

## **The challenges of protecting traditional knowledge through an IP regimen with regard to particular problems posed by traditional medicine**

**Golanna Ashtari**

### **Abstract**

The healing effects of herbs and the knowledge of using herbs have been practiced and recognized for centuries in developing countries. However the recognition of these herbs and the right of traditional knowledge holders, are not recognized and protected properly at national and international level. The result has been that pharmaceutical companies (especially Western multinational companies), have been able to exploit both knowledge and the natural resources of the TK holders through creation of new medicine and patenting. With the emergence of intellectual property rights (IPRs), especially patent, which is the strongest form of IPRs, concerns around protecting such knowledge and genetic resources have rose.

It worth mentioning that the concerns of protecting traditional knowledge, especially traditional medicine, through the IP regimen, is engaged with not only in cultural and belief system of TK holders towards the subject matter at national level, but also with economical and legal status of TK holders and the rights they have in benefits of such products . Great importance that patent has in agribusiness and pharmaceutical sectors, has resulted in creation of different international agreements to understand and define this knowledge and to regulate the way of protecting this knowledge.

**Key Words:** Traditional Knowledge; Intellectual Property Rights (IPRs); Traditional Medicine; Beliefs.

### Introduction

In order to discuss protecting Traditional Knowledge (TK) and examining the challenges posed by the intellectual property (IP) regime to protect this knowledge in medicinal area, we must first present a definition of TK. TK has been defined in different ways in different international agreements. It is enough to mention just one of the definitions in this paper. According to the UN Convention on Biological Diversity (CBD), "traditional knowledge (TK) refers to the knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles as well as "indigenous and local technologies"<sup>1</sup>. It is worth clarifying this type of knowledge, by stating that it is traditional in a sense that it has been practiced over many generations and its substance and use is developing continually. It is passed through generations "orally" and "collectively"<sup>2</sup>. Therefore, it does not belong to an individual but to the community as a whole.

The phenomenon called "globalisation" has many effects on different aspects of life. One of the positive aspects of this is the enabling of the transmission and accessibility of knowledge, education, technology, products and even languages between countries in an easier and faster way than before. The negative side of this phenomenon is that the lack of understanding and recognition of some knowledge and resources has resulted in misuse and over exploitation, in some parts of the world, mostly in developing countries. There is no doubt that TK and natural

resources have not been immune in this regard, especially when the multinational and cooperative companies found the importance of these resources in modern industries such as “pharmaceuticals”, “cosmetics” and “agribusiness”<sup>3</sup>

This paper will critically discuss the existing problems with protecting traditional medicine. In this regard, ideas of Anil K. Gupta (an expert on strategy and globalization), who calls for conservation and preservation of both the knowledge and natural resources at national and international levels,<sup>4</sup> and the famous Indian environmentalist “Vandana Shiva who draws attention to the over-exploitation, misappropriation of traditional knowledge and biopiracy<sup>5</sup>” will be examined. Such discussion will be made through the examination of different systems of protection of subject matter, and with reference to different international instruments.

### **UN Draft Declaration on Indigenous Rights 1993**

According to Article 12 of this Declaration:

“Indigenous people have the right to practice and revitalize their cultural traditions and customs. This includes the right to maintain, protect and develop the past, present and future manifestations of their culture ....and the right to restitution of cultural, intellectual, religious and spiritual property taken without their free and informed consent or in violation of their laws, traditions and customs<sup>6</sup>”.

It is worth mentioning here, the vital elements of this knowledge as described in this Declaration. First, the phrase ‘indigenous people have the right to practice their cultural

traditions and customs', demonstrates that the right to practice, has been recognized and confirmed as an absolute right for indigenous people. Secondly, maintenance, protection and development of cultures from the past, present and future confirms the point mentioned earlier that this knowledge is evolving over time. Thirdly, 'the right to restitution of cultural, intellectual, religious and spiritual property taken without their informed consent' backs up the fact that the knowledge has roots in religious beliefs and spiritual values which are very precious. Any usage of them requires free and informed consent, otherwise it would be considered unlawful and compensation to the indigenous people could be necessary.

