

[152] *Förordning 2004:162, Translation author's own.*

[153] Proposition 2003/04:55, p. 134

[154] *THE CONVENTION ON BIOLOGICAL DIVERSITY AND THE AGREEMENT ON TRADE-RELATED INTELLECTUAL PROPERTY RIGHTS (TRIPS): RELATIONSHIPS AND SYNERGIES*, UNEP/CBD/COP/3/23, p. 18-19

If one looks at the disclosure in the cases studied in this thesis a level to a greater or lesser extent can also be seen. Under the section on the background of the invention for the Ayahuasca, the origin is revealed as the *"Amazon rain-forest of South America"*[155], for Turmeric it is clearly stated that: *"Although it is primarily a dietary agent, Turmeric has long been used in India as a traditional medicine for the treatment of various sprains and inflammatory conditions (Rao T S et al., Indian J. Med. Res., 75:574-578, 1982)."* [156]

The Neem patent shows 3 different incarnations in term of disclosure. The initial U.S. patent states that *"One agent known to protect crops from pests is azadirachtin which is a natural product found in the seeds of the Neem tree (Azadirachta indica A. Juss.). The Neem tree is found in India, Pakistan, Bangladesh, Burma, Thailand, Malaysia and Africa, for example."*[157] The following two U.S. patents in turn state that the *"The biological activities of the Neem tree seeds have long been recognized."*[158] Finally the European patent discloses that: *"The Neem tree, a tropical evergreen, has been used for centuries as a source of pesticides to which insects have not developed a resistance."* [159] All four patents thus acknowledge the prior use of Neem as a pesticide and the EPO patent goes as far as clearly stating that it has been used *"for centuries"*. In terms of disclosure of geographical origin only the initial patent reveals where the Neem tree can be found, but as it correctly points out, the tree can be found in many different countries and not only in India.

Even though the disclosure shown obviously is less detailed than in the proposed mandatory system these cases show that information about origin or prior traditional use has *not* hindered the grant of these patents as well as showing in combination with the CBD study that disclosure, even without sanctions, is prevalent.

5.3 Moral Rights

As shown by the Ayahuasca case issues can sometimes arise which demand a different kind of protection than just ensuring that the standards for novelty and inventive step are upheld. Ensuring non-infringement of the religious integrity of TK-holders is another potential problem which calls for some form of solution within the system.

In the United Nations Universal Declaration of Human Rights Art. 27(2) it is declared that:

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[155] U.S. Plant Patent 5,751
[156] U.S. Patent 5,401,504
[157] U.S. Patent 4,556,562
[158] U.S. Patent 5,001,146 and 5,124,349
[159] EPO Patent no. 436257

" (2) Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author."[160]

Thus IPRs are declared to be a human right, the protection of scientific or artistic endevaours are recognised. Article 29 presents when rights can be limited:

"2) In the exercise of his rights and freedoms, everyone shall be subject only to such limitations as are determined by law solely for the purpose of securing due recognition and respect for the rights and freedoms of others and of meeting the just requirements of morality, public order and the general welfare in a democratic society."[161]

According to the Universal Declaration of Human Rights the right to scientific production can be limited if it infringes on the recognition and respect for the rights and freedoms of others. The Ayahuasca case displays a scenario where these opposing rights come into conflict and it warrants a discussion on whether a mechanism can be created to hinder the fact that patents are granted which somehow infringe on the moral rights of a community through patenting something which carries religious significance.

In the Ayahuasca case one of the reasons given in the opposition was 15 United States Code § 101 which states that the USPTO are permitted to deny patentability to inventions deemed *"injurious to the well being, good policy, or good morals of society."*[162] This claim was however ignored. A similar objection was raised by the opponents in the Neem case and also denied by the EPO Boards of Appeal.[163]

One system that has been suggested as a means of protecting moral rights is implementing a system similar to that found in the Berne convention on the moral rights of authors[164]. This system stems back to "droit moral" and the later works of Immanuel Kant, but was more fully developed by German legal theorists during the 19th century. Article 6bis was introduced into the Berne convention in 1948[165]:

"(1)Independently of the author's economic rights, and even after the transfer of the said rights, the author shall have the right to claim authorship of the work and to object to any distortion, mutilation or other

[160] Universal Declaration of Human Rights, Article 27(2)
[161] Universal Declaration of Human Rights, Article 29(2)
[162] 15 United States Code § 101
[163] Boards of Appeal of the European Patent Office, Case Number: T 0416/01, p. 2
[164] Downes, David R. *Intellectual Property as a Tool to Protect Knowledge*, 25 Columbia Journal of Environmental Law (2000), p. 276
[165] Strömholm, Bo., *Droit Moral from a Scandinavian Viewpoint* in Drahos, Peter (ed.) *Intellectual Property*, Darthmouth, Aldershot, 1999. p. 11-13

modification of, or other derogatory action in relation to, the said work, which would be prejudicial to his honor or reputation."[166]

An introduction of such a moral rights system is however currently hindered by the TRIPS Agreement. Art. 27(2) only grants the right to exclude from patentability for inventions which endanger ordre public or morality *within* the terrritory. The risk of danger must also be brought on by commercial exploitation and not the invention as such. Accordingly TRIPS would have to be amended for a moral rights system to be possible.[167]

[166] Article 6bis Berne Convention for the Protection of Literary and Artistic Works
[167] Gervais, Daniel. *The TRIPS Agreement: Drafting History and Analysis (2nd ed.),* 2003, Sweet & Maxwell, London. p. 2.261

6 Analysis

"*The fallacy of universality*"[168]

With the fallacy of universality former British High Court judge Sir Hugh Laddie points to the faulty assumption that IPRs will function equally well in all environments. Whether IPRs are of value to the developing nations is a question that is yet to be answered, so far progress is being made, albeit slowly. If one looks at the history of patents in the North one can see a similar journey to that which is currently being made in the South: the North has also historically had a tradition of communiarian knowledge, the important difference of course being that change matured over hundreds of years in the developed world whilst change in the developing world is being more or less enacted by the turn of a switch. This is not a natural progression and neither was in reality the progression in the North. A patent system is not a natural construct, it is a social and economic construction that creates an imaginary barrier that hinders free competition and use. It is a system which has theoretical justifications but which many feel sceptical about.

Whether or not the system works as it is intented is a question far beyond the scope of this thesis; one cannot prove or disprove it, but two points can be made, firstly that during the industrial age and onward there has always existed some form of protection, so how creativity would fare without protection in an extremely competitive environment is very unclear. Would investments of time and money be put into research to the same extent if competiting companies risked having identical copies produced by competititors only a short while after the initial release? Secondly as Domeij pointed out, the pharmaceutical industry and patents are linked in such a way that they probably couldn't exist if they couldn't guarantee that getting a successful drug onto the market would ensure them revenue during the period of protection. It can thus through common sense be assumed that for at least some areas of industry, which require high rates of investment, patents are an essential incentive. However, one cannot give a scientific response of yea or nay to the question of if patents are a good thing, simply due to the fact that no such one consistent answer is to be found. One can therefore only fall back upon one's own personal view on the subject, in this case I believe that it, despite its imperfections, is a good system, or at least the best currently available. This is then the starting point for this analysis, that the patent system is of value and worth protecting, for in answering questions relating to TK, and amending the patent system one is also faced with the question of what are the effects of the changes on the patent system as a whole.

[168] Laddie, Sir Hugh. As quoted by Gibson, Johanna. *Intellectual Property Systems, Traditional Knowledge and the Legal Authority of Community*, 7 European Intellectual Property Review (2004) p. 280

If one then starts to examine the first part of the purpose for this thesis, which is to establish if there is actual need for accommodating the current patent system to TK, one must, in the same way as the patent system above was assessed, assess the relative value of TK.

The common picture that is presented of TK and the patent system is one where they are irreconcilable opposites, and that the system requires dramatic changes, as well as a sui generis system of protection. I would argue that this is not the case. The relationship between the patent system and TK is in my view simply one of mistaken identity.

