The Patent Protection Regime as an Impediment to Protecting Traditional Knowledge

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Abstract

This paper presents the impediments posed by the patent protection regime against protecting traditional knowledge. It argues that the failure of traditional knowledge-based medicine to meet the requirements of patentability subject it to non-protection. The denial of protection opens the gate for bio-piracy by third parties who steal the traditional knowledge and readily utilize it without any intention of giving fair and adequate compensation or equal benefits to the traditional knowledge holders. The paper suggests an effective mechanism to protect traditional knowledge and thus enable traditional knowledge holders to receive just treatment in terms of compensation or equal benefits from those who utilize the knowledge they have stolen.

1. Introduction

1.1 Patent as an Intellectual Property Right

A patent is an intellectual property right granted to the owner of an invention. The patent protection regime gives a person an absolute right to exploit the invention for a specified period. The provision of this right encourages individuals by recognizing their creativity and offering the possibility of material reward for their marketable inventions.[1] Such recognition encourages innovation

[1] WIPO, "What is Intellectual Property?" available at http://www.wipo.int/export/sites/www/freepublications/en/intproperty/450/wipo_pub_450.pdf, accessed on 15th April 2014.

and promotes competition which in turn enhances the quality of human life.[2] The patented invention can either be a product or process which gives a solution to a specific problem in the field of technology.

The owner of the patented invention is vested with the exclusive right of restricting third parties from selling, making, using or offering for sale his or her invention without his or her consent for a protected period of twenty years.[3] Subject to the renewal fees, the owner's exclusive right comes to an end once the protected period of twenty years is over. This means that the owner's invention will be legally available to the public domain for commercial exploitation by third parties.

The patent protection regime is available for all new inventions in all fields of technology. They involve an inventive step not yet reported as a discovery or invention in the public forum and are capable of industrial application.[4] Such protection is available without any discrimination in terms of the place of the produced invention. Patent rights are usually granted by a national patent office or by the regional office after examining the invention to determine whether it qualifies for a patent in a relevant jurisdiction.

The applicant is obliged to file the patent application and to disclose the technical information of the invention in question and the best modes in which such information may be used by a person skilled in the art to which the invention relates.[5] Such technical information and the modes to be used are disclosed by the inventor at the filing date in the place where the priority is claimed.[6] The inventor's information may be accompanied by visual materials, drawings, plans or diagrams that describe the invention in greater detail.[7] An inventor is required to disclose technical information to the public. Such information intends to enable other inventors to make improvements on the existing invention and thereby promote

[2] WIPO, "What is Intellectual Property?" *loc. cit.*

[3] See article 28 and 33 of the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS Agreement)

[4] See TRIPS Agreement, article 27.1.

[5] See article 29 of the TRIPS Agreement.

[6] Cf. article 29 of the TRIPS Agreement

[7] WIPO, "What is Intellectual Property?", fn. 1.

the progress of science and technology.[8] The information disclosed will also help to determine whether the claimed invention is in fact new.[9]

1.2 Patent Protection Regime and Traditional Knowledge

Traditional knowledge (TK) refers to tradition-based literary, artistic or scientific works that include performances, inventions, scientific discoveries, designs, marks, names and symbols, undisclosed information, and all other tradition-based innovations and creations resulting from intellectual activity in the industrial, scientific, literary or artistic fields.[10] This knowledge may be created, developed, or practiced in a traditional setting or it may originate in the traditional milieu under the auspices of the indigenous communities. Therefore, these indigenous communities are the holders of the knowledge in tandem with the nature of their environment.

Various scholars regard TK as the knowledge of indigenous people thus using the terms TK holders and indigenous people interchangeably. This implies that indigenous knowledge is traditional knowledge, but traditional knowledge is not necessarily indigenous.[11] Indigenous people are defined by the International Labour Organization Convention 169 Concerning Indigenous and Tribal Peoples, article 1.1b, to mean those people in Independent Countries who may be regarded as indigenous on account of their descent from the populations which inhabited the country, or lived in a geographical region to which the country belongs, at the time

[8] M. Ruiz, *The International Debate on Traditional Knowledge as Prior Art in the Patent System: Issues and Options for Developing Countries*, Center for International Environmental Law, South Centre, 2002, 4.

[9] *Ibid*.

[10] WIPO *Report on Fact-Finding Mission of Intellectual Property and Traditional Knowledge (1998-9), Intellectual Property Needs and Expectation of Traditional Knowledge Holders*, WIPO Publication No. 768, Geneva, April 2001, 27.

[11] Cf. J. Mugabe, *Intellectual Property Protection and Traditional Knowledge: An Exploration and International Policy Discourse, African Centre for Technology Studies*, Nairobi, Kenya, 1998

of conquest or colonization or at the time of the establishment of present state boundaries and who, irrespective of their legal status, retain some or all of their own social, economic, cultural and political institutions.