Broadly speaking, there is no entity that can be protected properly without recognition. Traditional medicine is one of those important entities that requires specific attention. According to a WTO report in 1996, about 80 percent of the world's population relies on traditional medicine<sup>7</sup>. This shows the importance of practicing and protecting this type of medicine and the existence of high biodiversity and common use of herbs. Here is where Gupta emphasises the recognition and conservation of both knowledge and natural resources. In his paper on 'Compensating local communities for conserving Biodiversity' he mentions the customs and religious beliefs that local communities have surrounding natural resources and special herbalists who have "spiritual taboos against compensation".

In this regard, there are some issues which require mentioning. In a paper by the SRISTI (Society for Research and Initiatives for sustainable technologies and institutions) it is

suggested that local communities with valuable plants and great biodiversity can not protect these resources which results in the over exploitation by multinational companies or third parties. Issues involved are “high biodiversity”, “poverty”, “poor public infrastructure” and “unskilled labour”<sup>8</sup>. These are problems preventing local communities protecting their natural resources. Thus, foreign companies can easily exploit their knowledge and natural resources. It would be useful to consider these problems and different mechanisms of protecting these resources in the light of different international agreements. Also, there is a need to perceive how various instruments deal with them. Subsequently potential protective measures will be considered, focusing on which one can cover most of the issues and which agreements protect in the most equitable way.

### **Sui generis system**

National laws are the first instrument in protection and recognition of the rights of TK holders<sup>9</sup>. Therefore many countries such as India and China have adopted the sui generis system for their country in order to protect traditional knowledge. It is worth defining this system by stating that “a sui generis system simply means: one of its own kind”. (Defined by International Intellectual property institute). This system refers to “the creation of new national law or establishment of international norms that would afford protection of intellectual property dealing with genetic resources or biodiversity”<sup>10</sup>. These protections and “international norms” consider matters such as benefit sharing and the usage of genetic resources between contracting parties. However, there is no specific statement about the matters engaged with patents. This system is also deficient in

defining the owner of the right and the way in which the owner can access their right. Additionally, although these national laws and norms try to protect TK at a national level, they might not be in “compliance with international agreements”<sup>11</sup>. The lack of sufficient protection and recognition of the owner of the rights calls for protection at international level.

### **Convention on Biological Diversity (CBD)**

This Convention has tried to fulfil many deficits that are described in the sui generis system, especially in protecting the TK in aspects of biodiversity. As Heath puts it, “this convention can be seen as a bridge between the IP treaties and those on indigenous peoples’ rights”<sup>12</sup>. The most important aspects of the CBD about the traditional knowledge, are those mentioned in Article 8(j). This article gives authorization to traditional knowledge and respect for the knowledge of indigenous people and communities. In addition Article 15 of the CBD refers to the access and benefit sharing of genetic resources between contracting parties (ABS)<sup>13</sup>: Article 15.(4) states that:” access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article”.<sup>14</sup>

Moreover, the CBD has recognized the sovereign rights of States over their natural resources.<sup>15</sup> Paragraph 1 of Article 15 of the CBD illustrates:” recognizing the sovereign rights of states over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.”<sup>16</sup> Finally, Article 16 is also relevant as it mentions” technology transfer”. This means that any transfer of technology based on genetic resources should be

in compliance with this convention and also should be enforceable in this agreement. Together these articles describe that this knowledge should be respected and any usage of the genetic resources should be based on agreement, and sharing of benefits should be agreed between contracting parties.

