

Remshalden, 08 April 2006

**‘Biopiracy’ and Patents –  
Developing Countries’ fears are exaggerated**

**Master Thesis for LLM by coursework and dissertation  
in International Law**

by

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Research dissertation presented for the approval of Senate in fulfilment of part of the requirements for the Masters in Laws (LLM) in International Law in approved courses and a minor dissertation. The other part of the requirement for this qualification was the completion of a programme of courses.

I hereby declare that I have read and understood the regulations governing the submission of Masters in Laws (LLM) dissertations, including those relating to length and plagiarism, as contained in the rules of this University, and that this dissertation conforms to those regulations.

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# **‘Biopiracy’ and Patents – Developing Countries’ fears are exaggerated**

## **I. Introduction**

In the debate on ‘biopiracy’ developed countries have been reproached with exploiting developing countries’ genetic resources and their indigenous communities’ traditional knowledge without authorisation or compensation by granting patents on inventions derived from those genetic resources and traditional knowledge. The conflict between developing and developed countries in the context of intellectual property rights law and particularly in respect of patents, however, is not new. Developed countries have accused many developing countries, for example China, that they “pirate” their products, that is copying patented products without authorisation of the patentee and thus infringing patents. Developing Countries increasingly counter such accusations with the slogan ‘biopiracy’.

The debate on ‘biopiracy’ is heated and filled with many emotions. Politicians from developing countries, environmental and other activists as well as non-governmental organisations from all over the world are engaged in the discussion. In the discussion striking arguments have been used such as the ‘exploitation’ of indigenous communities in developing countries and the ‘extinction’ of their traditional ways of living by ‘biopiracy’. That is why this discussion has attracted so much attention worldwide. Demonstrations against alleged ‘biopiracy’ patents have been organised and thousands of people followed.

Developing countries have recognised that their genetic resources and traditional knowledge form valuable assets which have a great market value. They see that mainly foreign companies make profits with products that have been derived from their original resources. Indeed, according to Daniel Wüger “the value of developing countries’ germplasm to the pharmaceutical industry in the early 90s was estimated to be at least \$32billion per year”.<sup>1</sup> The figures for the annual global markets for products in the

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<sup>1</sup> Daniel Wüger, ‘Prevention of Missappropriation of Intangible Cultural Heritage Through Intellectual Property Laws’, in: J. Michael Finger and Philip Schuler (ed.), ‘Poor People’s Knowledge Promoting

healthcare, agriculture, horticulture, and biotechnology sectors derived from genetic resources are supposed to lie between US \$ 500 billion and US \$ 800 billion according to ten Kate and Laird.<sup>2</sup> It also “has been claimed that of the 120 active compounds derived from plants that are widely used in contemporary medicines, 75 per cent were already known within traditional knowledge systems”.<sup>3</sup> Thus, it does not surprise that the economic significance of genetic resources and traditional knowledge has been increasingly recognised and that developing countries have tried to get a share of this market.

Connected with the ‘biopiracy’ debate is the general debate on globalisation and in respect of intellectual property rights the debate on the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (‘TRIPS’). TRIPS is the first comprehensive legislation on intellectual property rights that is compulsory for all WTO member countries, therefore for almost all countries in the world.

This thesis will examine such ‘biopiracy’ patents’ and tries to evaluate whether the criticisms related with them are true and whether and how far these patents have indeed negative impacts on indigenous communities and developing countries. It will be shown that the fear of the slogan ‘biopiracy’ is exaggerated since the criticisms related with it are largely unjustified and since there is no direct impact on indigenous communities or developing countries. Even the few negative impacts can be resolved by the developing countries with the help of suitable national legislation. Thus, developing countries should rather enact appropriate legislation to make use of the available TRIPS regulations to promote innovation in their own territory to benefit better from their resources than it is the case up to now.

The second chapter will provide a definition of ‘biopiracy’ and the terms ‘genetic resources’ and ‘traditional knowledge’ that are related with the term ‘biopiracy’.

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*Intellectual Property in Developing Countries*’ (2004), available at [www.worldbank.org/research/Poor\\_Peoples\\_Knowledge.pdf](http://www.worldbank.org/research/Poor_Peoples_Knowledge.pdf), 183-206, at 160.

<sup>2</sup> Kerry ten Kate / Sarah A Laird, ‘*Bioprospecting Agreements and Benefit Sharing with Local Communities*’, in: J. Michael Finger and Philip Schuler (ed.), *Poor People’s Knowledge Promoting Intellectual Property in Developing Countries* (2004), 133-158, at 134.

<sup>3</sup> Coenraad J. Visser, ‘*Making Intellectual Property Laws Work for Traditional Knowledge*’, in: J. Michael Finger and Philip Schuler (ed.), *Poor People’s Knowledge Promoting Intellectual Property in Developing Countries*’ (2004), 207-240, at 213.

Moreover, a survey of the background of the topic will be given why those resources have been increasingly interesting for corporations.

In the third chapter the relevant TRIPS provisions are presented as they form the minimum standard of intellectual property protection every WTO member has to provide. Thus, these regulations are of importance for every WTO member's patent law. When examining the patent examples one has to keep in mind these minimum provisions.

The bulk of this dissertation is dedicated to the evaluation of the most known examples of 'biopiracy' patents. First a survey of the criticisms related to 'biopiracy' is given followed by a classification of those criticisms in actually two main parts which can be described as 'bad' patents and 'good' patents. The examples of 'bad' and 'good' patents are analyzed with regard to whether they actually were 'biopiracy' patents and in how far the criticisms connected with them were justified. An intermediate result in chapter V summarises the findings and concludes that there is just one real problem related with 'bad' patents, whereas the claims in respect of 'good' patents cannot be validated. The final chapter will show that developing countries are able to prevent the entire 'problem' of 'biopiracy' because they can prevent 'bad' as well as 'good' patents from being granted. Thus, the alleged problems would not emerge.

## **II. What is 'biopiracy'?**

The conflict between Developing Countries and Developed countries in the context of 'biopiracy' is strictly spoken not concerned with the violation of intellectual property rights. Although there is no generally accepted definition of 'biopiracy' it can be stated that it is concerned with the exploitation of genetic resources of Developing Countries and traditional knowledge of indigenous communities within these countries<sup>4</sup>.

### **A. Definition of "biopiracy"**

Most authors define 'biopiracy' as the (unauthorized and uncompensated) appropriation and commercial exploitation of genetic resources in Developing Countries and/or

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<sup>4</sup> Report of the British Commission on IPR, *'Integrating Intellectual Property Rights and Development Policy'*, at 74; Susan K Sell, *'Post Trips Developments: The tension between commercial and social agendas in the context of Intellectual Property'*, 14 Fla. J. Int'l L. 193, 202; Graham Dutfield, *What is 'biopiracy'?*, available at: [www.canmexworkshop.com/documents/papers/L3.pdf](http://www.canmexworkshop.com/documents/papers/L3.pdf), at 1.

traditional knowledge of indigenous communities by corporations, mostly from Developed Countries, which seek then “monopoly control”, usually patents, over these resources or inventions derived from these resources.<sup>5</sup>

Indeed, “intellectual property rights, especially patents”, as stipulated in the TRIPs Agreement “have been criticised” by many Developing countries and indigenous communities “because they are considered to encourage and legitimise ‘biopiracy’”.<sup>6</sup>

It is not obvious in which way intellectual property rights, particularly patents, can contribute to this alleged exploitation. Patents are supposed to stimulate innovation and new technologies by granting the inventor an exclusive right over the invention for a limited period of time and not to exploit genetic resources or traditional knowledge of indigenous communities.<sup>7</sup> Understanding the allegations demands to clarify the terms of “indigenous communities”, “traditional knowledge” and “genetic resources” and why they are said to be of interest to corporations.

## B. Genetic resources and traditional knowledge

There is neither a uniform or agreed definition of indigenous communities nor of traditional knowledge.<sup>8</sup>

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<sup>5</sup> Action Group on Erosion, Technology and Concentration (ETC Group) cited in: Report of the British Commission on IPR, note 4, at 74; Susan Sell, note 4, at 202; Dutfield, ‘What is ‘biopiracy’?’, note 4, at 1,3; Pollyanna Folkins, ‘Has the Lab Coat Become the Modern Day Eye Patch? Thwarting ‘biopiracy’ of Indigenous Resources By Modifying International Patenting Systems’, 13 *Transnat’ 1 L. & Contemp. Probs* (2003), 339 at 343; Gerard Downes, ‘Implications of TRIPs for Food Security in the majority world’, (2003) available at: [www.comlamh.org](http://www.comlamh.org), at 15; Ruchi Tripathi, ‘Implications of TRIPs on livelihood of poor farmers in developing countries’, ActionAid paper (2000), available at: [www.actionaid.org/wps/content\\_document.asp?doc\\_id=406](http://www.actionaid.org/wps/content_document.asp?doc_id=406), at 4.

<sup>6</sup> Graham Dutfield, ‘Indigenous Peoples, Bioprospecting and the TRIPs Agreement: Threats and Opportunities’, in: Peter Drahos / Ruth Mayne (ed.), *Global Intellectual Property Rights: Knowledge, Access and Development* (2002), 135 at 135; Folkins, note 5, at 340, 341, 342; David Downes, ‘Using Intellectual Property as a Tool to Protect Traditional Knowledge: Recommendations for Next Steps’, Center for International Environmental Law (CIEL) Discussion Paper 1997, available at <http://www.ciel.org/Publications/UsingIPtoProtectTraditionalKnowledge.pdf>, at 3; Manuel Ruiz, ‘Access to Genetic Resources, Intellectual Property Rights and Biodiversity: Processes and Synergies’, 2004, available at: [www.iucn.org/themes/pbia/wl/docs/trade/ipsdweek\\_may04/PGCS\\_TB\\_Ruiz.pdf](http://www.iucn.org/themes/pbia/wl/docs/trade/ipsdweek_may04/PGCS_TB_Ruiz.pdf), at 5.

<sup>7</sup> Report of the British Commission on IPR, note 4, at 5;14.; David Downes, CIEL, note 6, at 3.

<sup>8</sup> for the term **traditional knowledge**: Report of the British Commission on IPR, note 4, at p.75; Graham Dutfield, *Developing and Implementing National Systems For Protecting Traditional Knowledge: Experiences In Selected Developing Countries*, in: Sophia Twarog and Promila Kapoor (ed.), *Protecting and Promoting Traditional Knowledge: Systems, National Experiences And International Dimensions*, UNCTAD 2004, available at: [http://www.unctad.org/en/docs/ditcted10\\_en.pdf](http://www.unctad.org/en/docs/ditcted10_en.pdf), 141 – 153, at 141; Visser, note 3, at 207.

for the term “**indigenous communities**”: Wikipedia [http://en.wikipedia.org/wiki/Indigenous\\_people](http://en.wikipedia.org/wiki/Indigenous_people); United Nations, Secretariat of the Permanent Forum on Indigenous Issues, Background Paper PFII/2004/WS.1/3 (2004), available at: <http://www.un.org/esa/socdev/unpfii/documents/PFII%202004%20WS.1%203%20bDefinition.doc>, p.1.

Based on different formulations it can be stated that indigenous populations have the peculiarity that they are at least in part distinct from the surrounding populations in a nation state with regard to linguistic, cultural and social characteristics.<sup>9</sup> According to the U.N. Working Definition of Indigenous Populations / Peoples they are “composed of the existing descendants of peoples who inhabited the present territory of a country wholly or partially at the time when persons of a different culture or ethnic origin arrived there”.<sup>10</sup>

Sometimes definitions of traditional knowledge refer to indigenous communities, comprising “knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyle”.<sup>11</sup> Other formulations without reference to indigenous cultures are more far-reaching and comprise every innovation and invention based on tradition<sup>12</sup>. Agreement exists in so far as traditional knowledge is based on experience and is usually passed on through generations.<sup>13</sup> In the context of this thesis the term ‘traditional knowledge’ refers to such knowledge associated with genetic resources.

A definition of genetic resources is provided for in the United Nations Convention on Biological Diversity (CBD): Article 2 defines it as “any material of plant, animal, microbial, or other origin containing functional units of heredity”.<sup>14</sup>

### **C. Interest of corporations**

With the development of biotechnology multinational pharmaceutical and biotechnological corporations began research work on products on the basis of (plant) genetic resources.<sup>15</sup> According to Kerry ten Kate and Sarah A Laird “the annual global markets for products in the healthcare, agriculture, horticulture, and biotechnology sectors derived from genetic resources lie between US \$500 billion and US \$800

<sup>9</sup> Wikipedia [http://en.wikipedia.org/wiki/Indigenous\\_people](http://en.wikipedia.org/wiki/Indigenous_people); U.N. Working Definition of Indigenous Populations / Peoples (1982), cited in [http://www.humanrights.ch/cms/front\\_content.php?client=1&lang=1&idcat=513&idart=2170&m=&s=&zur=513](http://www.humanrights.ch/cms/front_content.php?client=1&lang=1&idcat=513&idart=2170&m=&s=&zur=513)

<sup>10</sup> U.N. Working Definition of Indigenous Populations / Peoples, (*adapted by the UN Working Group on Indigenous Populations in 1982*), cited in [www.humanrights.ch](http://www.humanrights.ch), available at [http://www.humanrights.ch/cms/front\\_content.php?client=1&lang=1&idcat=513&idart=2170&m=&s=&zur=513](http://www.humanrights.ch/cms/front_content.php?client=1&lang=1&idcat=513&idart=2170&m=&s=&zur=513).

<sup>11</sup> Preamble and Art. 8 (j) Convention on Biological Diversity, available at: [www.biodiv.org](http://www.biodiv.org).

<sup>12</sup> World Intellectual Property Organization (WIPO), *Report 2001 on Fact-Finding Missions on Intellectual Property and Traditional Knowledge* (“FFM”) (1998-1999) available at <http://www.wipo.int/tk/en/tk/ffm/report/final/pdf/part1.pdf>, p.25; Visser, note 3, at 207.

<sup>13</sup> Dutfield, in Peter Drahos, note 6, at 136; International Institute for Sustainable Development (IISD), *Trade and Development Brief No.7* (2003), available at: <http://www.iisd.org/publications/pub.aspx?id=555>, at 1; WIPO, FFM Report 2001, note 12, at 25.

<sup>14</sup> Kerry ten Kate / Sarah A Laird, *The Commercial Use of Biodiversity, Access to Genetic Resources and Benefit-Sharing*, 1999, Earthscan London, at 17.

<sup>15</sup> Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis*, 2nd ed., at 57.

billion”.<sup>16</sup> For this reason so called ‘bioprospecting’ has been carried out. Biological diversity in many countries has been explored and screened for potentially commercially valuable genetic resources<sup>17</sup>. In Developing countries most of the bioprospecting has been carried out as the highest biological diversity is located in tropical and subtropical regions, where also most of the Developing countries are concentrated.<sup>18</sup> For the search to be carried out cost-effectively and efficiently in regard of time, the corporations have used traditional knowledge of indigenous communities about plants and plant genetic resources. The knowledge of those communities is said to help identifying valuable substances in natural sources more easily.<sup>19</sup>

An additional patent protection on the “new” product ensures the company an exclusive exploitation right which is an economical very valuable asset. Developing countries noticed the increased importance of their genetic resources and traditional knowledge of indigenous communities within their territory. But due to the lack of a strong technological base, particularly in biotechnology, they have not been able to participate to the same extent in the economic exploitation of their genetic resources as the mostly foreign corporations could. Thus, the Developing countries fear that they are deprived of their biological and cultural resources without being rewarded for providing these resources.

### **III. TRIPS regulations on patents in the context of ‘biopiracy’**

The TRIPS agreement sets out minimum standards of intellectual property protection that every WTO member has to meet. It is the most important international treaty which is concerned with patents. A patent is defined as “a grant of a property right by the government to the inventor for an invention<sup>20</sup>”, “giving the inventor the right for a limited period to stop others from making, using, importing or selling the invention without the permission of the inventor”.<sup>21</sup>

<sup>16</sup> Kate / Laird, *Biodiversity*, note 14, at 134; Kate / Laird, *Bioprospecting*, note 2, at p. 134.

<sup>17</sup> Kate / Laird, *Biodiversity*, note 14, at 135 (definition of bioprospecting).

<sup>18</sup> Paul Gepts, *Who Owns Biodiversity, and How Should the Owners Be Compensated?*, *Plant Physiology*, April 2004, Vol.134,1295 at 1298, available at: <http://www.plantphysiol.org/cgi/content/full/134/4/1295>.

<sup>19</sup> Lakshmi Sarma, *‘Biopiracy: twentieth century imperialism in the form of international agreements’*, 13 *Temp. Int’l & Comp. L.J.* (1999), 107 at 113; Rural Advancement Foundation International (RAFI), *Bioprospecting / Biopiracy and Indigenous Peoples*, 2002, available at [http://www.kahea.org/lcr/pdf/bioprospecting\\_people.pdf](http://www.kahea.org/lcr/pdf/bioprospecting_people.pdf), at 1.

<sup>20</sup> <http://www.silo.lib.ia.us/specialized-services/patents-trademark/patent-definition.htm>

<sup>21</sup> The UK Patent Office: <http://www.patent.gov.uk/patent/whatis/definition.htm>; Report of the British Commission on IPR, note 4, at 12.