Ragavan views indigenous people, their traditional knowledge and their particular traits in what they do with that knowledge as follows:

a) People who live in small societies and may not have access to formal education may be indigenous people who are unaware of the worth of the knowledge they possess and are found more often in developing and underdeveloped countries where there is a concentration of ethnocentric societies.
b) Indigenous people may be people whose knowledge is presumed to be known to the entire community and remains exclusively within it.
c) Occasionally, indigenous people constitute a community of people whose knowledge of a special skill or art is limited to only a few members of the community.
d) Indigenous people may be those whose knowledge and its components are normally required for a regular lifestyle within the society. It is passed down through generations while still retaining its original specificity.
e) Indigenous people may be those whose knowledge is accessible in a certain art or literary form, such as pictorial art, music, or folklore, and can be developed into other forms more understandable to the rest of the world. However, these informal innovations do not get formal recognition.
f) Indigenous people often believe that intellectual property law is neither a necessary, nor a desirable, means of encouraging innovation within their communities. As a consequence, they are sometimes easily willing to share this knowledge without acquisition of benefit in return. Their mindset about intellectual property law easily leads to exploitation.[12]

The issue of patentability arises with respect to the body of knowledge corresponding to traditional medicine.[13] Traditional

[12] See S. Ragavan, "Protection of Traditional Knowledge", *Minnesota Intellectual Property Review* 2/2 (2001) 4-5.

[13] See S. Ragavan, "Protection of Traditional Knowledge", 8.

medicine refers to the knowledge, skills and practices that are based on the theories, beliefs and experiences of indigenous culture. Such knowledge is used in the maintenance of health, prevention, diagnosis, improvement or treatment of physical and mental illnesses.[14] The knowledge, skills, practices and beliefs that are used to prevent the illness or maintain the health of individuals incorporates plants, animals, mineral-based medicine, spiritual therapies and manual techniques.[15]

An example of plant materials that are used for curing illness are leaves, flowers, fruits, seeds, wood, bark and roots.[16] The said plants, which are either fresh or dry, are required to be entirely fragmented or powdered by brewing, boiling, grinding or heating in beverages, honey, tea, water, oil or other materials for them to be applied as medicaments upon a particular condition.[17] The practice and application of such medicament is presumed to be inherited from generation to generation. It is unique and known to the relevant community and cannot be found elsewhere.

Traditional medicines reinvigorate the health of people in various countries. Due to their affordability, traditional medicines have regained popularity in developing countries as well as in industrialized countries. They can be used for treating various infectious and chronic illnesses. Countries in Africa, Asia and Latin America use traditional medicines to help meet some of their primary health care needs. In Africa, up to 80% of the population uses traditional medicines for primary health care.[18]

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[14] See WIPO, "Intellectual Property and Traditional Medical knowledge", Background brief No. 6, available at http://www.wipo.int/export/sites/www/tk/en/resources/pdf/tk_brief6.pdf.

[15] *Ibid*.

[16] M.E. Hossein, "Traditional Medicines and the Requirement of Patentability: Do they have a Technical Character? The European Approach", *IPEDR* 17 (2011) 305-309.

[17] *Ibid*.

[18] See C.M. Correa, "Protection and Promotion of Traditional Medicine: Implications for Public Health in Developing Countries", Switzerland: South Centre, 2002; available at apps.who.int/medicinedocs/pdf/s4917e/s4917e.pdf, accessed on 19th July, 2014 and World Health Organization, Traditional Medicine, WHO Fact Sheet No. 134. Geneva: WHO, revised 2003, available

Traditional medicines are presumed to be the product of nature. Therefore they are excluded from patentability.[19] Traditional medicines are medicines derived from natural forms of plants, animals or mineral-based medicines. They are made manually without any involvement of chemical process for their production. Because they are the products of nature, traditional medicines are not invented by any one. They exist naturally; hence they are accessible so that everyone in that particular community may freely use them. These features impede the patentability of traditional medicines because in themselves they are not the product of human inventiveness; rather, they are products of nature.

2. How the Patent Protection Regime Impedes the Protection of Traditional Medicine

For a product or process to qualify for patentability, it must meet the requirements of novelty, inventive step and industrial applicability. Traditional medicines as the product of nature do not possess the patentability requirement. The reasons for this are as follows:

2.1 Novelty

An invention is required to be new, i.e., novel, to qualify for patentability. An invention is presumed to be new if it is not publicly known anywhere in the world or has not been accessed by any one at any time before the filing of patent application. It must not be known or used by other inventors wherever they may be. Upon comparison with an existing invention, a new invention must be capable of contributing new technical information to the existing one in a unique and distinguishable manner. The new invention must not resemble the prior art or earlier invention; nor

at http://www.who.int/media_centre/factsheets/2003/fs134/en/, accessed on 21st April, 2014.

[19] Article 27.3(b) of the TRIPS Agreement.

must it be an attempt to make improvements that are publically already known.[20] It must go beyond all pre-existing knowledge.[21]

The novelty requirement of the patent protection regime hinders all attempts to protect traditional medicines. This is due to the fact that traditional medicines are medicines that indeed are publically known, freely accessible to all people and used within the community. They are presumed to be quite old since they have been within the society for centuries. Everything that has been part and parcel of the public domain either by written or oral disclosure is considered to be prior art, and therefore presumed not to be a new invention.