For recognition and protection of these genetic resources, there should be some incentive measures. However, poverty and the lack of incentive have been obstacles in pursuing this aim in developing countries. This has resulted in the exploitation of these resources by foreign companies. A potential solution is research and development (R&D) on genetic resources and financing them through patent system.<sup>17</sup>

Local communities are often so poor that they cannot afford the process of patenting. However, it does not necessarily mean that a third party can patent the valuable resources and grant them as an invention and compound a new product by ignoring the knowledge and the natural resources which belongs to the indigenous people. Gupta argues that any usage of genetic resources or the knowledge of indigenous people should require compensation. In support of this the CBD in Article 15 mentioned equitable benefit sharing should be available for such local communities. The point is that the Convention has recognized the sovereign right of the State over the natural resources and the determination of the access to such uses. In addition, article 15 (4),(5) states the “mutually agreed terms and conditions between contracting parties”<sup>18</sup>. I believe that even if a lawful agreement exists between the contracting parties based on informed consent and benefit sharing, the right of the

communities and local people whose life depend on the medical resources has been infringed .This concern has been supported by Shiva. She argues that this article is “about the contracting parties and not about the sovereignty rights of local communities and traditional practitioners.”<sup>19</sup>

Now, I shall consider the famous case of the “Neem tree” in India as an example of the usage of such genetic resources. Neem tree has healing material and several other usages for local communities. Many multinational companies, especially US companies, have attempted to patent many derived healing materials .Three of the most derived uses on which patents were applied for were: “extracting a purer form of azhadirichtin, in a storable stable form of that and for extracting of this compound for cancer treatment”<sup>20</sup>.The case of the Neem tree was revoked after years of battles, based on lack of novelty and the revelation of “prior art” in a process of examination for grating patent. It is completely contrary to what According to Article 27.1 of TRIPS agreement. This article states: “patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application” <sup>21</sup>.Therefore the patenting of products derived from the Neem tree was revoked. In this regard, Shiva who opposes the third party patenting on genetic resources and exploitation of them, called this exploitation “biopiracy”. Biopiracy has been described as any claim on use and ownership of both knowledge and resources.<sup>22</sup>

The patent system has the most economic power to be an incentive for R&D. Moreover, it has tried to prevent the misappropriation of traditional knowledge. Although this IP

system tries to do so, it has failed for recent years in guaranteeing the misappropriation of genetic resources, and has been claimed as causing biopiracy.<sup>23</sup>

Different agreements have been introduced to cover much of the protection of traditional knowledge and genetic resources. One of the agreements that which has been mentioned (not explicitly about TK but about the patent system), is the WTO Agreements on Trade Related Aspects of Intellectual Property Rights (TRIPS). It is worth examining the relevant articles and to see how it has caused the failure and the lack of consideration to the TK.

### **WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)**

This agreement is the first intergovernmental agreement that has set minimum standards to protect knowledge .It has set its provisions in order to protect the knowledge through patenting in Article 27 by stating three key terms, novelty, involves an inventive step, and capability of industrial application.<sup>24</sup>

As the Neem tree case has shown us, there are many products derived from genetic resources which have failed in the process of examination for patenting. This failure was due to absence of prior art in these cases. As Ruiz describes in his article about prior art, he puts novelty and prior art opposite each other, and states patents are an exclusive right which are granted to the inventor. This is done in order to exercise and access commercial use of the product for a limited time by disclosing the information to show that it is novel and it has not been obvious to the public. As in traditional knowledge: "this disclosure of

information is part of the invention and the disclosure of the prior art will help the development of science and maintain the traditional knowledge”<sup>25</sup>Therefore, there are debates on gathering the information and whether setting up a data base will help to combat the ignorance of prior art and consequently biopiracy.

The point is that neither the CBD nor TRIPS could give such protection. A UNCAD sheet reports, the lack of clarity in Article 16(2)<sup>26</sup> of the CBD, and also in the TRIPS agreement about the access to and transfer of technology “adequate” and “effective” protection of intellectual property rights, implies the notion of deficiency in protection of intellectual property rights (IPRs)<sup>27</sup>.Therefore, modern IP laws have been unable to protect the innovations produced by developed countries based on the resources of developing countries. Consequently, the issue of biopiracy has been raised to describe the ‘free ride’ of developed countries on developing countries’ genetic resources.<sup>28</sup>

The challenges of protecting traditional  
Knowledge.....