The patent section of the TRIPS agreement is comprehensive both in scope and coverage. According to article 27.1 “patents shall be available for any inventions, whether products or processes, in all fields of technology. Countries cannot exclude entire technologies like biotechnology as they had extensively done in the past.”<sup>22</sup>

An ‘invention’ must fulfil three criteria, namely ‘novelty’, ‘inventive step’ and ‘industrial applicability’<sup>23</sup>, whereas the latter two “may be deemed by a member to be synonymous with the terms “non obvious” and “useful” respectively”.<sup>24</sup> Although there are no clear international standards and national legislation differs substantively, a common interpretation of the three patentability criteria is as follows:<sup>25</sup> “An invention must constitute new knowledge, i.e. when compared to the state of the art” at the time of application (novelty), must not be “obvious to a person skilled in the art”<sup>26</sup> (inventive step) and the invention must somehow be susceptible of industrial application

Article 27.1 also contains a non-discrimination principle as to the place of invention, the field of technology and whether products are imported or locally produced<sup>27</sup>. This means that WTO members cannot distinguish between goods that are, for example, essential to life or health and other goods and cannot require the local production for an invention to be patentable.<sup>28</sup>

Nevertheless there is some flexibility in the definitions of ‘invention’ and of the three criteria ‘novelty’, ‘inventive step’ and ‘industrial applicability’ as TRIPS does not define any of these concepts. The lack of clear definitions gives member countries flexibility with regard to the interpretation of these criteria and the scope of patentability.

Articles 27.2 and 27.3 contain some exceptions to patentability. WTO members may provide for an exemption to protect “ordre public or morality” and they may also exclude from patentability specified methods for the treatment of humans or animals and even plants and animals themselves.<sup>29</sup> Moreover member states are not obliged to grant patents on essentially biological processes for the production of plants or animals.<sup>30</sup> The protection by patents of micro-organisms and non biological processes, however, is

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<sup>22</sup> Carlos M Correa, *Intellectual Property Rights, the WTO and Developing Countries, The TRIPS Agreement and Policy Options*, Zed Books Ltd., London 2000, p. 50.

<sup>23</sup> Article 27.1 TRIPS.

<sup>24</sup> Footnote to Article 27.1 TRIPS.

<sup>25</sup> Philippe Cullet, *Food Security and Intellectual Property Rights in Developing Countries (2003)*, available at <http://www.ribios.ch/fr/documents/docs/Brochurespdf/Brochure6FoodsecDPI.pdf>, at. 23.

<sup>26</sup> *ibid.* at 23.

<sup>27</sup> Article 27 TRIPS, last sentence.

<sup>28</sup> Report of the British Commission on IPR, note 4, at. 6.

<sup>29</sup> Article 27.2, 27.3 a) TRIPS.

<sup>30</sup> Article 27.3 b) TRIPS.

mandatory.<sup>31</sup> But TRIPS does not give any definition of “essentially biological processes” or “micro-organism”.

Articles 30 and 31 of the TRIPS allow for limited exceptions to the exclusive exploitation right conferred by a patent.

In the context of ‘plant genetic resources’ it is important to note that the TRIPS agreement requires protection when a plant has been modified by technological processes that a new plant variety has originated. Plant varieties must be protected “either by patents or by an effective sui generis system or any combination thereof”.<sup>32</sup> TRIPS again does not define what a plant variety is.

Summarised, the TRIPS Agreement stipulates to grant patents in any field of technology, but allows for exceptions mainly in the field of biotechnology with the possible exclusion of plant, animals and biological processes. Thus, patents on inventions based on genetic resources are possible but not required (as long as the invention concerns plants or essentially biological processes). Protection becomes mandatory if the invention based on genetic resources or traditional knowledge covers a non-biological process. The agreement, however, does not directly address traditional knowledge. It sets out a minimum standard to be applied by all WTO members, but allows countries to expand the protection to new areas, for example to cover traditional knowledge provided that the requirements of patentability are met. Thus, TRIPS gives members the option, “within certain limits, of defining the scope of patentability in a quite a broad way”.<sup>33</sup>

#### **IV. Criticisms of ‘biopiracy’**

The use of genetic resources and traditional knowledge of indigenous communities and the patenting of inventions derived from these resources are seen as a new form of “western imperialism”.<sup>34</sup> ‘biopiracy’ is said to be unfair, unethical and a threat to the existence of indigenous cultures.<sup>35</sup>

It has been alleged that using traditional knowledge and then obtaining a patent on an invention derived from genetic resources and traditional knowledge is unfair to the indigenous communities. The patent will be the exclusive property of the company

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<sup>31</sup> Article 27.3 b) TRIPS.

<sup>32</sup> Article 27.3 b) TRIPS.

<sup>33</sup> Correa, *IPR*, note 22, at 50.

<sup>34</sup> Susan Sell, note 4, at 202.

<sup>35</sup> Gervais, note 15, at 61; Folkins, note 5, at 343, 344; Sarma, note 19, at 113.

although the indigenous community has contributed to the invention.<sup>36</sup> Traditional knowledge has been described as being “communal and sacred in nature” why it should not be “the private property of a corporation”.<sup>37</sup>

Another important allegation is that ‘biopiracy’ means exploiting the indigenous communities and Developing countries and also jeopardizing their way of living and their livelihood.<sup>38</sup> The “penetration of bioprospectors” and the collecting of biological resources from indigenous communities would amount to a violation of “sacred customs and traditions” and would have a “dramatic impact” on the indigenous group.<sup>39</sup> “It is also claimed that indigenous communities are bared from using or exporting their biological resources and traditional knowledge that they have developed<sup>40</sup>. Ultimately traditional knowledge would become extinct.<sup>41</sup>

In this context the TRIPS Agreement is blamed for only working in favour of transnational corporations and not recognizing or protecting traditional knowledge. Hence it would facilitate ‘biopiracy’.<sup>42</sup> It would use “Eurocentric concepts”, which would see creations of indigenous peoples as savage and primitive.<sup>43</sup> Particularly the current patentability standards introduced by the TRIPS Agreement are condemned. These, it is claimed, are too narrow for the protection of traditional knowledge and genetic resources and would discriminate indigenous communities.<sup>44</sup>

Particularly three points are made regarding this allegation. Firstly, the lacking definition of novelty in the TRIPS Agreement would make it possible to define novelty standards which do not recognize “the public use or oral transfer of traditional knowledge”.<sup>45</sup>

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<sup>36</sup> Gervais, note 15, at 61; Sarma, note 19, at 113.

<sup>37</sup> Jonathan Luna, ‘*Bioprospecting or Biopiracy, the Complex Relations of the Appropriation of Indigenous Knowledge*’ (2005), Florida State University D-Scholarship Repository, Article #85, available at: <http://dscholarship.lib.fsu.edu/undergrad/85>, at 18.

<sup>38</sup> Shiva, note 34, at p. 3; Sarma, note 19, at 113; Folkins, note 5, at 343, 344; Luna, note 37, at 19.

<sup>39</sup> Folkins, note 5, at 343, 344.

<sup>40</sup> Folkins, note 5, at 341.

<sup>41</sup> Sarma, note 19, at 112.

<sup>42</sup> Folkins, note 5, at 351.

<sup>43</sup> Folkins, note 5, at 348.

<sup>44</sup> Folkins, note 5, at 348,351; Vandana Shiva, ‘*Corporate Hijack of Biodiversity, How WTO-TRIPs Rules Promote Corporate Hijack of People’s Biodiversity and Knowledge*’, available at [www.vshiva.net](http://www.vshiva.net), at 30; David Downes, CIEL, note 6, at p.3.

<sup>45</sup> WTO IP/C/W/370, Note by the Secretariat, *The Protection of Traditional Knowledge and Folklore. Summary of Issues Raised and Points made* (08.08.2002), available at <http://docsonline.wto.org>, at 6; Gervais, note 15, at 233.

The TRIPS patentability requirement of “industrial application” and the notion of “invention” would prevent indigenous communities from obtaining a patent on their genetic resources or traditional knowledge because they are either seen as discoveries, thus as obvious, or as being in the public domain or not traceable to a specific inventor<sup>46</sup>. The companies that take genetic resources from indigenous communities and develop products (e.g. drugs) based on those resources and traditional knowledge, however, could own patents enabling the company to sell the invention back to its “true inventors”<sup>47</sup>. For these reasons Shiva accuses the modern intellectual property system to be a “denial of the collective innovation” of indigenous cultures “over thousands of years”<sup>48</sup>. Moreover, the TRIPS agreement is condemned for not providing for “fair and equitable sharing of benefits arising out of the patenting of genetic resources”.<sup>49</sup> The companies could earn “millions of dollars” by using traditional knowledge, but indigenous communities however would never be justly compensated for their contributions to the companies.<sup>50</sup>

Thus, the TRIPS agreement is seen to facilitate ‘biopiracy’. ‘Biopiracy’ itself, and indirectly the TRIPS agreement as well, are seen as a mean of exploitation of developing countries and indigenous communities. There is a general suspicion against developed countries and their transnational corporations to conduct a new form of colonialism.

Since the definition of ‘biopiracy’ comprises the formulation “seeking monopoly control” and because virtually all criticisms mentioned above refer to the grants of patents this thesis therefore will confine itself to this particular problem.

### **A. ‘Good’ patents / ‘bad’ patents**

The criticisms in the context of ‘biopiracy’ actually can be divided in two large categories. They actually comprise two points of contact to Patent law. They can be described as granting of ‘bad’ patents and granting of ‘good’ patents.<sup>51</sup>

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<sup>46</sup> Gervais, note 15, at 61; Folkins, note 5, at 351; Dutfield in: Peter Drahos, note 6, at 144; Background Note of the UNCTAD Secretariat, *Systems and National Experiences for Protecting Traditional Knowledge, Innovations and Practices*, Appendix II in: Sophia Twarog and Promila Kapoor (ed.), *Protecting and Promoting Traditional Knowledge: Systems, National Experiences And International Dimensions*, UNCTAD 2004, 353-372, at 360.

<sup>47</sup> Dutfield in: Peter Drahos, note 6, at 144; Sarma, note 19, at 114.

<sup>48</sup> Shiva, note 34, at p. 4.

<sup>49</sup> Shiva, note 34, at p. 30.

<sup>50</sup> Folkins, note 5, at 341; Luna, note 37, at 34.

<sup>51</sup> Report of the British Commission on IPR, note 4, at 74; IISD, note 13, at 1.

### 1. *'Bad' patents*

These are patents that have been granted for inventions based on genetic resources and traditional knowledge which actually did not fulfil the patentability requirements stipulated in the TRIPS agreement. They were “either not novel or not inventive having regard to traditional knowledge already in the public domain”.<sup>52</sup> These patents are described as plagiarism of traditional knowledge.<sup>53</sup> The mistake of granting ‘bad’ patents is not only blamed on lacking access of the patent offices to traditional knowledge but also on an improper application of the patentability requirements by the patent offices.<sup>54</sup> This kind of patents attracts allegations like the “exploitation” and “imperialism” arguments mentioned at the beginning of this chapter.

### 2. *'Good' patents*

Even if patents on inventions derived from genetic resources and traditional knowledge of indigenous communities are correctly granted according to the patentability requirements, they are deemed to be ‘biopiracy’ if there was no prior informed consent by the community or if the company did not enter into an agreement with the indigenous community on sharing the benefits accrued from the invention.<sup>55</sup>

In this context the TRIPS agreement is particularly blamed for not taking into consideration such requirements, thus exploiting the indigenous communities.

This work will go on to evaluate the best known examples of ‘bad’ and ‘good’ patents, how they could emerge and mainly if and to what extent the allegations connected with them were justified. Then it will be analyzed which possibilities developing countries have to solve possible problems.

## **B. Cases and evaluation of the criticisms**

### 1. *'Bad' patents*

Before a patent office grants a patent it has to review whether the patentability requirements are fulfilled. In the context of the ‘bad’ patents it is claimed that the

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<sup>52</sup> Report of the British Commission on IPR, note 4, at 74.

<sup>53</sup> Vandana Shiva, ‘*Who are the real pirates?*’, Third World Resurgence, Third World Network, Malaysia, No. 63, November 1995, (1995), 16 at.16,19.

<sup>54</sup> Report of the British Commission on IPR, note 4, at 74

<sup>55</sup> *ibid.* at p. 74; IISD, note 13, at 1; Sarma, note 19, at 116; Fritz Dolder, *Patente auf der Grundlage traditioneller Kenntnisse indigener Gemeinschaften*, in: Christoph Ann (ed.), *Festschrift für Reimar König*, Carl Heymanns Verlag, Köln 2003, 81, at 83.

patented invention does not meet the standards. Evaluating the most “famous” examples of ‘bad’ patents it will be analyzed why they could be granted whether they were actually ‘bad’ patents and whether the allegations combined with them were justified.

All patents that have been subject to this kind of allegation had been granted by the European Patent Office (“EPO”) or the United States Trademark and Patent Office (“USPTO”). Therefore the rules that are underlying the granting of patents must be presented shortly.

a) Convention on the Grant of European Patents (EPC)

Article 52 EPC contains the patentability requirements for an invention. As stipulated in article 27.1 of the TRIPS agreement inventions “which are new and which involve an inventive step” and are “susceptible of industrial application” are patentable.<sup>56</sup>

Inventions are delimited from not patentable discoveries in article 52.2 EPC.

The EPC uses the possible exceptions to the general patentability provided for in TRIPS only partially. Article 52.4 EPC excludes “methods for treatment of the human or animal body by surgery or therapy and diagnostic methods”; article 53 excludes plant or animal varieties and essentially biological processes from patentability. Biotechnological inventions are, in principle, patentable under the EPC. Rules 23 b – e of the Implementing Regulations to the Convention on the Grant of European Patents<sup>57</sup> are defining and limiting the patentability of certain biotechnological inventions. “Biological material”, which is defined in rule 23b.2, shall be patentable if it “is isolated from its natural environment or produced by means of a technical process” as well as plants or animals as long as “the technical feasibility of the invention is not confined to a particular plant or animal variety”.<sup>58</sup> Thus, inventions derived from plant genetic resources and traditional knowledge can be patentable provided they meet the novelty, inventive step and industrial application requirements and do not form one plant variety solely.

The only remaining restriction to those inventions is contained in the “ordre public” and “morality” exemption of article 53 a) EPC.

An invention is new according to article 54 EPC if “it does not form part of the state of the art”. State of the art comprises all knowledge in any part of the world that is in the

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<sup>56</sup> Article 52.1 EPC, available at <http://www.european-patent-office.org/legal/epc/e/ma1.html>.

<sup>57</sup> “Implementing Rules”, available at <http://www.european-patent-office.org/legal/epc/e/ma2.html#REG>.

<sup>58</sup> Rule 23 c) of the Implementing Rules, note 52; Article 53 b) EPC.

public domain either through written or oral description or in public use in any other manner<sup>59</sup>. The EPC uses an ‘absolute’ novelty standard as it includes all knowledge anywhere in the world. An ‘inventive step’ is existent according to article 56 EPC if “it is not obvious to a person skilled in the art”. Obvious is everything “which does not go beyond the normal progress of technology but merely follows plainly or logically from the prior art”.<sup>60</sup>

The third element “industrial application” is defined in a broad sense. According to the Guidelines for Examination “industry is an activity which belongs to the useful or practical arts as distinct from the aesthetic arts” and “does not necessarily imply the use of a machine or the manufacture of an article”.<sup>61</sup> The possibility of the production or use in a commercial, non private field is deemed to be sufficient.<sup>62</sup>

Following the application the patent office produces a search report on the issue whether an invention is ‘new’ and ‘inventive’ taking into consideration every document available to them.<sup>63</sup> Articles 99 and 100 EPC provide an opposition procedure in which every person can file an opposition to a patent granted within 9 months after publication on the grounds that the patent does not meet the requirements of patentability in Articles 52 to 57 EPC. As required by the TRIPs agreement the protection term of a patent is 20 years.<sup>64</sup> There is a uniform extent of protection which depends on the terms of the claims the inventor makes.<sup>65</sup> The rights actually conferred by the European patent, however, follow the rights conferred by a patent according to the national patent laws in each of the contracting parties in respect of which the European patent was granted.<sup>66</sup> In Germany a patent, and thus an European patent as well, gives the patentee the exclusive right to prevent every other person from producing, offering, using and importing the patented invention.<sup>67</sup> The protection is limited to the territories of the Contracting Parties of the EPC in respect of which the patent is granted.<sup>68</sup>

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<sup>59</sup> Article 54.2 EPC.

<sup>60</sup> Guidelines for Examination in the European Patent Office, Part C, Chapter IV 9.4, available at [http://www.european-patent-office.org/legal/gui\\_lines/e/index.htm](http://www.european-patent-office.org/legal/gui_lines/e/index.htm).

<sup>61</sup> Guidelines for Examination in the European Patent Office, Part C, Chapter IV, 4.1.

<sup>62</sup> Margarete Singer / Dieter Stauder, *Europäisches Patentübereinkommen (“EPC”)*, 2nd ed. 2000, article 57 Rn. 5,6.

<sup>63</sup> Article 92 EPC; Rule 44 Implementing Rules.

<sup>64</sup> Article 63 EPC.