The advocates of the biopiracy-cause have clearly identified the problems of TK and the patent system as a problem that can be painted in black and white. There are good guys and bad guys, and the patent system is constructed in such a way that it is an oppressive tool for the bad guys. Many studies and articles are very uncritical in their approach to biopiracy; it is taken for granted as a fact without in effect being substantiated by convincing empirical evidence. As the situation stands any patent granted which contains material or knowledge which somehow originates or is connected to the South is likely to be labeled as biopiracy. Many legal scholars even seem unsure of how to use it, sometimes it is used in a context as if it represented fact only to later in the same paper be questioned as a concept. Many misunderstandings about IPRs are also commonly reproduced in materials relating to TK and biopiracy. One of the most common misapprehensions is that a patent constitutes a patent on the specific plant or resource which is used in the patent, in discourse one often comes across commentators talking about “a patent on Neem” and “a patent on Turmeric”. A confusion which possibly stems from the difference between regular patents and plant patents. Comments which create a false image of the patent somehow disallowing the indigenous communites from using the plants or the connected traditional processes and also ignoring the fact that patents represent a negative right.

The South and the CSOs have within international forums got caught up in a battle of principle where both the main cause and the possible results of a victory can be called into question. One is tempted to quote the old maxim that law is a far too important subject to be left to politicians to decide. For this is currently where the subject is mired, deep in the battleground of international politics where “simple” adjustments within the patent system are hardly battled over, and even settling on guiding principles within the IGC is showing to be a real struggle. All these factors make it important to reclaim the issue from the political arena and from all the other issues it has become inmeshed with to truly appreciate what it represents and redefine its identity.

TK is put forward as an integral part of indigenous communities where the knowledge plays a pivotal role in society and everyday life. As well as respecting that important role, the argument is also made that the contribution of TK-holders as innovators must be respected and protected.

The culture of TK-holders must of course be respected and the right to their knowledge likewise. A question is however raised in context to this which relates to the deontoligical natural rights theory, and that is: who owns the more important right, the holders of the TK or those who have used it to innovate further? Who is entitled to reap the benefits, and whose claim is the most just? A difficult conundrum which lacks an obvious answer. If one however looks at what the TK-holder has lost, it amounts to nothing. If one takes the Neem patent as an example, the people of India would not be hindered from using their traditional pesticide as the process of creating it was different from that of the patent. Neither would the knowledge which is an integral part of society be diminished by a patent with connections to that knowledge.

As for the question of whether TK holds moral ownership over the knowledge my answer must be no, an exception of course being questions relating to moral rights which will be discussed later. The patent system is a bargain-system wherein some knowledge is protected and some is not, one purpose being that the protected knowledge will one day be part of the unprotected public domain and cumulatively lead to new and more advanced innovations. The interest and purpose of the patent system is to generate innovation, and while respect must be granted to TK-holders, their achievements do not justify a further and retroactive fencing off of the public domain. Their knowledge is useful and important but TK risks being underutilised if fruitful knowledge isn't spread and shared, and furthermore refined and devoloped. TK can hold the key to developing many ESTs, allowing for this to take place is important and also an objective of CBD in as much as it strives to promote biological conservation.

One could of course rightly raise the point that it is unfair to the developing nations to allow their TK to be used freely by all who so wish. This can be solved in part through ABS, but the question of to what extent ABS should and can be demanded is a delicate and complicated issue. The freedom of knowledge could however be embraced as an opportunity for local innovation. An ideal situation would of course be if local scientists in the countries themselves could utilize and develop the TK. This would be an important step in bridging the view which now sees IPRs as something which is forced upon the South by the North, and not something which in fact can be used to their advantage by making use of the unique knowledge that is found in devloping nations. Technologically however these countries are at a great disadvantage as their technological development level is often far behind that of the North. Therefore technology transfer from North to South which is an aspect of TRIPS is an important factor in improving the situation. But through and through the most important thing is not who innovates but that it is done at all, it may be seen as evil but in the course of things it may be the lesser evil as the pace of industrial development and the strains this puts upon the planet are beginning to show, which in turn means that any innovations of a more environmentally friendly nature are not only welcome, but also desperately needed.