As mentioned by Rajotte, “biopirates” are those individuals and companies who misappropriate of genetic resources through the patent system and undertake unauthorized collection of genetic resources for commercial use.”<sup>29</sup>It simply means that in the sense of medicinal use of a plant, company and individuals use the material and formula which belongs to indigenous people in order to patent it and with commercializing these products gain lots of profit.

It is worth saying that Shiva argues that patents, which are a Western construct, have been implemented in the TRIPS agreement and the IPR system which US patent law is based on,

is used in a way that has caused biopiracy, a lack of truthfulness and ignorance of the “Prior art” during the patenting process. This has caused great harm to developing countries<sup>30</sup>. Shiva strongly believes that wherever there is prior art in the process of patenting, it should be stopped and no patent should be granted to the product as it is counted as “double theft”.<sup>31</sup>

Emergence of such concerns about prior art and the feature of novelty in the patenting system, resulted in the creation of data bases of traditional medicine formulas in China and India. Both countries have high biodiversity and are therefore important source countries in this topic .In India, concerns resulted in the setting up traditional knowledge digital library (TKDL) as to documenting a great number of traditional medicine formulas and translation of them in different international languages and codification<sup>32</sup>. Similarly, in China in 2002,” the State Intellectual Property Office (SIPO) set up a Traditional Chinese medicine (TCM) patent data base to meet the needs of patent examination.”<sup>33</sup>

Although the establishment of such institutions and safeguarding measures tries to protect traditional medicine at a national level and protect the subject matter from biopiracy, they are still not fully recognized and understood at the international level. As formerly mentioned, two international agreements (CBD and TRIPS) are deficient in protecting traditional medicine through an IP regime. Therefore, the World Intellectual Property Organization (WIPO) got involved to try to synchronize these two international instruments.

**World Intellectual Property organization (WIPO 1998)**

One of WIPO's task is to harmonize intergovernmental agreements, such as the two previously mentioned agreements. It has tried to put these two agreements in line<sup>34</sup>. As an amendment to Article 27.3 of TRIPS<sup>35</sup> could not address and guarantee the interests of TK holders, WIPO has tried to focus on these aspects of agreements and balance the concerns related to IP rights in TK. It has undertaken a consultation. The TRIPS agreement appears to serve the powerful developed countries interest and negatively affect developing countries interests<sup>36</sup>. In this regard, in the international sphere WIPO is more influential than other intergovernmental agreements. The hope is that this organization can use a "practical" and "informed" method through which it can address the IP issues in TK area.<sup>37</sup>

**Conclusions**

This essay has examined the concerns surrounding the protection of traditional knowledge, especially focusing on the case of traditional medicine. The explanations have proved that such knowledge is an integral part of the lives of indigenous people and ignorance of such knowledge has moral and economical effects on local communities in developing countries.

The explanation of national protection system (*sui generis*) and other international agreement, demonstrated that the IP regime which is based on Western law and consensus of members of developed countries is not beneficial for developing countries and is not protecting the subject matter. As a Western

idea of law can never truly understand the needs of indigenous people, it cannot possibly regulate effectively.

It has also revealed that the biopiracy is a phenomenon which should be avoided from being practiced .And it is just possible through understanding and defining the subject matter in an appropriate way in different international instruments.

The final point is that traditional medicine has embedded in indigenous people belief and it is not possible to protect it by ignorance or separation by IP regime. It should be recognized, understood and preserved in national level first and then slowly moved to the international level through amending international instruments.