<sup>65</sup> Article 69 EPC.

<sup>66</sup> Article 64 EPC.

<sup>67</sup> Article 64 EPC, §9 German Patent Law (PatG), available at <http://www.gesetze-im-internet.de/patg/index.html>.

<sup>68</sup> Article 3 and 64 EPC – so called “territorial principle”.

b) US Patent Act

The US Patent Act is codified in title 35 of the United States Code<sup>69</sup>. According to section 101 a patent can be obtained for every invention or discovery<sup>70</sup> of a “new and useful process, machine, manufacture, or composition of matter, or any new and useful improvements thereof”.

Since the “Chakrabarty” decision of the U.S Supreme Court even living organisms and cells are seen as patentable objects in accordance with section 101 Patent Act.<sup>71</sup> In principle, natural phenomena as well as natural products in their natural state are excluded from patentability (laws of nature doctrine)<sup>72</sup>. Patents on processes and concrete applications of ‘laws of nature’, however, are possible. As soon as natural substances are modified in any way these inventions also can be patented. Thus, “an isolated or purified form of a natural product” is counted among the patentable objects and is new in a prior art sense.<sup>73</sup>

The Patent Act does not make use of the possible exceptions to patentability provided in the TRIPS agreement what is in contrast to the EPC.<sup>74</sup> The Patent Act even does not provide for an exception to patentability based on “ordre public” or on moral grounds as the EPC does in article 53 a).

Another important difference is the definition of novelty in the Patent Act. Novelty of an invention is defined in Sec. 102 a) of the Patent Act. An invention is not regarded as new if it “was patented or described in a printed publication” in the United States or in a foreign country “before the invention thereof by the applicant”. Public use or public knowledge only counts among prior art if “the invention was known or in use” in the United States, thereby ignoring use or knowledge in any other country in the world<sup>75</sup>. This definition of novelty is called ‘relative novelty’<sup>76</sup>. The same problem is true for Section 102 b) according to which the inventor loses the right of obtaining a patent if more than one year has elapsed between a printed publication of the invention by the applicant or others and the application for patent. Public use or sale in foreign countries

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<sup>69</sup> available at [http://www.uspto.gov/web/offices/pac/mpep/consolidated\\_laws.pdf](http://www.uspto.gov/web/offices/pac/mpep/consolidated_laws.pdf).

<sup>70</sup> Section 100 a) Patent Act: the term “invention” also covers “discovery”.

<sup>71</sup> U.S. Supreme Court, in *GRUR International* 1980, 627 at 627, 629.

<sup>72</sup> *ibid.* at 627, 629.

<sup>73</sup> Correa, *IPR*, note 22, at 177.

<sup>74</sup> confer Article 52.4, 53 EPC.

<sup>75</sup> both: Section 102 a) Patent Act.

<sup>76</sup> Correa, *IPR*, note 22, at 58.

does not bar patentability<sup>77</sup>. Since the TRIPS agreement does not provide a definition of novelty the “relative” novelty definition does not violate article 27.1 of the TRIPS agreement.

The criterion “utility” which is deemed to be synonymous with the term “industrial application” in article 27.1 TRIPS<sup>78</sup> is fulfilled if the invention is operable and “capable of satisfying some function of benefit to humanity”.<sup>79</sup> This definition is somewhat lower than the one in the EPC. The third requirement of TRIPS, namely inventive step, is mentioned in section 103 a) of the Patent Act. The invention must not be obvious for a person “having ordinary skills” in the art.<sup>80</sup> Lastly, the patent application must contain a written enabling disclosure.<sup>81</sup> For biological inventions, however, it is acknowledged to be sufficient to deposit the biological material.<sup>82</sup>

As the Patent Act does not exclude plants it acknowledges patents for plants, in contrast to the EPC.<sup>83</sup> However, only asexually produced “distinct and new varieties of plants” are covered by this section. Section 161 excludes uncultivated plants from patentability. Apart from that the normal criteria for patentability, namely novelty and utility, are to be applied.

There is a comprehensive research of state of the art before a patent is granted.<sup>84</sup> Generally the patent examiners just have access to patent literature and older patents. Thus, information on public use or knowledge often is overlooked. Moreover, public use in foreign countries does not destroy novelty why it does not have to be examined.

After the grant of a patent “any person at any time may cite to the Patent Office in writing prior art consisting of patents or printed publications” which is believed to bar patentability of a particular patent.<sup>85</sup> Additionally in section 302 Patent Act any person at any time can file a request for re-examination of a patent on the basis of prior art cited

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<sup>77</sup> Section 102 b) Patent Act.

<sup>78</sup> footnote to article 27.1 TRIPS.

<sup>79</sup> Correa, *IPR*, note 22, at 60.

<sup>80</sup> „non obvious“ may be deemed to be synonymous with “inventive step” according to footnote 5 to article 27.1 of the TRIPS.

<sup>81</sup> Section 112 Patent Act.

<sup>82</sup> 37 C.F.R. section 1.801 et sqq., available at [www.uspto.gov/web/offices/pac/mpep/consolidated\\_rules.pdf](http://www.uspto.gov/web/offices/pac/mpep/consolidated_rules.pdf).

<sup>83</sup> Section 161 Patent Act.

<sup>84</sup> 37 C.F.R. section 1.104 a) (1).

<sup>85</sup> Section 301 Patent Act.

under section 301. It must be mentioned that there is no possibility of re-examination on the basis of public use or knowledge. This has a particular effect on plant patents. Descriptions of plants generally do not meet the requirement of an enabling disclosure (section 112).<sup>86</sup> That is why descriptions of plants alone cannot destroy novelty.<sup>87</sup> On basis of public use of a plant there is no possibility of re-examination. Thus, an application of re-examination in the case of a plant patent just can be based on prior patents.

A patent lasts 20 years in accordance with the relevant provision in the TRIPS agreement.<sup>88</sup> The patentee has the exclusive right to make, use, offering for sale, sell and to import the patented invention in the United States as well as to prevent others from doing those actions.<sup>89</sup> In the case of a plant patent, “the grant shall include the right to exclude others from asexually reproducing the plant, and from using, offering for sale, or selling the plant so reproduced, or any of its parts, throughout the United States, or from importing the plant so reproduced, or any parts thereof, into the United States”.<sup>90</sup>

### c) Summary Patent systems

As seen both the EPC and the US Patent Act exclude the grant of patents on natural products and genetic resources that are not modified by human beings because they are not seen as new or including an inventive step. However, biological material that is isolated, purified, or modified by a technical process is patentable in both systems<sup>91</sup>. Mere knowledge of the (medicinal etc.) effect of a genetic resource is not eligible for being patented. Theoretically, inventions that are based on genetic resources or traditional knowledge collected from indigenous communities are not patentable without any innovation and modification by the patent applicant.

But there is the practical possibility in both patent systems that patents are granted although the requirements of patentability have not been met. The main reason is that the examiners in the patent offices when examining the state of the art are restricted to

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<sup>86</sup> Cf. section 162 Patent Act: “No plant patent shall be declared invalid for noncompliance with section 112 of this title if the description is as complete as is reasonably possible.” The inversion of this argument is that generally descriptions of plants do not meet the requirements of section 112.

<sup>87</sup> Cf. 37 U.S.C. §1.906 a).

<sup>88</sup> Section 154. 2 Patent Act.

<sup>89</sup> Section 154 Patent Act.

<sup>90</sup> Section 163 Patent Act.

<sup>91</sup> Article 52 EPC, Rules 23 b – e of the Implementing Regulations; Section 101 Patent Act, U.S. Supreme Court, *GRUR International* 1980, at 627, 629.

sources that are accessible to them. Mainly these sources are written documents in patent literature. Inventions based on genetic resources and traditional knowledge are problematic since traditional knowledge is usually transferred orally from generation to generation and tends not to be written down. Under these circumstances it is practically impossible for the patent offices to consider traditional knowledge as state of the art because they normally do not have access to this information.

Even if traditional knowledge is written down there is still the problem of access to these documents. It can be presumed that also traditional knowledge which was written down has not been published in patent literature. This kind of literature, however, is the main source of information for the patent offices. Another reason for the grant of those ‘bad’ patents can be seen in the cost factor and time factor which restrict the examination.

In the case of the US Patent Act the relative novelty with respect to the public use and knowledge in foreign countries combined with the lacking possibility of re-examination on the basis of public use could facilitate the grant of patents on inventions based on genetic resources and traditional knowledge that have been developed and used by indigenous communities for a long time. Although those patents meet the patentability requirements of the Patent Act, provided they are considered non-obvious and useful, they must be considered as ‘bad’ patents as well.

Now it must be analyzed whether the patents which are claimed to be ‘bad’ patents were in fact granted unlawfully and whether the allegations against those patents are legitimate.

d) Neem patent

*(1) Grant of the patent and opposition*

The neem tree is indigenous to the Indian subcontinent and parts of South and Southeast Asia.<sup>92</sup> In 1994 the multinational corporation W.R. Grace and the US Department of Agriculture was granted a patent by the EPO “covering a (special) method for controlling fungi on plants by the aid of a hydrophobic extracted neem oil” that is

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<sup>92</sup> Shiva, note 34, at p. 7; Report of the British Commission on IPR, note 4 at 76; Linda Bullard, ‘*Freeing the Free Tree*’, (March 2005) available at <http://www.wloe.de/WLOE-en/information/globalization/global-fs.html>.

diluted with a certain percentage of water.<sup>93</sup> The company claimed that the formulation, in contrast to the traditional one, is stable over a long period of time and that the processing of neem seeds involves steps that are novel.<sup>94</sup>

On the 14.06.1995, nine months after the grant a member of the European Parliament of the Green Party joined by the Research Foundation for Science, Technology, and Natural Resource Policy from India and the International Federation of Organic Agriculture Movement (IFOAM) based in Germany filed an opposition to this patent which mainly was based on the claim of lack of novelty and inventive step as well as on insufficient enabling disclosure.<sup>95</sup> The opponents claimed “that the fungicidal effect of hydrophobic extracts of neem seeds was known and used for centuries on a broad scale in India” both in traditional medicine to fight human skin fungi and in agriculture to protect crops<sup>96</sup>. Even the concentration of neem oil in the emulsion that was claimed by the patent to be new had been discovered before.<sup>97</sup> The same was said to be true for the “claimed method to produce the hydrophobic extracted neem oil”.<sup>98</sup> Thus, the opponents claimed that the invention lacked the two major patentability requirements “novelty” and “inventive step”. Apart from that it was alleged that the neem patent violates old Indian traditions of sharing the neem tree and the knowledge related with it by allowing private ownership of this important resource.<sup>99</sup> This privatization of traditional knowledge would threaten the livelihood of countless Indian farmers and indigenous cultures as many applications and products related with the neem tree as well as the evaluation of new uses would become illegal.<sup>100</sup> The TRIPS agreement would enable the patent holder to enforce his patent worldwide with the result that the patentee would be able to claim exclusive use of neem even in India<sup>101</sup>. Moreover, the increasing demand for neem seeds by the W.R. Grace corporation had caused the prices

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<sup>93</sup> Shiva, note 34, at p.6; Report of the British Commission on IPR, note 4 at 76; Gerard Downes, note 5, at 18; EPO document T 0416/01, available at <http://legal.european-patent-office.org/dg3/pdf/t010416eu1.pdf>.

<sup>94</sup> Philip Schuler, ‘*Biopiracy and Commercialization of Ethnobotanical Knowledge*’, in: J. Michael Finger and Philip Schuler (ed.), *Poor People’s Knowledge Promoting Intellectual Property in Developing Countries (2004)*, 159-181, at 161, 162.

<sup>95</sup> Shiva, note 34, at p.6,7; Report of the British Commission on IPR, note 4, at 76; Bullard, note 92, at 3.

<sup>96</sup> Bullard, note 92, at 3; Shiva, note 34, at 7.

<sup>97</sup> Notice of opposition 14.05.1995 to patent EP0436257B1, available at epoline® Online Public File Inspection service <http://ofi.epoline.org/view/GetDossier>, at p. 4; Schuler, note 94, at 163

<sup>98</sup> Shiva, note 34, at 7; Schuler, note 94, at 162.

<sup>99</sup> Bullard, note 92, at 1; Shiva, note 34, at 7

<sup>100</sup> Luna, note 37, at 19.

<sup>101</sup> Folkins, note 5, at 345.

“to skyrocket beyond the reach of the ordinary people”.<sup>102</sup>

### *(2) Decision of the European Patent Office*

In 2000, five years after filing the opposition, the Opposition Division of the EPO revoked the patent entirely.<sup>103</sup> It based its ruling on the grounds that the submitted evidence had destroyed novelty and inventive step of the invention because it had shown prior public use respectively prior art with regard to inventive step.<sup>104</sup> Even the auxiliary request of W.R. Grace and the US Department of Agriculture in which the concentration of the neem formulation was slightly changed as to fall just outside the range that was publicly used was rejected on the ground that it was lacking an inventive step.

The issue was taken to the EPO’s Technical Board of Appeals, when W.R. Grace and the US Department of Agriculture appealed the decision in accordance with article 106 EPC. On 08.03.2005 the body dismissed the appeal and decided to uphold the decision of the Opposition Division to revoke the patent in its entirety.<sup>105</sup> The ruling was based on the lack of an inventive step.<sup>106</sup>

### *(3) Comment*

The invention claimed by the successfully challenged patent was indeed one based on a genetic resource of a Developing Country, the neem tree, and based on traditional knowledge related with that tree. The traditional knowledge used was the knowledge about the fungicidal effect of neem oil. The invention apparently did not involve a sufficient inventive step. Thus, it must be seen as a ‘bad’ patent. This example also shows that the examination process of the Patent Office was insufficient. With a little more effort the examiner must have noticed that neem fungicides had been used in India for a long time and that the claimed extraction process was not fundamentally different from the traditional one. With regard to the opposition procedure of the EPO it can be determined that it is working to fight ‘bad’ patents, particularly because prior use in foreign countries can be a ground of a challenge. However, the deadline of nine months for notification of an opposition is quite short. Particularly for possible

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<sup>102</sup> Bullard, note 92, at 2.

<sup>103</sup> Report of the British Commission on IPR, note 4 at 76; Bullard, note 92, at 5; Shiva, note 34, at 7,8.

<sup>104</sup> Bullard, note 92, at 5; Shiva, note 34, at 7; Report of the British Commission on IPR, note 4 at 76.

<sup>105</sup> Bullard, note 92, at 6.

<sup>106</sup> Notification of Decision to patent EP0436257B1 by the Boards of Appeal, 08.03.2005, available at epoline® Online Public File Inspection Service, confer note 97, at 25.

opponents from non EPC countries it is very difficult to learn of the patent in such a short period of time as the patent is not published in those countries.

However, the allegations put forward need some comment.

The argument that the patenting is a contradiction of the Indian practice of sharing the knowledge related with the neem tree and would affect the livelihood of Indian farmers reveals a misunderstanding of the effects and goals of Patent law. The Patent law was developed to stimulate innovation by rewarding the inventor with a monopoly for a limited period of time.<sup>107</sup> It does not aim at goals of development politics.

Moreover, the patent granted by the EPO would not have given the inventor any right on the neem tree itself or on the neem seeds. Such allegations brought against this patent are too far reaching.<sup>108</sup> The patent just would have granted the patentee an exclusive right to make use of the patented invention, namely the special method of processing the emulsion and fighting fungi on plants, and to prevent others from doing so. However, the protection is strictly limited to the territory of the Contracting Parties of the EPC in respect of which the patent was granted. There is no worldwide enforcement of a patent; neither the EPC nor the US Patent Act can be enforced in other countries.<sup>109</sup> Neither of both Patent laws give the patentee a right which would allow him to restrict or prohibit local communities in foreign countries the use of their genetic resources. Thus, the use of the neem tree or the neem seeds as well as the products in India which are based on them could not have been prohibited by the W.R. Grace patent. The local communities in India still would have been able to invent other products or processes related with the neem and to use them. They even could have used the patented invention without any restriction as long as there would not have been a patent in India on the same subject-matter. The tradition of freely sharing the neem tree still could have been carried on. Certainly Indian companies could not have been prevented from commercialising their own neem fungicides by the controversial patent. In fact they have produced neem based pesticides and sold it to the world market.<sup>110</sup>

Although W.R. Grace drew upon traditional knowledge of practices in India, the

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<sup>107</sup> Report of the British Commission on IPR, note 4, at p.5; 14.; David Downes, CIEL, note 6, at 3.

<sup>108</sup> vide: David Downes, CIEL, note 6, at 18.

<sup>109</sup> for the EPC vide Articles 3, 64 EPC. General principle that national laws cannot be applied abroad (territorial principle); Gepts, note 18, at 1296; Correa, *IPR*, note 22, at 176.