Finally the biggest reason for granting more defensive protection to TK is maybe surprising but at the same time obvious. TK should not, in reality be protected so much for the good of the TK-holders as for the good of the patent system itself. Flawed patents which do not meet the standards set by patentability critera ought not be granted as they undermine the legitimacy of the system and distort the bargain upon which the system is built.

One question that at this time can be answered is whether TK and the patent system interact well. To that question the answer is no, but not as badly as one is brought to believe.

If one starts by looking at the Turmeric and Neem cases the basic problem which is presented is one of the patent system not being able to live up to to its own standards of novelty and inventive step through not being able to track down prior art references which are not immediately available through the standard databases used. Even though prior art has existed in written form one can hardly blame the patent examiners for not locating ancient texts written in sanskrit. Even though theoretically such publication should be enough the system cannot be expected to find every obscure reference. As such getting TK-databases introduced into the standard searches is of utmost importance as well as coding the knowledge in a scientific manner to which patent examiners are accustomed. TK-databases and improved search methods include the most simple defensive measure and one which has already to a great extent been implemented. Poor searching and documentation can be seen as direct reasons behind the Turmeric and Neem patents being granted. As a defensive measure this is undoubtedly the most efficient. Certain worries are however raised by indigenous communities that collecting TK in an easibly accessible database will make it easier to "steal". A solution to this could be one such as that adopted by India, with a non-disclosure agreement between the keepers of the database and those who access it for prior art searches.

One must however move away from the notion of patents such as the Turmeric and Neem patents being a result of cynical abuse and intentional suppression. Although Northern corporations have undoubtebly been found to have patented TK, one can question whether this is a result of illwill or simply the more common occurrence of having a patent rejected after an opposition board found it not to pass the patentability criteria. A fate that befalls not only patents based on TK but also "regular" patents. Moreover companies also have a heightened sense of corporate social responsibility, not always maybe emanating from the goodness of their hearts, but certainly emanating from a dislike of losing revenue over scandals relating to how they handle themselves. A factor which shouldn't be ignored as a means of placing pressure on companies to act correctly without threats of patent invalidation hanging over them.

Furthermore if one studies the development of the Neem patent, it was a result of a nearly thirty year old Northern interest in Neem as a pesticide, and the Turmeric patent was the invention of two Indian scientists

developing knowledge which is arguably a part of their own heritage. Neither can obviously be seen as theft in the traditional sense of the word. The development of TK into a patent is not principally wrong, it is wrong that patents are granted for an invention which failed to reach the standards required but just the fact that a U.S. company attempted to develop a pesticide based on TK should not be viewed as a bad thing per se. Technological developments that can diminish our reliance on environmentally harmful products are essential for longterm sustainability and can possibly be the "magic bullet" for a problem with no apparent solution. Hindering pathways to new ESTs would therefore be foolish.

At the same time patents should not be granted simply because they combine TK with western public domain knowledge without actually inducing some inventive step, mere fusing of Northern and Southern knowledge should not be rewarded by an exlcusive right.

Another defensive measure discussed it that of disclosure. It may seem a light burden to place on a patentee; simply revealing where the knowledge or biological material originated from, but the arguments put forth in support of a mandatory disclosure are partly as an aid in keeping track of whether patentees have got PIC and if ABS is in place. Even so it remains a defensive measure and this analysis excludes PIC and ABS implications so its significance in relation to those issues are not considered. As shown in the thesis, both through the case studies and from the more extensive study of the CBD, most patent applications already reveal the source country or region. In reality this means that all the mandatory requirement in fact does is present a system of possibly declaring the patent null and void if the disclosure of origin hasn't been properly performed. The natural problems that arise from this are of course that disclosing isn't as easy as it sounds. Sometimes the origin can be unknown or consist of several countries, the Neem tree can for example be found in both Asia and Africa. A disclosure could however be useful in aiding in a more efficient prior art search, therefore an article like the Swedish 5a§ patentkungörelsen would be of value. Even though one might argue the case over how much efficacy a non-mandatory regulation will have, the fact that most patents have been shown to already disclose this information, a regulation on a recommendation level is probably sufficent as it offers a guide to a preferred and proper disclosure without putting patents at risk of becoming invalid solely on the grounds that the patentee wasn't aware of using any TK or from which country in a large region the knowledge or material is viewed as originating from. The claims that the importance of bioprospecting have been diminished are also worth considering in attempting such an extensive change of the system. If any form of measure should be introduced it should be based in the civil system and not as a part of the patent system.