## Footnotes

- 1- Definition cited in Raja, Kanaga *New avenues to protect TK urged by experts*, Available at <http://www.twinside.org.sg/title/avenues.htm>, [Accessed 23 May 2009]
- 2- Raja, Kanaga *New avenues to protect TK urged by experts*, Available at <http://www.twinside.org.sg/title/avenues.htm>, [Accessed 23 May 2009]
- 3- Ibid
- 4- Gupta, Anil K. *Compensating local communities for conserving Biodiversity: How much, who Will, How and When*. Published at [www.sristi.org/paper/compensating](http://www.sristi.org/paper/compensating) [Accessed 23 April 2009]
- 5- Shiva, Vandana. *Protecting Our Biological and Intellectual Heritage in the Age of Biopiracy*. Research Foundation for science, Technology and Natural Resources Policy ,New Delhi 1996,5
- 6- UN Draft Declaration on Indigenous Rights 1993,Article 12
- 7- Gupta. Op cit
- 8- Ibid
- 9-WIPO document, Intellectual Property and Traditional Knowledge,. available at:  
[http://www.wipo.int/freepublications/en/tk/920/wipo\\_pub\\_920.pdf](http://www.wipo.int/freepublications/en/tk/920/wipo_pub_920.pdf)  
[Accessed 17May2009]
- 10- *Is a Sui generis System Necessary?* International Intellectual Property Institute. Available at <http://www.iipi.org/speeches/newyork011404.pdf>  
[Accessed 18 April 2009]
- 11- Ibid,p6
- 12- Heath, Christopher, Weidlich, Sabine .*Intellectual property: suitable for protecting traditional medicine?*, I.P.Q. 2003, 1, 69-96
- 13- Convention on Biological Diversity ,Article 15
- 14- Ibid ,Article 15(4 )
- 15-Bragdon, Susan. et al. *Safe guarding Biodiversity: The Convention on Biological Diversity(CBD)*,Electronic Newsletter,2008, volume 11,number 10
- 16- The Convention on Biological Diversity entered into force in 1993,Article 15(1)
- 17- Bragdon ,Susan et al. *Safeguarding biodiversity: the convention on Biological Diversity* .Available at:[www.idrc.ca/en/ev-119999-201-1-DO\\_TOPIC.html](http://www.idrc.ca/en/ev-119999-201-1-DO_TOPIC.html) [Accessed 18 April 2009]
- 18- CBD Article 15 (4).
- 19- Shiva, Vandana. *Protecting Our Biological and Intellectual Heritage in the Age of Biopiracy*. Research Foundation for science, Technology and Natural Resources Policy ,New Delhi 1996,5
- 20-Heath, Op cit
- 21-TRIPS agreement , Article 27.1
- 22-Dutfield,G, International Expert Workshop on Access to Genetic Resources and Benefit Sharing

I. Identification of Outstanding ABS Issues: Access to GR and IPR. What is biopiracy?

<http://www.canmexworkshop.com/documents/papers/I.3.pdf> [Accessed on 20 April 2009]

23- Ruiz, Manuel. ,The International debate on traditional knowledge as Prior Art in the Patent system:Issues and Options for Developing Countries, Available at <http://www.ciel.org/Publications/pubbbaw.html> [Accessed 20 April 2009]

24-

25- Ruiz, op,cit

26- CBD<Article 16(2)

27-UNCTAD-ICTSD, 2005, in Bragdon ,et al op cit

28- Rajotte, Tasmin. *The negotiations Web: Complex Connections*. available at :[www.idrc.ca/en/ev-119999-201-1-DO\\_TOPIC.html](http://www.idrc.ca/en/ev-119999-201-1-DO_TOPIC.html) [Accessed 18 April 2009]

29-Ibid

30- Shiva, Vandana, "U.S Monopolists Continue Biopiracy Against India" .progress report.Available at <http://www.progress.org/archive/patent03.htm> [Accessed on 23 April 2009]

31- Ibid,

32- The *Economic Times* (reported online on October 31, 2007).as cited in Milius, Djims . "*Justifying intellectual property in traditional knowledge*" I.P.Q 2 (2009): 185-216.