<sup>110</sup> Schuler, note 94, at 165.

corporation nevertheless also used many industrial techniques that are in the public domain in industrialised countries. Thus, the inventor also used knowledge developed from other people or communities in respect of which nobody of the opponents complained about unauthorised exploitation. As Graham Dutfield stated correctly “if one argues that patenting of inventions based on traditional knowledge is exploitative of the indigenous communities, one also has to argue that it is inherently exploitative of all people past and present that had contributed to the state of the art relevant to the patent”. This position would be difficult to sustain as “state of the art includes... also the industrial techniques that can be applied to produce neem derivatives that are in one way or another more useful than the natural product”.<sup>111</sup> “In other words, traditional and Western technologies in the public domain were exploited equally”.<sup>112</sup>

Besides, the neem patent is a good example to weaken the argument that taking genetic resources for producing a new product amounts to an exploitation of the genetic resources of indigenous communities.<sup>113</sup> Genetic resources are quite difficult to assign to a specific “owner”. The neem tree, for example, is found in many countries what makes it virtually impossible to give one local community an “exclusive ownership” over this genetic resource. It could also be treated as being available for everyone. With traditional knowledge the same problem can arise if more than one local community has developed the same or very similar knowledge about a specific genetic resource.

As to the allegation of rising prices because of the patent it must be stated that it is possible that an increasing demand for neem seeds has led to higher prices.<sup>114</sup> But this problem is the effect of an increasing demand without higher supply and is not always and by all means connected with the grant of a patent. Even without patent protection corporations can invent something for which they need a natural substance. If this invention is successful the demand for this particular natural substance which is needed for the production of the invention will increase and therefore the price will rise as well. “Even if Indian firms had commercialised the new product, the same impact would have been observed”.<sup>115</sup>

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<sup>111</sup> Dutfield in: Peter Drahos, note 6, at 141.

<sup>112</sup> David Downes, CIEL, note 6, at 18.

<sup>113</sup> ETC Group in: Report of the British Commission on IPR, note 4, at 74; Susan Sell, note 4, at 202; Dutfield, *What is 'biopiracy'?*, note 4, at 1,3; Folkins, note 5, at 343; Gerard Downes, note 5, at 15.

<sup>114</sup> Bullard speaks of „skyrocketing prices“, Bullard, note 92, at 2; Schuler, note 94, at 165.

<sup>115</sup> Schuler, note 94, at 165.

Besides this negative impact there can be a positive effect of rising prices. There is a chance of rising income. Farmers, for example, could grow the natural substance (e.g. neem) that is demanded and earn an additional income which they would not have been able to achieve without that invention based on a genetic resource. Of course, not everybody who previously used the neem seeds will be able to profit from rising prices. Linda Bullard in her article refers to the healers and local oil millers who previously could access the neem seeds freely and now are not able to do it anymore due to higher prices.<sup>116</sup> But as mentioned this particular problem of higher prices cannot be exclusively connected with the grant of a patent. The existing system of a free market economy must be blamed for.

The allegation that the neem patent did not meet the statutory patentability requirements of inventive step and novelty can be ascertained to be true. Those accusations that the local communities would be prevented from using the neem tree as they did before are too far reaching.

#### e) Turmeric Patent

##### *(1) Grant of the patent and opposition*

The plant Turmeric belongs to the ginger family.<sup>117</sup> It has long been used predominantly in Asia as a spice and colouring agent as well as in the traditional Indian Ayurvedic medicine.<sup>118</sup> In the medicinal context it has been traditionally used to treat a variety of ailments, particularly “to heal wounds and rashes”<sup>119</sup> as Turmeric possesses an ingredient which is particularly effective in treating “inflammatory conditions”.<sup>120</sup> In 1995 the USPTO granted two Indian nationals at the University of Mississippi patent no. 5,401,504 for a “method of promoting healing of a wound in a patient” by “administering a wound healing agent consisting of an effective amount of turmeric powder”.<sup>121</sup>

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<sup>116</sup> Bullard, note 92, at 2.

<sup>117</sup> Report of the British Commission on IPR, note 4, at 76.

<sup>118</sup> Schuler, note 94, at 166;

<sup>119</sup> Report of the British Commission on IPR, note 4, at 76.

<sup>120</sup> Gerard Downes, note 5, at 18; World Intellectual Property Organization (“WIPO”), ‘*Intellectual Property and Traditional Knowledge*’, booklet no.2; available at: [www.wipo.org/freepublications/en/tk/920/wipo\\_pub\\_920.pdf](http://www.wipo.org/freepublications/en/tk/920/wipo_pub_920.pdf) at 28.

<sup>121</sup> WIPO, *IP and TK*, note 120, at 28; Schuler, note 94, at 167; Report of the British Commission on IPR, note 4, at 76; Gerard Downes, note 5, at 18; Tripathi, note 5, at 4; J. Michael Finger, *Introduction and Overview*, in: J. Michael Finger and Philip Schuler (ed.), *Poor People’s Knowledge Promoting Intellectual Property in Developing Countries (2004)*, 1-36, at 22.

The patent applicants recognized the traditional use of turmeric in India but claimed that they had been the first who administered Turmeric powder orally and topically as a single agent modality for wound healing.<sup>122</sup>

This patent was challenged by the Indian Council for Scientific and Industrial Research (“CSIR”) in 1996 on the ground of prior art.<sup>123</sup> In the re-examination process the CSIR claimed “that turmeric has been used for thousands of years for healing wounds and rashes and therefore its medicinal use was not novel” and produced an old Sanskrit document as well as a scientific article published in 1953 in the Journal of the Indian Medical Association.<sup>124</sup> Moreover the CSIR claimed that both the oral and the topically application of Turmeric powder for the purpose of healing wounds had been known.

### *(2) Decision of the US Patent Office*

The USPTO upheld these objections and revoked the patent in its entirety in April 1998.<sup>125</sup> It based its decision on the grounds of lacking novelty and obviousness of the invention.<sup>126</sup>

### *(3) Comment*

The Turmeric patent was based on genetic resources and traditional knowledge of a developing country and indeed it was not novel therefore it was a ‘bad’ patent. The claimed “invention” was the known traditional use of the plant.

This case illustrates that ‘bad’ patents are often granted because prior art references are not available or even inaccessible to the patent office examiners.<sup>127</sup> Most of traditional knowledge tends not to be written down therefore it cannot be examined by the Patent Office. At the time of the patent application the USPTO had no documentation available about possible prior art in other countries. Thus, it is important for developing countries to make accessible to the Patent Offices as much information and documentation as possible. But changing the examination process of the Patent Offices is just as urgent. It must be more comprehensive and include more databases, even from foreign countries.

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<sup>122</sup> WIPO, *IP and TK*, note 120, at 28; Schuler, note 94, at 167.

<sup>123</sup> Schuler, note 94, at 167; Tripathi, note 5, at 4; Report of the British Commission on IPR, note 4, at 76; David Downes, CIEL, note 6, at 18.

<sup>124</sup> Report of the British Commission on IPR, note 4, at 76; Tripathi, note 5, at 4; J. Michael Finger, note 121, at 22.

<sup>125</sup> Report of the British Commission on IPR, note 4, at 76; Tripathi, note 5, at 4; Schuler, note 94 at 167.

<sup>126</sup> *Ibid.*

<sup>127</sup> WIPO, *IP and TK*, note 120, at 28; Carlos M Correa, ‘*Traditional Knowledge and Intellectual Property: Issues and Options surrounding the protection of traditional knowledge*’, (November 2001) available at:

<http://www.iucn.org/themes/pbia/themes/trade/training/TK%20and%20Intellectual%20Property.pdf>, at 7.

However, in this case novelty could only be denied because the traditional use had been documented in written form. As mentioned above, the US Patent Act does not recognize prior use in foreign countries as prior art. This is a disadvantage for indigenous communities and developing countries that possess genetic resources and traditional knowledge. The likelihood of ‘bad’ patents granted on such traditional use or knowledge is higher than under the rules of absolute novelty. At least the opposition provisions in the US Patent Act worked as they should and this ‘bad’ patent could be revoked. This decision was the “first time that a patent based on the traditional knowledge of a developing country had been successfully challenged”.<sup>128</sup>

As to the effect of the patent it must be stated that the Indian local communities would not have been negatively affected by the patent, just as seen in the neem case. There would not have been an exploitation of those communities. The patent was confined to the exclusive right to use the claimed method and limited to the territory of the USA. The Indians could still have used the Turmeric for medicinal and other purposes.

#### f) Ayahuasca Patent

##### *(1) Grant of the patent and opposition*

In 1986 Loren Miller, an American, obtained a plant patent granted by the USPTO to a variety of *Banisteriopsis caapi*.<sup>129</sup> The so called Ayahuasca is a South American vine which is used in traditional rituals by indigenous Indian tribes for religious and medicinal purposes.<sup>130</sup>

The applicant claimed that he had bred a new variety of Ayahuasca from samples which he had obtained from a indigenous family in Ecuador and that this variety, which he called “Da Vine”, “represented a new and distinct variety of *B. caapi*, primarily because of the flower colour” and leaf shape.<sup>131</sup> The patentee never made commercial products from the plant.

In 1994 the Coordinating Body of Indigenous Organizations of the Amazon Basin (“COICA”) became aware of the patent and organized protest against it. It objected to

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<sup>128</sup> Report of the British Commission on IPR, note 4, at 76.

<sup>129</sup> Luna, note 37, at 6; Schuler, note 94, at 169;

<sup>130</sup> Manuel Ruiz Muller, *Regulating Bioprospecting and Protecting Indigenous Peoples’ Knowledge in the Andean Community: Decision 391 and its Overall Impacts in the Region*; in: Sophia Twarog and Promilla Kapoor (ed.), *Protecting And Promoting Traditional Knowledge: Systems, National Experiences And International Dimensions*, UNCTAD 2004, 241-262, at 249; Wüger, note 1, at 193; Finger, note 121, at 26.

<sup>131</sup> Report of the British Commission on IPR, note 4, at 77; Luna, note 37, at 6; Schuler, note 94, at 169.

the patent because it would give foreign people rights to a plant of the Amazon basin that is regarded as sacred by many indigenous communities there.<sup>132</sup> On behalf of this organisation the Center of International Environmental Law (“CIEL”) filed a re-examination request at the US Patent Office. It was protested that the variety “Da Vine” was neither new nor distinct from known varieties. The plant had been widely known in literature in foreign countries and even was “identical to other specimen of Ayahuasca found in the U.S. herbarium collections”<sup>133</sup>. The variety was claimed not to be useful because it would violate the religious feelings of many indigenous communities therefore violating section 101 Patent Act.<sup>134</sup>

### *(2) Decision of the US Patent Office*

In November 1999 the USPTO revoked the patent on the basis that the claimed variety was identical to other specimens in the U.S. herbarium collections, thus it was not novel and not distinct why the patent never should have been granted.<sup>135</sup> The Patent Office, however, did not address the issue whether the sacred status of the Ayahuasca in the Amazon basin prevented its patentability on the grounds of non-utility.<sup>136</sup>

After the patentee appealed the decision the USPTO reinstated the patent in 2001 on the grounds that there was not enough evidence to show non novelty.<sup>137</sup> However, two years later, in June 2003, the 17 year protection period of the patent expired.<sup>138</sup>

### *(3) Comment*

The Ayahuasca plant patent was only granted on the basis of unique characteristics as the flower colour. Thus it did not include traditional knowledge or medicinal interesting compounds possibly contained in the plant and did not grant intellectual property rights with regard to these contents. The patent granted protection only to the variety “Da Vine” and to the asexually reproduction of this variety.<sup>139</sup> “Da Vine” only was patentable because the US Patent law does not exclude plants from patentability as allowed under article 27.3 b) of the TRIPS agreement. Indeed it recognizes patents on

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<sup>132</sup> Schuler, note 94, at 170.

<sup>133</sup> Wüger, note 1, at 194; Luna, note 37, at 10; Schuler, note 94, at 170; Report of the British Commission on IPR, note 4, at 77.

<sup>134</sup> Finger, note 121, at 26; Wüger, note 1, at 194.

<sup>135</sup> Schuler, note 94, at 170; Report of the British Commission on IPR, note 4, at 77; Luna, note 37, at 11; Wüger, note 1, at 194.

<sup>136</sup> Wüger, note 1, at 194.

<sup>137</sup> Wüger, note 1, at 194.

<sup>138</sup> Luna, note 37, at 14.

<sup>139</sup> Section 163 Patent Act: “the using, offering for sale, or selling the plant so reproduced or importing the plant so reproduced” are prohibited as well.

plants. Moreover it could only be granted because of the relative novelty definition in section 102 of the Patent Act. The plant features were not known in the USA and prior use in foreign countries could not be recognized by the USPTO according to the relative novelty definition.<sup>140</sup> Additionally the problem that descriptions of plants generally do not destroy novelty because they do not meet the criteria of an enabling disclosure in section 112 became relevant in this case.<sup>141</sup> Although there arguably was scientific literature about the plant the USPTO did not regard it as destroying novelty. It just relied on the argument that the claimed variety could be found in herbarium collections, respectively could not be found in the collections when reinstating the patent. Luna in his article claims that the USPTO “conveys an inconstancy in” its actions by revoking a patent that “did not meet their own stated criteria”.<sup>142</sup>

Although the Ayahuasca patent was only based on the unique characteristics of the variety that was claimed to be new there were allegations that this patent would amount to a misappropriation of an important religious symbol and of a violation of sacred customs. One could concede that this criticism is partly true because, according to the provisions of the Patent Act, patents even could be granted on plants that are used for religious ceremonies by indigenous communities. Indeed, the USPTO in the Ayahuasca case “did not recognize claims that patents should not be granted to sacred plants”.<sup>143</sup> The Patent Act does not offer a solution for moral objections.<sup>144</sup> But on the other hand a plant patent cannot in any case block the indigenous communities’ right to perform their traditional uses of the plant. An uncultivated plant in its status found in nature cannot be patented. Just asexually reproduced “new” and “distinct” varieties may be the subject of a plant patent. Even if the USPTO would grant a patent to a plant variety that is not new or distinct contrary to the provisions of the Patent Act the patentee just could exclude others from using the asexually reproduced plant, “or any of its parts”.<sup>145</sup> The patent protection only covers the asexually reproduced variety claimed by the applicant, i.e. one variety within the whole Ayahuasca genus. Moreover the protection is limited to the territory of the United States. In no case indigenous communities in other countries

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<sup>140</sup> The USPTO in its appeal decision held that the Da Vine variety is not identical to the specimens documented in the U.S. herbarium collections; Wüger, note 1, at 194.

<sup>141</sup> Vide part IV B b) and footnotes 81, 82.

<sup>142</sup> Luna, note 37, at 14.

<sup>143</sup> Schuler, note 94, at 170.

<sup>144</sup> Vide part IV B 1. b): The Patent Act does not provide for a “morality” exception from patentability.

<sup>145</sup> Section 163 Patent Act.; Against such a patent a re-examination would be possible on the grounds of non-novelty or non-distinctness.

could be affected in their sacred customs. They could even use the “Da Vine” variety. Thus, the Ayahuasca patent cannot be seen as a violation of sacred traditional uses. According to Schuler the Ayahuasca patent also shows that “simply receiving a patent does not translate into their commercialization or preventing existing uses of a product”<sup>146</sup>. The patentee never made attempts to commercialise the patent at indigenous communities’ expense.

Another argument can be put forward to support the patentability of genetic resources traditionally used in religious contexts. An exclusion of the patentability of those resources would be a legally unjustified preferential treatment. There would be an exclusive right (protection) in favour of genetic resources that are traditionally used in religious contexts. Such an exclusive right, however is criticised when it is granted by a patent. Moreover it would be difficult to draw a line which genetic resources are regarded as sacred and which not. The approach to make no differences at all seems to be fairer.

#### g) Summary ‘bad’ patents

In contrast to the allegations the main reason for the grant of ‘bad’ patents generally seems not to be the patentability requirements but the Patent Offices’ practice of novelty examination. Both the EPC and the US Patent Act theoretically require a comprehensive examination<sup>147</sup> but in practice the research is confined to patent based information like patent literature.<sup>148</sup> Moreover the examination is limited by economical and time reasons. And traditional knowledge tends not to be documented and therefore is almost impossible to access for Patent Offices. However, the relative novelty in the US Patent Act must be criticised for increasing the likelihood that a ‘bad’ patent is granted. In this respect one could also criticise the TRIPS agreement for allowing such a definition of novelty.

As seen, neither the EPC nor the US Patent Act grant the patentee a right that would prevent local communities in developing countries from using their genetic resources and traditional knowledge. Patents do not have legal effect in foreign countries. Thus

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<sup>146</sup> Schuler, note 94, at 171.

<sup>147</sup> For the US Patent Law: US Title 37, § 1.104 demands a “thorough investigation of the available prior art relating to the subject matter of the claimed invention”. For the EPC: vide Rule 44 of the Implementing regulations to the European Patent Convention.

<sup>148</sup> Report of the British Commission on IPR, note 4, at 82.

patentees cannot prohibit the use, production and sale of their invention in other countries where they do not have a patent. The indigenous communities even could use, copy and sell the patentee's invention in their country, at least as long as there is no patent on the invention.

Against this background Schuler notes that it should be recognized that “simply awarding a patent in an industrial country generally does not cause economic harm to those who developed the traditional knowledge”.<sup>149</sup> In “none of these cases had the new product displaced the traditional product in the developing country”.<sup>150</sup>

The neem case is a good example for these statements. Even without patent protection the W.R. Grace Corporation could have “invented” the method of fighting fungi on plants and could have built factories that produce the neem oil emulsion and for which the neem seeds are needed. The traditional practices would not have been affected differently. Thus, a possible economic impact “comes from commercialization of products rather than awarding IPR protection”.<sup>151</sup>

In this respect ‘bad’ patents do not exploit indigenous communities or developing countries and the criticisms are exaggerated.