There is value in keeping the patent system a neutral instrument which only judges the value of patent applications and patents on their technical merit and how well they match the criteria for obtaining a patent and steer clear of placing any value on what the patents actually do or could lead to. Patents

are a negative right, they do not present anyone with a carte blanche to do as they wish. The patent system is not truly equipped to and neither should it be asked to frequently judge on moral or politcal grounds. This lies outside its scope and competence. An exception however could and should be made for the moral rights of TK-holders in some instances.

In all three cases discussed in this thesis the opposition parties argued that the patents should be invalidated on moral grounds. In all three these arguments were denied and in the case of Neem and Turmeric those decisions were correct. If one studies the Ayhuasca case however, an opposition on moral grounds is warranted. Any patent which could be deemed as sacrilegious toward the beliefs of the TK-holders should be allowed to be challenged on such grounds. The number of cases would probably be extremely limited, and that is a good thing considering this is not a primary and natural function for the patent system to handle. This right should however only be used sparingly and only if the moral rights of the indigenous peoples in this specific circumstance are more important than the patent. Thus a patent for a lifesaving pharmaceutical should not be declared void on those grounds whereas a patent for a beauty crème for example would be more likely to be discounted against a legitimate moral rights claim.

Finally another issue which crops up throughout is that naturally within the patent system mistakes are made, but often competitors will challenge the patent on the grounds of infringement or lack of novelty. But in the case of TK the holders often lack the knowledge or resources to pay for an eventual oppostion process. Even though as CSIR pointed out the costs are not as great as one may think they still may be too much for an indigenous tribe or smaller collective organisation attempting to mount a challenge. Thus some sort of mechanism or intergovernmentally funded organisation to help aid in cases that may arise may be worth considering as a means of easing the burden on indigenous people, and the CSOs who have often provided aid in opposition cases so far. Furthermore aid and assistance should be given to help the countries themselves patent innovations based on their TK as a part of technology transfer obligations and hopefully level the playing field by these countries developing more innovation based industries of their own.

7 Conclusion

In conclusion the identity of TK and the patent system is not as much a question of two diametrically opposed ways of viewing knowledge as an issue which has been built up to become a huge stumbling block for the politcal and IPR-development debates within the international arena. The true problem is not that of biopiracy, but of adjusting the patent system to accommodate TK and adjusting TK through databases to more easily become part of the system. There is value in protecting TK both in terms of protecting the legitimacy of the patent system and protecting the knowledge systems of indigenous communites from being incorrectly appropriated.

The conclusion which I have reached in this thesis is that TK should in general be part of the public domain with some rights reserved. Exceptions due to ordre public and public morality should be expanded to also include exceptions due to subject matter causing offence toward the religious beliefs of TK-holders. The rights which are reserved would be a moral rights system which should be introduced into article 53 EPC. TRIPS Article 27(2) should be amended to allow for this and VI, 7.8 in the GUIDELINES FOR EXAMINATION IN THE EUROPEAN PATENT OFFICE could be used to enlarge the examining division with someone qualified to make such a judgment.

Further development of search methods and further investment into databases is essential in staving off the grant of incorrect patents. Examiners must be given clear instructions on where to search in relation to TK and patent offices must also include TK-databases in their standard searches.

In relation to the issue of disclosure of origin no mandatory requirement should be implemented. Disclosure requirements akin to those in the Swedish 5a§ patentkungörelsen should however be implemented as the disclosure of origin could aid in the prior art search and also help with the transparency of the patent system.

A final suggestion would be to establish or finance through aid, one or several legal institutions who can aid TK holders and developing countries both with patent filing and formal issues in developing their TK, as well as legal aid in patent opposition procedures. Thus the legal gap would not be so great and it would heighten the chances that patents that should in reality be declared invalid are not upheld simply because the indigenous commuties lack the funds or the competence to fight the case.

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