33- Y. Liu and Y. Sun."China Traditional Chinese Medicine(TCM Patent Database)" 2004,24 *World Patent Information* 91

34-Bragdon, Susan.et al. op cit

35- Article 27 TRIPs agreement.

36- Milius, Djims . "*Justifying intellectual property in traditional knowledge*" I.P.Q 2 (2009): 185-216.

37- Ibid.

#### References

- Bragdon, Susan. et al. Safe guarding Biodiversity: The Convention on Biological Diversity(CBD),Electronic Newsletter,2008, volume 11,number 10
- Convention on Biological Diversity ,Article 15
- Dutfield,G, International Expert Workshop on Access to Genetic Resources and Benefit Sharing
- Identification of Outstanding ABS Issues: Access to GR and IPR. What is biopiracy?
- <http://www.canmexworkshop.com/documents/papers/I.3.pdf> [Accessed on 20 April 2009]
- Elian, G. (1979). *The Principle of Sovereignty over Natural Resources*. Germantown: Alphen aan den Rijn: Sijthoff and Noordhof.

- Gupta, Anil K. Compensating local communities for conserving Biodiversity: How much, who Will, How and When. Published at [www.sristi.org/paper/compensating](http://www.sristi.org/paper/compensating) [Accessed 23 April 2009]
- Heath, C, (2003), Weidlich, Sabine .Intellectual property: suitable for protecting traditional medicine?, I.P.Q. 1, 69-96
- International Intellectual Property Institute,' Is a Sui generis System Necessary?' Available at <http://www.iipi.org/speeches/newyork011404.pdf> [Accessed 18 April 2009]
- Kaur V, Surinder. (2005)"Protecting Traditional Knowledge, Is a Sui generis System an Answer?"The journal of the World Intellectual Property 7.6: p 768
- Makinde, M. (1988). African philosophy, culture, and traditional medicine. Athens, Athens, Ohio: Ohio University Center for International Studies.
- Milius, D. (2009): "Justifying intellectual property in traditional knowledge" I.P.Q (2) 185-216.
- Raja, Kanaga .New avenues to protect TK urged by experts, Available at <http://www.twinside.org.sg/title/avenues.htm>, [Accessed 23 May 2009]
- Rajotte, Tasmin. The negotiations Web: Complex Connections. available at :[www.idrc.ca/en/ev-119999-201-1-DO\\_TOPIC.html](http://www.idrc.ca/en/ev-119999-201-1-DO_TOPIC.html) [Accessed 18 April 2009]
- Ruiz, Manuel. ,The International debate on traditional knowledge as Prior Art in the Patent system:Issues and Options for Developing Countries, Available at <http://www.ciel.org/Publications/publaw.html> [Accessed 20 April 2009]
- Shiva, V. (1996)"Protecting Our Biological and Intellectual Heritage in the Age of Biopiracy. Research Foundation for science, Technology and Natural Resources Policy ,New Delhi,5
- UN Draft Declaration on Indigenous Rights 1993
- WIPO document, Intellectual Property and Traditional Knowledge,. available at: [http://www.wipo.int/freepublications/en/tk/920/wipo\\_pub\\_920.pdf](http://www.wipo.int/freepublications/en/tk/920/wipo_pub_920.pdf) [Accessed 17May2009]
- Y. Liu and Y. Sun."China Traditional Chinese Medicine(TCM Patent Database)" 2004,24 World Patent Information 91

#### Author's Note

Golana Ashtari received BA degree in Law, she is a Postgraduate student pursuing MA degree in Biotechnological Law and Ethics (The University of Sheffield). Researcher of the Iranian research Center fo Ethics and Law in Medicine.

Email: [golanna.a@gmail.com](mailto:golanna.a@gmail.com)

**Date of reception:** Jan 10, 2010

**Date of review:** March 20, 2010