In fact, many arguments that criticise patentability of genetic resources of developing countries or indigenous communities are therefore based on moral grounds. The patents are alleged to violate sacred customs *inter alia*. This criticism can be dismissed as well. Firstly, Patent Law was not developed to protect cultural traditions, thus it is a “poor instrument for blocking cultural degradation”.<sup>152</sup> Secondly, as seen in the neem case, if one speaks about “exploitation” of knowledge, one has to keep in mind that generally both western and indigenous knowledge is being exploited by ‘biopiracy’ patents. There is no legal reason to treat biological inventions for which genetic resources of developing countries have been used in a different way as inventions based on genetic resources from developed countries. Apart from the fact that they originate in other parts of the world there is no significant difference. Both can be the basis of biotechnological inventions which must be patentable. This is being said particularly against the background that there is no direct exploitation related with those patents. The sacred traditions and customs related with the genetic resource can still be

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<sup>149</sup> Schuler, note 94, at 177.

<sup>150</sup> *Ibid.*

<sup>151</sup> *Ibid.*

<sup>152</sup> Schuler, note 94, at 171.

performed as long as there is no ('bad') patent in the developing country itself. Moreover, there are many possibilities for a developing country to prevent a 'bad' patent to be granted that are shown later in this thesis.

There is, however, a negative economic impact for developing countries that can be connected with 'bad' patents. Based on his exclusive right the patentee can prevent the import of the patented invention into the country in which the patent was granted. According to article 28.1 TRIPS a patent must confer, among other rights, the right to prevent the import of the patented product or, "where the subject matter is a process" to prevent third parties from importing at least the product directly obtained by the patented. The USA and the markets of the European countries that are Contracting Parties of the EPC are important export markets for developing countries. The loss of these export markets and the loss of revenues appear possible. In a case where a patent was granted contrary to the Patent law provisions to an invention based on a genetic resource and traditional knowledge that was already known and used in developing countries, the loss of a possible or existent export market seems to be particularly painful. These 'bad' patents can be challenged but this procedure takes time and involves considerable costs.<sup>153</sup> Until there is a revocation of the 'bad' patent the patentee can prevent any "infringement" of the patent and block any unauthorised import. Valuable revenues for a developing country get lost.

This particular problem, however, can occur in the case of properly granted patents as well. It is the purpose of Intellectual Property Rights to promote technological innovation and development by giving an inventor a monopoly for a limited period of time and thus awarding him for his innovation. In return, the innovation becomes public knowledge after the time of protection and is accessible for everyone for other inventions. In contrast to the grant of a 'bad' patent the properly granted patent is novel invention that is just derived from genetic resources or traditional knowledge. Thus, the indigenous communities or companies from the developing countries could still export their traditional products without infringing the granted patent. In this case there is not the same danger of losing export revenues. The problem here is that the 'old' traditional invention has to compete with a 'new' one. This situation, however, is a normal process in an economy when new, presumably better, products are invented and compete with

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<sup>153</sup> For example in the case of the Neem patent 5 years; Turmeric case: 2 years; Ayahuasca: 4 years.

other products. Therefore, there is no sound legal reason to treat proper patents on inventions derived from genetic resources or traditional knowledge different from “usual” biotechnological inventions. If a patent is granted to a microbiological process, for example, this process and products directly obtained by this particular process cannot be imported without the authorisation of the patentee.<sup>154</sup> In this respect there is not as much criticism regarding the exclusive rights of a patentee. Additionally one has to keep in mind that companies from developing countries as well as the indigenous communities can also patent inventions based on their own genetic resources and traditional knowledge and profit from the import ban. Of course, considering that those countries generally do not have the same technological basis as more advanced countries, it is more difficult for them to profit. However, they could and should make use of the technological knowledge that is freely available in Western countries, either never patented or now in the public domain, to create new inventions based on their own knowledge and genetic resources. Developing countries can adjust their national legislation for this purpose as shown later in chapter VI.

As to the allegation that transnational corporations are the main beneficiaries of ‘biopiracy’, Dutfield notes in his article: “It is not the fault of the patent system per se that the main beneficiaries from trade in products derived from genetic resources appear to be corporations” from technologically advanced countries. “In the absence of a patent system, corporations would most probably still dominate this trade”.<sup>155</sup>

## 2. ‘Good’ Patents

The criticism that is related to ‘good’ patents does not refer to the actual grant of the patent. It is concerned with the allegation that those genetic resources and traditional knowledge that are the basis of an invention have been obtained illegally in violation of the Convention on Biological Diversity (“CBD”) without prior informed consent of the developing country or indigenous community concerned and that the indigenous community is not given a share in the benefits arising out of the commercialisation of

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<sup>154</sup> Article 37.3 b) TRIPS requires the patentability of microbiological processes. Article 28.1 b) extends the rights over patented process to products “obtained directly by that process”.

<sup>155</sup> Dutfield in: Peter Drahos, note 6, at 145.

that invention<sup>156</sup>. This practice would amount to an “uncompensated exploitation of their plant genetic resources” and is characterised as ‘biopiracy’.<sup>157</sup>

The developing countries and indigenous communities argue “that they have an entitlement to their plant genetic resources and traditional knowledge” and that they are the ‘root source’ of the invention what would give them a right to be compensated<sup>158</sup>. Most of the corporations that use those genetic resources and traditional knowledge deny any legal obligation to compensate local communities from which they obtained genetic resources or traditional knowledge<sup>159</sup>. For them traditional knowledge is in the public domain which is freely accessible to everyone<sup>160</sup>. Sarma also alleges that “transnational corporations enjoy large profits” from “products created by indigenous knowledge”.<sup>161</sup>

#### a) Hoodia Case

##### *(1) Case and opposition*

A very well known case that is concerned with those allegations is the Hoodia plant Case. The San people, indigenous inhabitants of Southern Africa, “have traditionally eaten” stems of the Hoodia plant “to stave off hunger and thirst on long hunting trips”.<sup>162</sup> Hoodia is a succulent plant that is indigenous to the semi-arid areas of Southern Africa.<sup>163</sup> After the Council for Scientific and Industrial Research in South Africa (“CSIR”) had identified and extracted the ingredient of the plant that acts as an appetite suppressant it applied for a patent on this active agent called P57 for different countries in accordance with the PCT.<sup>164</sup> The CSIR in its application claimed both “a

<sup>156</sup> Report of the British Commission on IPR, note 4, at 74, 77; , note 10, at p. 1; Sarma, note 19, at 116; Dolder, note 55, at 83.

<sup>157</sup> Sarma, note 19, at 116, 117; Report of the British Commission on IPR, note 4, at 74; Dolder, note 55, at 83.

<sup>158</sup> Sarma, note 19, at 117; Luna, note 37, at 9.

<sup>159</sup> Sarma, note 19, at 118.

<sup>160</sup> Sarma, note 19, at 118; Jorge A. Cabrera Medaglia, ‘Access to Genetic Resources, Protection of Traditional Knowledge, And Intellectual Property Rights: The Costa Rican Experience’, in: Sophia Twarog and Promila Kapoor (ed.), *Protecting and Promoting Traditional Knowledge: Systems, National Experiences And International Dimensions*, UNCTAD 2004, 197-210, at 197.

<sup>161</sup> *Ibid.*, at p. 112.

<sup>162</sup> Report of the British Commission on IPR, note 4, at 77; Carolina Lasén Díaz; ‘Intellectual Property Rights and Biological Resources: An Overview of Key Issues and Current Debates’, Science Centre North-Rhine-Westphalia, Wuppertal Institute for Climate, Environment and Energy, 2005, available at <http://www.wupperinst.org/Publikationen/WP/WP151.pdf>, at 18; Rachel Wynberg, *Benefit-Sharing in South Africa: Fact or Fiction?*, in: Sarah A Laird (ed.), *Biodiversity and Traditional Knowledge: Equitable Partnerships in Practice*, Earthscan Publications (2001), at. 3; Dolder, note 55, at 83.

<sup>163</sup> Díaz, note 162, at 18.

<sup>164</sup> Dolder, note 55, at 83,84; International Patent Application under the Patent Cooperation Treaty (1970), Appl. No. PCT/GB98/01100; Publication No. WO 98/46243, available at <http://www.wipo.int/pctdb/en/>.

process for preparing an extract of a plant ... of the genus Hoodia ... comprising an appetite suppressant agent” and the extract itself, respectively a composition of the extract. Even “a method of suppressing an appetite by administering ... an effective dosage of a composition as claimed” should be covered by the patent.<sup>165</sup> Dolder notes that the invention hardly contained any new “intellectual input” compared to the traditional knowledge used.<sup>166</sup>

In 1997 the CSIR came to an agreement with the UK pharmaceutical corporation Phythopharm in which the later received the licence for further development and commercialisation of the active agent of the Hoodia plant.<sup>167</sup> Phytopharm announced in 1998 that it had sold its licence to the US company Pfizer for \$32 million in royalty and milestone payments.<sup>168</sup> When the San learned from that case in 2001 the then established ‘South African San Council’ spoke of ‘biopiracy’. It “claimed that their traditional knowledge had been stolen and CSIR had failed to comply with the rules of” the Convention on Biological Diversity.<sup>169</sup> The San claimed a fair share of the benefits arising from the commercialisation of P57.

## *(2) Reach of an agreement*

Urged by international pressure CSIR entered an agreement with the San Council in March of 2003. The agreement provided for a 8% share of milestone payments, “a payment to be made by CSIR’s licensee Phytopharm during the drug’s clinical development” and for a 6% share of the royalties CSIR will receive when the drug derived from P57 is being marketed.<sup>170</sup> This benefit sharing agreement attracted criticism immediately. One of the criticisms relates to the small payment that that the San will receive. It was estimated that they will receive “less than 0,003% of net sales of the product, which will come from the CSIR’s share” whereas Pfizer and Phytopharm will not pay anything. The fair distribution of the payments among the San in the different countries in Southern Africa was seen as problematic.<sup>171</sup>

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<sup>165</sup> both Dolder, note 55, at 84.

<sup>166</sup> Ibid. at 85.

<sup>167</sup> Report of the British Commission on IPR, note 4, at 77; Díaz, note 162, at 19.

<sup>168</sup> Wynberg, note 162, at 3; Report of the British Commission on IPR, note 4, at 77; Kate / Laird, *Bioprospecting*, note 2, at p. 146; Díaz, note 162, at 19.

<sup>169</sup> Report of the British Commission on IPR, note 4, at 77.

<sup>170</sup> Díaz, note 162, at 19; Press release CSIR, 24.03.2003, available at [www.csir.co.za](http://www.csir.co.za); Report of the British Commission on IPR, note 4, at 77.

<sup>171</sup> Both Díaz, note 162, at 20.

(3) *Comment*

Although the figure of 0,003% of the net sales appears to be very small at the first glance, the sum that could be received could still be substantial as the potential market for an anti-obesity drug is possibly considerable.<sup>172</sup> Thus, the IPR Commission came to the conclusion that the “case would appear to demonstrate that with goodwill on all sides, mutually acceptable arrangement for access and benefit sharing can be agreed”.<sup>173</sup> However, in 2003 Pfizer decided to cease the clinical development of P57 and returned its sub-licence back to Phytopharm.<sup>174</sup> Since 2004, a Hoodia preparation coming directly from South Africa is marketed by Canadian and US companies which share a portion of the net sales with the San people.<sup>175</sup>

b) Legal basis for benefit sharing / prior informed consent

The TRIPS agreement as the main legal framework for Intellectual Property Rights is not concerned with how genetic resources should be collected nor does it require prior informed consent of the indigenous community or developing country for patentability of inventions based on genetic resources or traditional knowledge. TRIPS also does not provide for compelling benefit sharing when a patent was granted to an invention derived from genetic resources or traditional knowledge. From this it follows that neither the EPC nor the US Patent Act provide such provisions.

Thus, it is uncertain on which legal basis the claimed requirement of prior informed consent and the right of benefit sharing could be grounded.

Many proponents of the requirement of prior informed consent and the right of benefit sharing refer to a violation of the CBD when genetic resources have been collected without prior informed consent or no benefit sharing has been agreed on.<sup>176</sup> Indeed, the CBD in its articles 3 and 15.1 declares that states have sovereign rights over their genetic resources and have the right to regulate access to them in national law.<sup>177</sup> Article 15.5 requires “that access to genetic resources should be subject to prior informed consent” of the respective country in which genetic resources are being

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<sup>172</sup> Report of the British Commission on IPR, note 4, at 77.

<sup>173</sup> Ibid. At p. 78.

<sup>174</sup> Díaz, note 162, at 20.

<sup>175</sup> Díaz, note 162, at 19; Press release [www.prweb.com/releases/2004/2/prwebxml105321.php](http://www.prweb.com/releases/2004/2/prwebxml105321.php); also [www.hoodia-dietpills.com](http://www.hoodia-dietpills.com).

<sup>176</sup> vide note 154.

<sup>177</sup> Convention on Biological Diversity, available at: [www.biodiv.org](http://www.biodiv.org)

collected.<sup>178</sup> This expression could indicate that there is an obligation to prove ‘prior informed consent’.

With respect to benefit sharing the CBD is more reserved. Article 15.7 CBD ‘encourages’ the equitable and fair sharing of benefits derived from the use of genetic resources under mutually agreed terms. Regarding the utilisation of traditional knowledge article 8 j CBD also just ‘encourages’ benefit sharing<sup>179</sup>. The Convention’s language in respect of benefit sharing is not compulsory but leaves ample discretion to the contracting parties. It is debatable whether article 8j confers a right to the holders of traditional knowledge.

Another problem regarding the presumption of a legal basis stems from the nature of the CBD as an international treaty. It just binds its contracting parties, i.e. states, and not individuals.<sup>180</sup> It does not confer rights or obligations on private individuals.<sup>181</sup> The obligations and rights provided for in the CBD must be transferred in national law before they can be applied to individuals and before individuals can claim rights<sup>182</sup>. As long as there is no national legislation in this regard indigenous communities cannot claim a right to benefit sharing nor is there an obligation to obtain prior informed consent from the indigenous community when collecting their genetic resources.

A more general problem regarding the application of the obligations and rights in the CBD stems from the controversial issue of the relationship between the CBD and the TRIPS agreement. Some countries argue that there is a contradiction between TRIPS and the CBD with regard to the provisions on access to genetic resources and benefit sharing in which the CBD would prevail.<sup>183</sup> Some others, particularly from the developed world, deny any connection between the CBD and TRIPS.<sup>184</sup> Every obligation of ‘prior informed consent’ or ‘benefit sharing’ in patent law would have to match with the TRIPS regulations. This controversy has not been settled up to now. Since this thesis does not deal with this issue, this question will not be discussed further.

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<sup>178</sup> IISD, note 13, at 2.

<sup>179</sup> Correa, *TK and IP*, note 127, at p. 8; IISD, note 13, at 2.

<sup>180</sup> Susette Biber-Klemm, ‘*Protection of Traditional Knowledge on Biological Diversity at the International Level: Reflections In Connection with World Trade*’, in: Sophia Twarog and Promila Kapoor (ed.), *Protecting and Promoting Traditional Knowledge: Systems, National Experiences And International Dimensions*, UNCTAD 2004, 95-105, at 99

<sup>181</sup> *ibid* at 99

<sup>182</sup> *ibid* at 99; UNCTAD Secretariat, note 46, at 356.

<sup>183</sup> WTO, IP/C/W/368, Note by the Secretariat, *The relationship between the TRIPS agreement and the Convention on Biological Diversity*, (2002), available at <http://docsonline.wto.org>, at 2, 6.

<sup>184</sup> *Ibid.* at p. 3.

Even in the case of a contradiction one could argue in accordance with the international principles for interpretation of a treaty codified in the Vienna Convention on the Law of Treaties 1969 that the TRIPS agreement as the later treaty prevails<sup>185</sup>.

So far regulations on prior informed consent or benefit sharing are not provided for by the TRIPS agreement. Thus, any national legislation in accordance with the CBD that provides for such an obligation or right in its intellectual property rights law must be examined whether it is compatible with the TRIPS agreement. That will be done in the next chapter when analyzing in which ways developing countries can prevent 'biopiracy'.

Based on the arguments mentioned above one can state that indigenous communities do not have a legal basis for their claim to benefit sharing or prior informed consent as long as there is no national legislation that transfers the CBD provisions in a manner that is compatible with the TRIPS agreement. In this respect patents on inventions based on traditional knowledge or genetic resources are not obtained illegally.

#### c) Moral grounds for benefit sharing / prior informed consent

The claims to benefit sharing and prior informed consent are also based on moral arguments.<sup>186</sup> There is the picture of exploitation of indigenous communities and of the developing country as a whole by transnational corporations from technological more advanced countries that successfully commercialise patented products derived from genetic resources and traditional knowledge that did not belong to them.<sup>187</sup> It is claimed that indigenous communities contribute to an invention by providing either genetic resources or traditional knowledge, sometimes both, but are in no way awarded for their contribution. This situation is considered as being inequitable.

Developing countries and indigenous communities as well are in a dilemma. They do not have the same financial and technological resources to make use of Intellectual Property Law and to profit from their own genetic resources and knowledge by

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<sup>185</sup> Article 30.3, 30.4 of the Vienna Convention; confer also article 31.

<sup>186</sup> Footnote 155, 156.

<sup>187</sup> Confer: Sarma, note 19, at 116, 117, 118; Luna, note 37, at 9 (citing the Union de Medicos Indigenas Yageceros de la Amazonia Colombiana), p. 51; Vijaya Kumar, *Protecting Traditional Knowledge: Systems and Experiences in Sri Lanka*, in : Sophia Twarog and Promila Kapoor (ed.), *Protecting and Promoting Traditional Knowledge: Systems, National Experiences And International Dimensions*, UNCTAD 2004, 299-304, at 302 ("unethical exploitation").

inventing new products. On the other hand technologically more advanced countries can extend their advantage with the help of patents and other intellectual property rights. This brings, respectively holds developing countries in a weak position in worldwide trade. Thus, the criticism of 'biopiracy' is arguably a general complaint about their current status in worldwide trade. The demand to participate in the profits of western corporations which are partly favoured by the contributions of indigenous communities might be legitimate and understandable.

However, arguing on moral basis in the context of Intellectual Property Rights Law is problematic. Patent Law neither aims at rewarding contributions to inventions nor does it regulate access to resources that are not protected by patents. In this respect Intellectual Property Law does not know moral arguments. Neither is TRIPS nor are national Patent Laws equipped to deal with moral arguments for benefit sharing. TRIPS in article 27.2 provides for an exception to patentability if the commercialisation of an invention is contrary to "morality"<sup>188</sup> but it does not provide for an obligation of the patentee based on morality to share the benefits that accrue from the invention. Arguably IPR law is not the right place to deal with such moral arguments.

Moreover there are also counter-arguments that could be put forward against a moral obligation to share benefits with indigenous communities that have contributed genetic resources or traditional knowledge.

As mentioned in the neem case, inventors of inventions derived from genetic resources and traditional knowledge of indigenous communities certainly draw upon knowledge that originated from local communities. But at the same time they also make use of many practices and knowledge that are in the public domain in industrialised countries, such as biotechnological techniques, either because they never were patented or patents had expired. One could say that in both cases technologies and knowledge that are available in the public domain are being exploited "without compensating those who originated them or their descendants".<sup>189</sup> Thus, it is supposed that traditional knowledge as every other knowledge is part of the public domain. Knowledge in the public domain,

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<sup>188</sup> Correa, IPR, note 22, at 62,63.

<sup>189</sup> David Downes, CIEL, note 6, at 18; Dutfield in. Peter Drahos, note 6, at 141.

however, is generally seen as freely accessible.<sup>190</sup> If the patentability requirements are applied accurately, the inventor must prove sufficient own creativity to obtain a patent. The changes to a genetic resource or traditional knowledge therefore must be significant to speak of an inventive step and novelty. If this is the case and patents are granted properly one could argue that there is no moral basis to demand benefit sharing as the new invention cannot be said to be one of the indigenous community. Rewarding the inventor only seems not to be illegitimate. Furthermore it appears to be “impossible to attribute an objective economic value overall” to the knowledge and the genetic resources that are contributed by the indigenous community.<sup>191</sup> For that reason David Downes proposes that an implementation of a benefit sharing provision in accordance with article 8j CBD should orientate itself to “the costs incurred by the indigenous community concerning their knowledge and biodiversity, rather than” to the value of it.<sup>192</sup>

One also has to keep in mind that there is a significant number of voluntary benefit sharing agreements between corporations and indigenous communities though particularly the Rural Advancement Foundation International criticises most of those agreements heavily.<sup>193</sup> The existence of voluntary benefit sharing could weaken the allegation that there is no benefit sharing.

These arguments demonstrate that it is almost impossible to argue firmly on moral grounds. There are always two sides and arguments in favour as well as against each of them. Moreover, morality can be defined in many different ways and in fact is defined variously in different countries.<sup>194</sup> There is not one single worldwide accepted definition. Thus, “it is impossible to deduce a single fair and equitable IPR system from the general human rights principle available to us” as David Downes notes correctly.<sup>195</sup>

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<sup>190</sup> Correa, *TK and IP*, note 127, at 3; Ana María Pacón, ‘*The Peruvian Proposal For Protecting Traditional Knowledge*’, in: Sophia Twarog and Promila Kapoor (ed.), *Protecting and Promoting Traditional Knowledge: Systems, National Experiences And International Dimensions*, UNCTAD 2004, 175-180, at 176, 178; WIPO, FFM Report 2001, note 12, at p. 36; Patricia Kameri-Mbote, ‘*Community, Farmers’ and Breeders’ Rights in Africa: Towards A Legal Framework For Sui Generis Legislation*’, International Environmental Law Research Centre, available at: [www.ielrc.org/content/a0302.pdf](http://www.ielrc.org/content/a0302.pdf), p. 11.

<sup>191</sup> David Downes, CIEL, note 6, at 8.

<sup>192</sup> Ibid. at p. 8.

<sup>193</sup> WIPO, *IP and TK*, note 120, at 24; Luna, note 37, at 43, 44; RAFI, note 16, at p. 4, 6 with examples; Medaglia, note 160, at 207.

<sup>194</sup> Correa, *IPR*, note 22, at 62.

<sup>195</sup> David Downes, CIEL, note 6, at 5.

One must conclude that the claim for a right to benefit sharing cannot be decided on moral grounds either. There are arguments in favour as well as against such a “right”. Thus, the claims relating to an obligation of ‘prior informed consent’ and a right of ‘benefit sharing’ cannot be validated. Firstly, there is no legal right unless the CBD provisions mentioned have been transformed in national law in a manner compatible with TRIPS. Secondly, it is by no means clear that indigenous communities can rely on moral obligations.

However, it will be shown that developing countries can nevertheless provide for compulsory benefit sharing with the help of suitable legislation outside Intellectual Property Law, namely in connection with regulations on access to genetic resources.

Thus, the criticisms regarding ‘good’ patents are exaggerated as well.

## **V. Intermediate Result**

As illustrated by the cases in chapter IV B) ‘bad’ patents have been granted under types of patent law as stipulated by the TRIPS agreement. The flexibility of TRIPS contributes to this problem since it does not prevent countries from defining novelty in a way that does not recognize traditional use in foreign countries as prior art. But as seen, for example, in the Turmeric case the main reasons for the grant of ‘bad’ patents are the non availability of documentation of traditional knowledge and the poor examination of novelty by the Patent Offices.

The relative broad flexibility of defining the patentability requirements makes it also possible that patents are granted for inventions that arguably do not involve significant own creativity. It could be the case that the ‘inventor’ mixes “scientific and technical expertise with certain aspects of the appropriated traditional knowledge or with the extracted active ingredient from native biological resources” and is able to obtain a patent<sup>196</sup>. Whether this mixture involves a sufficient inventive step that is worthy enough be patented or not or whether traditional knowledge should only be patented by its ‘creators’ is a question of ethics and morality. IPR law, however, is generally not concerned with morality<sup>197</sup>. If the invention meets the requirement of inventive step as stipulated in the respective patent law it should be ‘worth’ obtaining a patent though it

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<sup>196</sup> Confer Folkins, note 5, at 347.

<sup>197</sup> Aside from the possible exception to patentability in TRIPS if the commercialisation of an invention would be contrary to „morality“ (article 27.2) there is no provision that is explicitly concerned with morality.

also used aspects of traditional knowledge. There is no significant difference to the case where an inventor used other knowledge in the public domain.

Moreover, the same flexibility of TRIPS gives developing countries freedom to adjust their patent laws in a way that does prevent the grant of 'bad' patents at least in their territory and to develop a patent law that acknowledges their needs. Furthermore there are some limits in defining the patentability requirements of TRIPS. It would appear that the normal meaning of the words "novelty, inventive step and industrial applicability" are the outer limits of defining them. Applied in a proper way, patents on inventions derived from genetic resources and traditional knowledge should only be eligible if they in fact contain an inventive step and are not just "plagiarisms".

Even despite the 'bad' patents indigenous communities are not prevented to use their genetic resources and traditional knowledge as they have always done in the past. There is no violation of 'sacred customs' or other traditions. They could even try to profit from the "new" product or invent similar products. The economical effect of raising prices in the case of neem seeds could not be traced back to the grant of the patent. As far as this goes there is no injury or exploitation of the indigenous communities and developing countries through 'bad' patents. The criticisms in this respect are exaggerated.

Thus, it is more about moral allegations and moral obligations. This is also demonstrated by the discussion about benefit sharing which is more concerned with arguments based on morality than with one based on law. The supposed problems relating to 'bad' and 'good' patents refer only partially to patent law. Moral arguments, however, are no sound basis for the claimed "right" of benefit sharing. Indeed it is problematic to argue on moral grounds if one wants to ascertain a legal right. Thus a right to benefit sharing could not be determined.

The discussion about 'biopiracy' appears to be only one aspect of the wider topic of biodiversity protection and the worry about a just distribution of the benefits arising from its use and commercialisation. This discussion is therefore closely linked with the "old" conflict between developing and more developed countries which exists particularly in the context of worldwide trade and the issue of equal opportunities.

Patent law is not able to solve this kind of problems. Intellectual property rights cannot satisfy such needs since they were not developed for such purposes. Indigenous communities have protected and transferred their traditional knowledge and genetic resources over thousands of years without legal protection. So it might be assumed that they will do it in future as well despite an apparently “unfair” intellectual property system.

However, there are negative impacts on developing countries and indigenous communities that are related with ‘biopiracy’ and problems of intellectual property rights law that facilitate these problems.

There is the problem of losing export markets when a ‘bad’ patent is granted to an invention derived from genetic resources and traditional knowledge. Since the patent is the traditional invention itself the indigenous community or anybody else from the developing country that has traditionally used this invention cannot continue to export the traditional invention to the country in which the ‘bad’ patent was granted without infringing this patent. The patent gives the patentee the right to prevent the import of the patented invention without his authorisation<sup>198</sup>. Even with correctly granted patents a similar problem can arise. The traditional invention can still be exported but now the traditional product has to compete with a new patented product which has been derived from the traditional one and for which the indigenous community has not obtained any compensation although it had contributed the genetic resource and often related traditional knowledge as well.

As mentioned above the TRIPS agreement allows relative novelty definition which facilitates the possibility of granting patents that are essentially plagiarism of traditional knowledge although this is not the main reason for the grant of ‘bad’ patents.

Another aspect has to be addressed in this context. Until now the problems that ‘biopiracy’ causes have been dealt with but not how much ‘biopiracy’ actually occurs. From this question depends how heavily the developing countries and indigenous communities are in fact affected by ‘bad’ and ‘good’ patents. In this respect there are, of course, different opinions. Some authors claim that there is widespread bioprospecting

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<sup>198</sup> Confer article 64 EPC, §9 German Patent Act; section 154 US Patent Act.

and thus ‘biopiracy’ taking place in developing countries<sup>199</sup> whereas most authors conclude as Dutfield does that it is “by no means clear how much ‘biopiracy’ actually goes on”.<sup>200</sup> He and others state that “there are very little data” but pharmaceutical corporations would generally consider themselves to be less dependent than ever on natural product research.<sup>201</sup> Kate and Laird in their study found out that the commercial demand for traditional knowledge and genetic resources is decreasing.<sup>202</sup> The former Minister of the Environment in Colombia stated that the “great demand for access to the genetic resources” of the developing countries in South America which was foreseen has not happened.<sup>203</sup> Altogether it can be ascertained that there is a lack on information on how much ‘bad’ patents or ‘good’ patents have been granted. Moreover, this also depends on how one distinguishes between legitimate and unfair exploitation. The extent to which the few impacts of ‘biopiracy’ mentioned above occur therefore cannot be ascertained. Thus it might be “possible to be too concerned about ‘biopiracy’”.<sup>204</sup>

In sum one can state that the main impact related with ‘biopiracy’ on indigenous communities and developing countries is the possible loss of export markets, particularly in the case of a ‘bad’ patent. The main reason for the grant of ‘bad’ patents is the non availability of documentation of traditional knowledge and the poor examination of novelty by the Patent Offices. The grant of ‘bad’ as well as ‘good’ patents without compensation is facilitated by the flexibility of TRIPS with main regard to the definition of the patentability requirements. However, a right of indigenous communities to benefit sharing or to require prior informed consent could not be found.

## **VI. Possibilities for developing countries under TRIPS**

In this chapter it will be demonstrated that developing countries can adjust their national legislation in a way as to avoid the few negative impacts of ‘biopiracy’ mentioned above. They are able to prevent the granting of ‘bad’ patents in their own territory as well as to prevent largely the grant of such patents in other countries. They could therewith prevent the negative economic impact of loss of a possible export market as well as the alleged exploitation of indigenous communities and developing countries

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<sup>199</sup> RAFI, note 16, at p. 2; Medaglia, note 160, at 197;

<sup>200</sup> Dutfield, in UNCTAD 2004, note 8, at 145. confer notes 195-197.

<sup>201</sup> Dutfield, *What is ‘biopiracy’?*; note 4, at 4; Muller, note 130, at 243;

<sup>202</sup> Kate / Laird, *Bioprospecting*, note 2, at 143, 156.

<sup>203</sup> Medaglia, note 160, at 204.

<sup>204</sup> Dutfield, *What is ‘biopiracy’?*, note 4, at 4.

though this was shown to be an unjustified accusation. They even can require prior informed consent and benefit sharing agreements if foreign corporations want to use genetic resources or traditional knowledge from the respective developing country. This can be done in the context of regulations on access to those resources. Moreover developing countries could make the TRIPS like IPR system work to economically benefit them and their indigenous communities. One must, however, keep in mind that national legislation in Intellectual Property Rights Law must be consistent with the TRIPS agreement which “mandates the level of protection of intellectual property rights”.<sup>205</sup>

## **A. Proposals for regulations with national effect**

These proposals aim at adjusting the national IPR law in order to prevent the granting of ‘bad’ and ‘good’ patents in the developing countries’ own territory. The goal should be only to grant proper patents as well as to obtain prior informed consent of the indigenous community or the state itself before genetic resources or traditional knowledge can be used and to provide for compelling benefit sharing.

### ***1. Prior informed consent in patent legislation***

One proposal that is often given is that national Patent law could require the patent applicant to prove prior informed consent of the party that provided genetic resources or traditional knowledge for the invention. This requirement could be limited to inventions where “natural genetic resources are employed” and active components have not been isolated from those resources.<sup>206</sup> That restriction, however, is not compelling. A more comprehensive construction would also cover inventions that are derived from genetic resources or traditional knowledge.

Additionally an obligation to share the benefits arising out of the commercialisation of the patent could be linked with the prior informed consent requirement. The requirement of prior informed consent would prevent the “misappropriation of traditional knowledge” and genetic resources by means of patents “against the will of the indigenous communities”<sup>207</sup>. Thus it would avoid the problems related to ‘good’

<sup>205</sup> Visser, note 3, at 207.

<sup>206</sup> So: Nuno Pires de Carvalho, ‘*Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications Without Infringing The TRIPS Agreement: The Problem and The Solution*’, 2 Wash.U.J.L.& Pol’y (2000), 371, at 373.

<sup>207</sup> Sophia Twarog, ‘*Preserving, Protecting and Promoting Traditional Knowledge: National Actions And International Dimensions*’, in: in: Sophia Twarog and Promila Kapoor (ed.), *Protecting and Promoting Traditional Knowledge: Systems, National Experiences And International Dimensions*, UNCTAD 2004, 61-69, at 62.

patents. However, it would not prevent the acquisition and commercialisation of genetic resources and traditional knowledge by third parties without obtaining a patent. This case could be covered by other legislation that is presented later (access regulations).

However, the definition of the “PIC” requirement as an “additional substantive requirement for patentability” arguably contravenes the provisions of the TRIPS agreement. Article 27.1 TRIPS contains the statutory patentability conditions, namely ‘novelty’, ‘inventive step’ and ‘industrial applicability’. Exceptions are only provided in article 27.2 and 27.3 with regard to the scope of patentability, respectively in article 65.4 and article 70.8 with regard to the implementation time. In other respects article 27.1 states clearly that “patents shall be available and patent rights enjoyable without discrimination”. Thus it would seem that the substantive patentability requirements are finally regulated in article 27.1 TRIPS where a requirement of prior informed consent is not included. Moreover, prior informed consent is not covered by the flexibility that TRIPS leaves in defining the patentability requirements. The conditions in article 27.1 all “refer to the invention per se, i.e. they result from the technical characteristics of the invention”.<sup>208</sup> The requirement of prior informed consent, however, would not refer to the invention itself. Since there is no exception of article 27.2 or 27.3 evident, this requirement cannot be included as a patentability condition<sup>209</sup>.

Visser, however, argues that lacking prior informed consent could be a ground to revoke a patent.<sup>210</sup> Both Visser and Correa hold that TRIPS does not provide for grounds for revocation of a patent therefore it would “not limit the grounds on which such a decision may be adopted”.<sup>211</sup> Instead of a revocation Visser also proposes the transfer of the patent to the successful revocation applicant.<sup>212</sup> Article 32 TRIPS indeed does not provide grounds for revocation of a patent. However, grave arguments militate against the compatibility of both suggestions with the TRIPS Agreement. The systematic connection of article 32 and its position after the patentability requirements would rather speak for the interpretation that a revocation should only be possible on grounds of non-compliance with a patentability requirement in article 27 or the disclosure requirement

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<sup>208</sup> Carvalho, note 206, at 379.

<sup>209</sup> Carvalho, note 206, at 372, 379; Visser, not 3, at 214.

<sup>210</sup> Visser, note 3, at 215; similarly Correa, *IPR*, note 22, at 195.

<sup>211</sup> Correa, *IPR*, note 22, at 195; Visser, note 3, at 215.

<sup>212</sup> Visser, note 3, at 215.

in article 29. If any ground would be sufficient to revoke a patent, the patentability requirements of TRIPS in article 27.1 would be seriously undermined. The prior informed consent requirement could indirectly become a patentability requirement although it is acknowledged that such a condition would be incompatible with article 27.1 TRIPS. Moreover, Carvalho cites the negotiation history of article 32 as an argument against the compatibility of prior informed consent as a revocation criterion.<sup>213</sup>

Thus one must conclude that the requirement of prior informed consent cannot be included in national Patent legislation neither as a patentability requirement nor as a revocation ground due to a contradiction of the TRIPS agreement.

An interesting alternative is given by Carvalho who proposes that a patent that was granted without prove of prior informed consent should be deemed not enforceable.<sup>214</sup> Article 8 of the TRIPS would allow for such an interpretation. One could again argue that the practical effect of such an interpretation would be the same as if prior informed consent would be a patentability requirement. The patent would lose its economical advantage. Thus this proposal also could be deemed to be incompatible with TRIPS.

However, as it is shown later, developing countries can provide for such a requirement in legislation outside IPR law, namely in regulations on access to genetic resources and traditional knowledge.

## ***2. Disclosure of the country of origin in patent legislation***

In order to prevent ‘bad’ patents and in order to have a basis for the requirement of benefit sharing it has been suggested to expand the disclosure requirement in article 29 as to cover the country of origin of genetic resources or traditional knowledge.<sup>215</sup> If the patent applicant would fail to meet this requirement the patent either could not be granted or the revocation of a granted patent would be possible.<sup>216</sup> The disclosure requirement “would have the advantage of legally forcing patent applicants to double

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<sup>213</sup> Carvalho, note 206, at 388.

<sup>214</sup> Carvalho, note 206, at 395, 396.

<sup>215</sup> Ruiz, note 6, at 5; Report of the British Commission on IPR, note 4, at 85; Carvalho, note 206, at 374, 375; Visser, note 3, at 215; Cullet, note 25, at 54.

<sup>216</sup> Atul Kaushik, ‘*Protecting Traditional Knowledge, Innovations And Practices: The Indian Experience*’, in: Sophia Twarog and Promilla Kapoor (ed.), *Protecting And Promoting Traditional Knowledge: Systems, National Experiences And International Dimensions*, UNCTAD 2004, 85-90, at 88; Correa, *TK and IP*, note 127, at 19.

check prior art in their field”.<sup>217</sup> The patent offices could more easily examine prior art when they know that traditional knowledge and genetic resources have been used and where those originated.

Again it is controversial whether this requirement is consistent with TRIPS.<sup>218</sup> Article 29 and 62.1 are the relevant provisions. Disclosure according to article 29 requires that a person skilled in the art can carry out the invention therefore it mainly “aims at ensuring the reproducibility of the invention”.<sup>219</sup> The disclosure of the source of genetic resources and traditional knowledge, however, is not necessary to carry out the invention, thus it has no direct relation to article 29. Neither is this requirement covered by article 27. According to article 62.1 TRIPS “members may require ... compliance with reasonable procedures”, provided they are “consistent with the provisions of this agreement”. Carvalho refers to the negotiation history and argues soundly that “reasonableness” implies procedures that support the Patent Offices in identifying and assessing the “substantive conditions of patentability” in articles 27 and 29<sup>220</sup>. A requirement of disclosure of the source of genetic resources and traditional knowledge, however, does not help the Patent Offices in examining whether the invention is new or inventive or whether the disclosure according to article 29 is precise enough. Furthermore one could argue that the disclosure requirement contravenes the non-discrimination principle in article 27.1 as it only refers to inventions that used genetic resources and traditional knowledge<sup>221</sup>.

Thus, this disclosure requirement cannot be included in Patent Law either. A possible voluntary disclosure of the source of genetic resources without any sanctions appears to be worthless as probably few inventors would observe it.

### ***3. Use of the flexibility and exceptions to patentability in the TRIPS agreement***

The British Commission on Intellectual Property Rights recommended that developing countries should allow as few biotechnological patents as possible and thus should

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<sup>217</sup> Cullet, note 25, at 54.

<sup>218</sup> confer WTO, IP/C/W/368, *TRIPS and CBD*, note 183, at 7,8; Ruiz, note 6, at 16.

<sup>219</sup> Correa, *IPR*, note 22, at 73.

<sup>220</sup> Carvalho, note 206, at 387.

<sup>221</sup> WTO, IP/C/W/368, *TRIPS and CBD*, note 183, at 9.

make use of the exceptions to patentability allowed in the TRIPS agreement.<sup>222</sup> They could avoid patents on traditional knowledge and genetic resources almost entirely therefore ‘bad’ patents could not emerge either. Patents like the Ayahuasca example could be prevented. Developing countries should prohibit the patentability of plants, animals, plant varieties, essential biological processes and of “biological materials found in nature, even if isolated therefrom”.<sup>223</sup> Microbiological processes and micro-organisms must be patentable though.<sup>224</sup> Since the TRIPS Agreement does not define any of these terms countries have considerable leeway to manoeuvre. They should therefore define the mentioned terms of ‘micro-organisms’ and ‘microbiological processes’ as restrictive as possible in order to exclude as much biotechnological inventions as possible from patentability. Moreover the ‘morality’ exception could be used to counter the alleged violation of ‘sacred customs’ although this criticism was seen as unjustified in chapter IV. As the notion of morality is not defined uniformly but “is relative to the values prevailing in a society” patent examiners “could be directed to consider the extent to which the patent application” might infringe special cultural or religious feelings of indigenous communities in the country.<sup>225</sup> In a case of ‘violation’ the patentability could be refused. Such a decision based on the morality exception cannot be challenged under the WTO dispute settlement system, “unless it is clearly beyond the reasonable meaning of the concept of ‘morality’ ”.<sup>226</sup>

The requirement of ‘novelty’ should be defined carefully as to contain an absolute novelty standard and should be examined carefully in patent applications. This is another element to prevent the grant of ‘bad’ patents. The same is true for the patentability requirement ‘inventive step’. A high standard ensures that inventions involving increments to traditional knowledge and minimal creative input cannot be patented therefore the question whether mixtures between western techniques and traditional knowledge are worthy to be patented would not arise.<sup>227</sup> The inventor would have to prove sufficient own creativity why his invention should be patentable without any problems. Encouraging domestic innovation could be facilitated with the provision of exceptions to patent rights for teaching, private and non-commercial as well as

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<sup>222</sup> Report of the British Commission on IPR, note 4, at 114 et sqq., 122.

<sup>223</sup> Correa, *IPR*, note 22 at 186; Article 27.3b) TRIPS.

<sup>224</sup> Article 27.3b) TRIPS.

<sup>225</sup> Correa, *IPR*, note 22, at 62, 63; Visser, note 3, at 216.

<sup>226</sup> Correa, *IPR*, note 22, at 63.

<sup>227</sup> confer chapter V.

experimentation purposes.<sup>228</sup> This could lead to more domestic inventions based on own genetic resources and traditional knowledge what would further decrease the fear of ‘exploitation’.

#### ***4. Sui generis protection of traditional knowledge***

A sui generis protection of traditional knowledge could be another possibility for developing countries. With the help of such an intellectual property protection they could provide for benefit sharing with indigenous communities and require prior informed consent and could thus avoid any discussion about ‘good’ patents. The TRIPS Agreement does not provide for a special system for traditional knowledge, on the other hand it does not prohibit sui generis protection either.<sup>229</sup> Even developed countries that generally are critical of interpreting TRIPS broadly have not contested the possibility to provide a specific traditional knowledge protection system.<sup>230</sup>

The CBD’s Panel of Experts on Access and Benefit-sharing proposed inter alia the recognition of sui generis ‘intellectual community rights’ that indigenous communities can obtain over traditional knowledge associated with genetic resources.<sup>231</sup> Those rights could include “a right to prevent the unauthorised use of traditional knowledge, and a right to prevent any reproduction of a fixation of traditional knowledge that is unauthorised or distorting”.<sup>232</sup> The legislation could also provide “administrative and judicial review processes to resolve disputes, benefit sharing mechanisms, and registers of traditional knowledge.”<sup>233</sup> One of the main tasks for the composition of such a system would be the precise definition of traditional knowledge that is to be protected. There are many alternatives and possibilities to form such a sui generis system. Countries are free to adopt a system which effectively takes into account the special needs and characteristics of the country.

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<sup>228</sup> Report of the British Commission on IPR, note 4, at 119.

<sup>229</sup> WTO, IP/C/W/370, *Traditional Knowledge*, note 45, at 11. Correa, *IP and TK*, note 127, at 26;

<sup>230</sup> European Community in WTO, IP/C/W/368, *TRIPS and CBD*, note 183, at 11; Correa, *IP and TK*, note 127, at 26.

<sup>231</sup> World Intellectual Property Organization, Note by the Secretariat, WIPO/GRTKF/IC/4/8 (2002), Intergovernmental Committee on Intellectual Property And Genetic Resources, *Traditional Knowledge and Folklore: Elements Of A Sui Generis System For The Protection Of Traditional Knowledge*, Geneva 2002, available at [http://www.wipo.int/documents/en/meetings/2002/igc/pdf/grtkfic3\\_8.pdf](http://www.wipo.int/documents/en/meetings/2002/igc/pdf/grtkfic3_8.pdf), at 25; Medaglia, note 160, at 201; UNCTAD Secretariat, note 46, at 362.

<sup>232</sup> Gervais, note 15, at 64; WIPO Secretariat, WIPO/GRTKF/IC/4/8, note 231, at 26.

<sup>233</sup> UNCTAD Secretariat, note 46, 362.

Visser in his article introduces an interesting proposal which he names “compensatory liability regime”.<sup>234</sup> Under this system ‘first comers’ of (small scale) innovations on traditional knowledge, i.e. indigenous communities, are “entitled to a reasonable royalty from third parties who commercially exploit” these contributions without prior informed consent.<sup>235</sup> The goal of this system is to reward the indigenous community for its first contribution (traditional knowledge) as well as the “second comers, i.e. those who build on the community’s cultural heritage, without impeding access to the public domain or the flow of new products”.<sup>236</sup> This kind of system provides both benefit sharing for the indigenous community but at the same time allows corporations to use indigenous communities’ genetic resources and traditional knowledge to invent another product which they can sell. Thus both sides could be satisfied and the criticisms related to ‘good’ patents be prevented.

One must, however, consider that with a sui generis protection system traditional knowledge would be given more rights than other knowledge in the public domain.

With the help of these proposals developing countries can avoid the alleged problem of ‘biopiracy’ patents to emerge in their own countries. They can provide for an IPR system that protects indigenous communities and traditional knowledge related to genetic resources.

## **B. Proposals for regulations with international effect**

The effects of the proposals mentioned above are restricted to the territory of the respective country. They would not affect the Patent legislation and the manner of granting patents in other countries like the US or European countries where ‘bad’ and ‘good’ patents have been granted. Those countries would have to enact own legislation that, for example, provide for benefit sharing.

With the help of legislation outside intellectual property law developing countries can fight the impacts of ‘biopiracy’ and prevent the granting of ‘bad’ patents in foreign countries though.

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<sup>234</sup> Visser, note 3, at 231, 232.

<sup>235</sup> Ibid. at 231.

<sup>236</sup> Ibid. at 231.

### ***1. Databases of traditional knowledge***

A recommendation which has been submitted many times<sup>237</sup> and that could be very useful from my point of view to prevent the granting of ‘bad’ patents in foreign countries is the development of “traditional knowledge digital libraries” in developing countries. By documenting and publishing such public domain knowledge it becomes part of the prior art even under a relative novelty system and can destroy the novelty of an invention based on such knowledge.<sup>238</sup> The library should take into account international patent classification standards and be made easily accessible for patents examiners from all over the world, for example by being searchable over the Internet<sup>239</sup>. This defensive protection of traditional knowledge would help to improve the novelty examination by the Patent Offices thereby eliminating the main reason for ‘bad’ patents.<sup>240</sup> Clear cases of plagiarism of traditional knowledge related to genetic resources could be avoided certainly. The Turmeric patent, for example, most probably would not have been granted when the USPTO had access to written traditional knowledge related to Turmeric.

In cases where the inventor at least used some own creativity patent examiners could at least scrutinise the issue of novelty more closely. The Neem patent is an example for such a case. If the EPO had access to traditional knowledge from India it could have considered the question of novelty more detailed and probably would not have granted the patent in the first place.

There are, of course, some concerns related to such a database. The main concern expressed is that companies could use these databases as a source of information of so far unknown or undisclosed traditional knowledge thus the database itself might “in effect roll out the red carpet for ‘biopiracy’”.<sup>241</sup> However, this concern can just relate to the discussion of benefit sharing which is dealt with in the next section. The clear benefit of such a digital database of preventing ‘bad’ patents to be granted is not impaired even if a company might learn new traditional knowledge. Developing

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<sup>237</sup> WTO, IP/C/W/370, *Traditional Knowledge*, note 45, at 6; Report of the British Commission on IPR, note 4, at 82; Cullet, note 25, at 54, 63; Visser, note 3, at 215; Dolder, note 55, at 90; Ruiz, note 6, at 6; Kaushik, note 216, at 86, 87.

<sup>238</sup> Cullet, note 25, at p 116; UNCTAD Secretariat, note 46, at 364; Visser, note 3, at 215; Correa, *IPR*, note 22, at 58; Correa, *TK and IP*, note 127, at 18.

<sup>239</sup> Report of the British Commission on IPR, note 4, at 82; Switzerland in WTO IP/C/W/370, *Traditional Knowledge*, note 45, at 6; Twarog, note 207, at 65.

<sup>240</sup> Confer chapter IV B e) (3) and V.

<sup>241</sup> Twarog, note 207, at 64; Kaushik, note 216, at 87; WTO, IP/C/W/370, *Traditional Knowledge*, note 45, at 7.

countries could even avoid that disadvantage by restricting access only to Patent Offices. Access protected by passwords could be given to the Patent Offices of foreign countries. In practice the authorities of the developing country could mandate the Foreign Service of a country to take the function of transmitting the password to the relevant authorities in the foreign country.

In the event of rejection of a patent application by a Patent Office due to prior art found in the database, this relevant knowledge must be disclosed to the applicant for him to prepare a possible opposition to the refusal. This could be seen as a counter argument to those databases. However, in such a case the ‘inventor’ had already learned from this part of traditional knowledge by other means why the disclosure of the knowledge to him would appear irrelevant. The applicant would not learn more than he had already done.

Another possibility to weaken that concern would be to disclose traditional knowledge solely that is already in the public domain.<sup>242</sup> This, of course, would impair the effectiveness of the database in preventing ‘bad’ patents since not all traditional knowledge would be available to patents examiners in the world.

In any case, prior informed consent of the indigenous communities should be obtained before publishing their knowledge in order to protect their rights over their traditional knowledge. With the help of this procedure indigenous communities could decide on their own whether they want to use the protection provided by such a database or whether they rather want to hide their knowledge.

Dolder is critical regarding such databases because they would not generate economical benefits.<sup>243</sup> This might be true, but such databases are supposed to make available prior art to the Patent Offices therefore preventing the grant of ‘bad’ patents. They are not developed to produce economic benefits for the holders of traditional knowledge. This can be achieved by a sui generis protection system for traditional knowledge as mentioned above or with the help of regulations on the access to genetic resources as will be mentioned in the next section.

A sufficient level of protection for traditional knowledge could be secured by incorporating traditional knowledge databases in a sui generis protection system for

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<sup>242</sup> WTO, IP/C/W/370, *Traditional Knowledge*, note 45, at 7; Twarog, note 207, at 65.

<sup>243</sup> Dolder, note 55, at 90.

such knowledge. Concerns that “a collection of traditional knowledge in such a database ... may undermine claims to rights in the traditional knowledge” could be countered therewith.<sup>244</sup>

Thus, one can conclude that a “traditional knowledge digital library” is an important and effective element to prevent the granting of ‘bad’ patents in every part of the world. This clear benefit is not being countervailed by the concerns mentioned above. Moreover, the British Commission on IPR concluded that “greater documentation of traditional knowledge ... may [also] contribute to the preservation, promotion and possible exploitation [by the holders] of traditional knowledge”.<sup>245</sup>

## ***2. Regulations regarding access to genetic resources and traditional knowledge***

The Convention on Biological Diversity asserts the sovereign rights of a country over its genetic resources and encourages member countries to enact access legislation with regard to such resources.<sup>246</sup> The TRIPS agreement on the other hand does not prohibit access regulations regarding genetic resources or traditional knowledge outside IPR law that are just accompanying Patent law.<sup>247</sup> Thus, developing countries are free to adopt regulations on access both to genetic resources and traditional knowledge associated with such resources.

Access regulations are not only useful to strengthen the power of developing countries over their genetic resources, they also can serve as an important element in requiring prior informed consent and providing for compelling ‘benefit sharing’ to avoid ‘biopiracy’ patents worldwide. The logic behind this presumption is that without access to genetic resources and traditional knowledge associated to such resources no invention derived from those resources can be developed. The inventor depends on access to genetic resources and traditional knowledge in order to produce a pretended ‘biopiracy’ patent. Access to these resources normally takes place in the country of origin where the genetic resources and traditional knowledge are available that in most cases are developing countries.<sup>248</sup>

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<sup>244</sup> WIPO Secretariat, WIPO/GRTKF/IC/4/8, note 231, at 20.

<sup>245</sup> Report of the British Commission on IPR, note 4, at 82.

<sup>246</sup> Article 15 CBD.

<sup>247</sup> WTO, IP/C/W/370, *Traditional Knowledge*, note 45, at 11.

<sup>248</sup> Confer chapter II C).

The country of origin should therefore enact access legislation with the following requirements. Access to genetic resources and traditional knowledge associated with such resources should be subject to prior informed consent of the state or other owners of genetic resources or traditional knowledge, as for example indigenous communities.<sup>249</sup> The legislation should require compensation for the access to genetic resources or traditional knowledge or obligatory benefit sharing for the case of commercialisation of a product derived from the resources accessed.<sup>250</sup> The regulations could provide for a minimum amount to be paid or set up a percentage in relation to gross sales.<sup>251</sup> It must be defined, however, who is the beneficiary of which resources. If a company refuses to commit itself to these conditions access to the resources could be denied. Enforcement mechanisms like a requirement to present to the national authorities a certificate of ‘prior informed consent’ and civil or even criminal sanctions such as high fines for illegal access should be provided.<sup>252</sup> Therewith some kind of deterrence is ensured and the circumvention of the access legislation could be minimized.

The commitments mentioned above are still valid and must be fulfilled if the ‘collector’ of genetic resources and traditional knowledge is not the inventor at the same time but transfers the resources to somebody else. The obligation to share the benefits arising from the commercialisation of a product derived from the resources accessed continues to exist and the ‘collector’ has to ensure this obligation to be met, e.g. by transferring this obligation to the company that develops the final product.

There are many possibilities to implement such access regulations. Some countries have enacted special access legislation<sup>253</sup> others have used general Biodiversity Legislation with access regulations incorporated.<sup>254</sup> A country could also incorporate access regulations on genetic resources and traditional knowledge in a sui generis protection system of traditional knowledge.<sup>255</sup> The community rights of indigenous communities

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<sup>249</sup> Kate / Laird, *Biodiversity*, note 14, at 20; Twarog, note 207, at 68.

<sup>250</sup> Twarog, note 207, at 67; Kate / Laird, *Biodiversity*, note 14, at 20.

<sup>251</sup> Pacón, note 190, at 178.

<sup>252</sup> Kate / Laird, *Biodiversity*, note 14, at 24; Medaglia, note 160, at 200, 202, 206.

<sup>253</sup> For example Costa Rica: Medaglia, note 160, at 202 et sqq.

<sup>254</sup> For example: India, Kate / Laird, *Biodiversity*, note 14, at 22; South Africa: Arts. 80 et sqq Biodiversity Act 2004, available at: [http://www.kznwildlife.com/PDF/biodiversity\\_act.pdf](http://www.kznwildlife.com/PDF/biodiversity_act.pdf).

<sup>255</sup> UNCTAD Secretariat, note 46, at 361.

as mentioned in VI A) 4. could include the rights to demand prior informed consent and benefit sharing. These rights could be exercised when access to the protected traditional knowledge is sought.

However, countries should pay attention to define ‘access’ as to include also access to gene banks, in situ as well as ex situ collections of genetic resources and registries of traditional knowledge in the respective country.<sup>256</sup> Otherwise the protection against non-compensation and unauthorised access would not be comprehensive. Ten Kate points out that both access on private as well as on public land should be regulated.<sup>257</sup> With regard to the obligation to ‘benefit sharing’ a rule could provide for the payment of compensation to a special development or biodiversity fund in cases where the holders of traditional knowledge or genetic resources cannot be clearly identified.<sup>258</sup> It is conceivable that a country could make an exception to the strict regulations for national research activities in order to promote domestic research and facilitate domestic innovations.

Thus, access legislation could serve the goals ‘conserving genetic resources and traditional knowledge, preventing improper use and appropriation, especially through IPR system and providing for a compelling benefit sharing mechanism’.

With the help of such a positive protection of genetic resources and traditional knowledge of indigenous communities developing countries can effectively enforce the requirements of prior informed consent and compelling benefit sharing for inventions derived from those resources though these inventions are developed abroad. The link is not patent law when patent protection is sought for the invention since the incorporation of prior informed consent in IPR law is not possible (VI A 1). Developing countries can intervene earlier though. They possess the resources in demand why they also can regulate the access to them. Without having access nobody is able to exploit those genetic resources or traditional knowledge. Without an invention there is no ‘good’ patent either. Thus, carefully designed access regulations are an effective pressurising medium which developing countries can use to prevent ‘good’ patents from being granted in foreign countries.

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<sup>256</sup> Medaglia, note 160, at 200.

<sup>257</sup> Kate / Laird, *Biodiversity*, note 14, at 21.

<sup>258</sup> Pacón, note 190, at 178.

Developing countries should pay attention not to discourage access altogether by making the regulations too bureaucratic. Economical participation in the commercialisation of products derived from the protected genetic resources is not possible without applications for access in the first place. Medaglia notes that without access “it is impossible to talk about benefit sharing”.<sup>259</sup> Moreover, the more restricted access is the more likely it is that companies try to access genetic resources through sources outside the territory and therefore outside the regulation scope of the respective country. However, the more developing countries enact access legislation the less the likelihood of such a circumvention will be.

### ***3. Education of the indigenous communities***

Another accompanying component of a sound national policy regarding ‘biopiracy’ would be to educate indigenous communities to raise awareness of the possible danger and of their rights under national legislation to protect their genetic resources and traditional knowledge. It also has been emphasised that “strengthening the innovative capacity of indigenous and local communities” and the “exchange of experience and skills among” such communities would be important to “promote the further development and use of traditional knowledge”.<sup>260</sup> National authorities could provide indigenous communities with guidelines to take into consideration for negotiation of benefit sharing agreements.<sup>261</sup>

Capacity building both in legal and innovative skills can help those communities to ‘harness their traditional knowledge for development and trade’.<sup>262</sup> Well educated communities could assert their rights (under a possible access legislation or sui generis protection system) against transnational corporations better than it is the case up to now. The success of national legislation proposed above to prevent ‘bad’ patents and to provide for prior informed consent and benefit sharing could be enhanced therewith.

### ***4. Promoting commercialisation at home***

In chapter IV B h) it was noted that the problem of loss of export market might even appear in the case of properly granted patents. Commercialisation of products and services based on traditional knowledge may provide opportunities for developing

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<sup>259</sup> Medaglia, note 160, at 203.

<sup>260</sup> UNCTAD Secretariat, note 46, at 364; Twarog, note 207, at 66.

<sup>261</sup> Kate / Laird, *Bioprospecting*, note 2, at p. 152, 153.

<sup>262</sup> UNCTAD Secretariat, note 46, at 366.

countries, particularly with traditional medicines.<sup>263</sup> Specific legislation as for example ‘petty patents’ or ‘improvement patents’ could be “developed for patenting ‘new’ traditional medicines and herbal remedies”.<sup>264</sup> The requirements of inventive step and novelty could be defined less exacting as to cover traditional innovations<sup>265</sup>. China is an example that has enacted such legislation and whose use “has been growing rapidly”.<sup>266</sup> It is conceivably to cover other traditional products based on genetic resources as well.

### **C. Intermediate Result**

With the help of appropriate legislation as proposed under A. and B. developing countries can prevent ‘bad’ patents both in their own territory and also in other countries. As seen this can be done by adjusting patent as proposed under A. 3. and establishing databases of traditional knowledge associated with genetic resources (B 1.). Furthermore developing countries can prevent ‘good’ patents because they are able to enforce the requirements of prior informed consent and compelling benefit sharing outside IPR law in context of access regulations. Everybody, thus even foreign corporations, who wants to access genetic resources or traditional knowledge has to comply with these conditions. It is irrelevant whether the invention derived from those resources will be patented or not. Accompanying measures as education and promotion of commercialisation at home can support the prevention of the negative impacts of ‘biopiracy’.

## **VII. Conclusion**

This thesis demonstrated that there are many criticisms related with ‘biopiracy’ but just one real problem, namely the possible loss of export markets. The debate is concerned with patents that can be divided in two parts: ‘bad’ patents and ‘good’ patents. For both it can be stated that they do not jeopardise the way of living of indigenous communities in developing countries, as it has been alleged. The effect of the patents granted is limited to the territory of the country in which they were granted. There is no worldwide enforcement of patents.

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<sup>263</sup> UNCTAD Secretariat, note 46, at 364, 365.

<sup>264</sup> Twarog, note 207, at 66; Report of the British Commission on IPR, note 4, at 121.

<sup>265</sup> UNCTAD Secretariat, note 46, at 360.

<sup>266</sup> Twarog, note 207, at 66; WIPO, *IP and TK*, note 120, at 18.

With respect to **'bad' patents** one must conclude that the use of the traditional practices and genetic resources in the developing country cannot be prohibited by the patentee of an 'invention' that is in fact the traditional product and that was wrongly patented in another country. The same is true for the use of plants that have been patented. The indigenous communities can live their lives as they have done over generations. Possible economical impacts like raising prices in the Neem case could not be traced back to the patent granted. These effects are based on the commercialisation of products and are not dependent on the grant of a patent. The alleged 'exploitation' of indigenous communities and developing countries by inventions that are allegedly 'bad' patents could therefore not be confirmed. Rather there was an 'exploitation' of both traditional knowledge and industrial techniques. Only from a moral point of view there could be a difference. However, moral arguments are problematic means to prove alleged problems. There is no uniform notion of morality and thus arguments can be put forward in favour as well as against a criticism. Morality is a rather foreign matter in Intellectual Property law. Apart from an exception to patentability based on moral grounds there is generally no consideration of 'morality' in patent law.

Moreover, as an author concluded correctly, "simply awarding a patent in an industrial country generally does not cause economic harm" to developing countries or indigenous communities.<sup>267</sup> In none of the examples of 'bad' patents had the 'new' product displaced the traditional one in the developing country.

The only disadvantage directly connected with 'bad' patents that could be found is the possible loss of export markets. The patentee could prevent the 'invention' which in the case of a 'bad' patent is the known traditional invention to be imported in the country where the patent is valid. This economic harm, however, comes through commercialisation of the product as just in this case the patentee is interested in preventing competing products from being imported.

The main reason of 'bad' patents being granted is the non-availability and inaccessibility of traditional knowledge to the Patent Offices. Thus, when examining the patentability requirements, particularly 'novelty' and 'inventive step', they do not know that the invention is based on traditional knowledge associated with the genetic resource used in the invention. However, the 'relative novelty' standard, that is possible under

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<sup>267</sup> Schuler, note 94, at 177.

the TRIPS regulations and used in the USA, for example, contributes to the problem of granting 'bad' patents to a large extent.

With the help of appropriate national legislation developing countries can prevent 'bad' patents from being granted both in their own territory and abroad. Databases of traditional knowledge that are made easily accessible for foreign Patent Offices help to prove prior art in foreign countries, even in those with a 'relative novelty' standard. Therewith the main reason of 'bad' patents would be averted. The respective developing country should adjust its IPR legislation and should use the exceptions to patentability provided in the TRIPS agreement to avoid patents on 'inventions' based on genetic resources and traditional knowledge as much as possible. Accompanied by an 'absolute' novelty standard, a high standard for 'inventive step' and a comprehensive examination procedure of their Patent Offices developing countries can effectively avoid the grant of 'bad' patents in their own territory. All examples of 'bad' patents that were given in this thesis could have been prevented by the proposed legislation.

Without 'bad' patents the only problem of 'bad' patents, the loss of export markets for the traditional product, does not emerge either. One must, however, concede that the loss of export markets might also be possible in the case of a properly granted patent on an invention derived from genetic resources and traditional knowledge. In such a case the traditional product has to compete with the new patented product. Competition, however, is the driving power of a market economy and therefore is desirable. Moreover, competition is not confined to products derived from traditional knowledge, but it is a general phenomenon of an economy. Intellectual Property Rights are restricting pure competition in respect of the patented invention for a limited period of time though, but in exchange the public is given new and presumably significant knowledge. After the protection time everybody can use the knowledge embodied in the invention, make use of it and can compete with the formerly protected invention.

Thus, the 'problem' of competition does not relate to the problem 'bad' patents and in this respect cannot be considered. The criticisms put forward against 'bad' patents are exaggerated therefore.

With respect to **'good' patents** one must note that there is no legal obligation for the patent applicant to prove prior informed consent of the respective holder of genetic

resources and traditional knowledge or to share the benefits accruing from the invention unless the provisions of the Convention on Biological Diversity have been transformed in national law. But as seen, a transformation of said requirements in IPR law would contravene the TRIPS agreement. Thus, indigenous communities do not have a legal right to require these conditions. Moral arguments, however, have been found not to be a sound basis for the claimed right of 'benefit sharing' and 'prior informed consent'. Firstly, there is not uniform notion of 'morality' and its specification. Secondly there are moral arguments in favour as well as against the claimed rights. Thus, the criticisms related to 'good' patents are not justified either.

Moreover, developing countries are able to require patent applicants worldwide to share benefits arising out of the invention and to prove prior informed consent even though the applicant does not apply for a patent in the respective developing country. The link for the said requirements is not IPR law but the access to the genetic resources and / or traditional knowledge. For an invention to be invented based on genetic resources and traditional knowledge of a developing country or respectively an indigenous community the inventor has to access those resources in the first place. As every country has the sovereign right to regulate access to its resources and the TRIPS agreement is not concerned with regulations outside IPR law developing countries can incorporate the desired requirements in special access legislation or in sui generis protection systems of traditional knowledge.

Though these requirements are not patentability requirements and a patent theoretically could be granted in a foreign country without the developing country's requirements of access have been fulfilled they effectively can be enforced by the developing country. It just has to enforce the access to its resources strictly by providing enforcement mechanisms with civil and criminal sanctions. Interesting alternatives for such access legislation have been proposed.

When discussing the problem 'good' patents one also has to keep in mind that developing countries can also profit from intellectual property rights. In conjunction with 'bad' patents it has been mentioned that even in the case of a properly granted patent on an invention derived from traditional knowledge the 'problem' of competition will emerge. Competition, however, also entails economic chances for developing countries. They own the bulk of genetic resources and their indigenous communities

own the very valuable asset of ‘traditional knowledge’. By enhancing innovations by educating indigenous communities and promoting commercialisation of products derived from this knowledge and providing protection through ‘petty patents’ or ‘utility models’ they are certainly able to produce competitive products. The example of China was mentioned where ‘petty patents’ can be granted on new products of traditional medicine that are used widely. ‘Modern’ drugs that base upon traditional medicine almost certainly do not have more success in fighting an ailment since the essentially just contain the active ingredient extracted from the traditional medicine put in a pill. That is why promoting traditional products often will bring success both in the home country as well as abroad. This is confirmed by the UNCTAD Secretariat that sees economic opportunities for developing countries with the commercialisation of products based on traditional knowledge, particularly in the field of herbal medicines.<sup>268</sup> It cites the example of India which supported by appropriate legislation exports herbal products of about US \$ 8 million annually with fast growing figures.<sup>269</sup> Additionally Indian Ayurveda products are entering the global market as well. In countries with weaker technological basis cooperation between foreign companies and indigenous communities could be a reasonable solution, especially when access and benefit sharing regulations are in place.

In sum one must come to the conclusion that the fear of ‘biopiracy’ patents and the criticisms related to them are exaggerated and with respect to the impacts not justified. The criticisms apart from one could not be validated. Moreover, developing countries themselves are able to prevent internationally ‘bad’ as well as ‘good’ patents from being granted. Thus they themselves are able to avoid the alleged negative impacts by enacting appropriate national legislation. Moreover, they are also able to profit from their genetic resources and traditional knowledge by enacting appropriate IPR and accompanying legislation.

The debate on the phenomenon ‘biopiracy’ is basically not an original problem of patent law. It appears to be more a worry about opportunities to benefit from own resources and about a just distribution of the benefits arising from its use and commercialisation by foreign companies. The ‘biopiracy’ discussion is therefore closely linked with the “old” conflict between developing and more developed countries which exists in the

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<sup>268</sup> UNCTAD Secretariat, note 46, at 365.

<sup>269</sup> UNCTAD Secretariat, note 46, at 365.

context of worldwide trade and the issue of equal opportunities. The debate on this topic seems to be a possibility for developing countries to point out their points of view and their positions. Although developing countries might have a disadvantage in regard to technological and financial resources they are, however, able to benefit from their own resources with the help of appropriate legislation as demonstrated. The fear of the slogan 'biopiracy' therefore is exaggerated.

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