2.2 Inventive Steps

The patent protection regime grants a monopoly to an inventor who has used his or her knowledge and skills to produce a product or process which is new and involves an inventive step.[22] An invention is presumed to involve an inventive step if it is not obvious to a person skilled in the pertinent art on the date of filing the application or if priority is claimed. That is why, at the time when she or he submits the application, the inventor is obliged to disclose the technical information of his or her invention which is presumed to be new. The technical information is disclosed in order to be used by a person skilled in the art to which the invention relates to test its obviousness. If the invention in question is obvious to the person skilled in that art, it will not qualify for patenting. Therefore an invention must involve an inventive step in making an improvement which is regarded as non-obvious. Again, an inventive step in an invention must identify the particular problem in a field of technology that it intends to address and offer a precise solution for it.

The requirement of inventive step impedes the patentability of traditional medicine from the viewpoint of the existing patent protection regime. The traditional medicines do not qualify to be

[20] See the case of *General Tire and Rubber Company v. Firestone Tire and Rubber Company* (1972) RPC457

[21] See the case of *Wind Surfing International Inc. v. Tabur Marine* (GB) Ltd (1985) RPC 59.

[22] M. Ruiz, *The International Debate*, 4.

protected because they are presumed to be obvious within the society that has used it for a long time as their inheritance from one generation to the next. Their inventions are regarded as coherent with already existing knowledge that is obvious within a particular community.

2.3 Industrial Applicability

The absence of applicability to industry disqualifies an invention from patentability. An invention is disqualified when it fails to meet the market demand, and thereby hurts the public interest.[23] An invention is capable of industrial applicability if it is capable of being made or used in a technological sense in any kind of industry. That being the case, an inventor is obliged to disclose any useful purpose that his or her invention serves. An inventor is required to show how his or her invention will facilitate the development of science and technology in correspondence to the objectives of the patent protection regime.

Traditional medicines fail to meet the industrial applicability requirement and, thus, do not qualify for patentability. It is worth repeating that traditional medicines are regarded to be the product of nature. They are neither technological nor produced through a technological process.[24] Traditional medicines are nature's creations; no chemical process has been used for their production. This means that they do not meet the standard of human intervention and thus fail to become inventions that qualify for patentability. Traditional knowledge holders use their traditional medicines such as plants in their natural state. They produce their medicines through simple and conventional methods that do not add anything to the natural product, such as drying, boiling, powdering or brewing[25] without involvement of any technological process. The simple and conventional methods that are used to produce traditional medicines do not change the essential nature of the plant and hence cannot be construed to be inventions.

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[23] See *Association for Molecular Pathology et al v. Myriad Genetics Inc.* et al, US 12-398, 13.

[24] See M.E. Hossein, "Traditional Medicines", 305.

[25] Traditional Methods and the Requirement of Patentability, p. 307.

Apart from the above requirements, patent protection is only available for private property.[26] An intellectual property right recognizes private property as an exclusive right granted to an identified person, be it a natural or juridical person. The identified person must come up with a new invention. The traditional knowledge holders own communally their traditional knowledge-based medicines as the symbol of their culture. Communal ownership of the knowledge signifies communal identity and survivorship. The traditional knowledge-based medicines are inherited from one generation to the next. That being the case, it is difficult to identify individual ownership for protection qualification.

3. The Absence of Protection as a Stimulus to Bio-Piracy[27]

The failure of meeting the requirement of patentability exposes the traditional medicines to the perils of non-protection. The denial of protection has opened up space for pharmaceutical companies in technologically advanced countries to misappropriate the traditional knowledge-based medicine by isolating, purifying and then altering the plants' active substances in a way that does not occur in nature.[28] The pharmaceutical companies use their modern

[26] The preamble of TRIPS Agreement recognizes all intellectual property rights as a private right.

[27] Bio-piracy can be described as a grant of false patents to inventions that are neither novel nor inventive having regard to TK already in public domain. Such patents may be granted due to lack of documentation or recognition of TK as a prior art. It is a misappropriation of genetic resources or related traditional knowledge by means of a fraudulent patent system. It is the exploitation of resources of a community which lacks development. Such misappropriation allows the theft of creativity and innovation and hence establishing exclusive rights on stolen knowledge. This situation leads to the continuity of stealing economic options of everyday survival of indigenous communities on the basis of their common knowledge. This is due to the fact; indigenous people never get the equal benefit resulting from the utilization of their knowledge. See M. Hirwade – A. Hirwade, "Traditional Knowledge Protection: An Indian Prospective", *DESIDOC Journal of Library & Information Technology*, 32/3 (2012) 240-248.

[28] *Ibid*.

technology to transform traditional medicines into modern medicines. Later they patent their inventions despite the fact that the invention created is not novel. The misappropriation[29] of traditional knowledge by these pharmaceutical companies is done without the provision of fair and adequate compensation or equal benefits to the traditional knowledge holders who have been maintaining their traditional knowledge for centuries.

Once the third parties have established the exclusive rights on stolen knowledge, they bar the traditional knowledge holders from using their biological resources and associated traditional knowledge,[30] despite the fact that they have developed, maintained and preserved as their cultural heritage for centuries. The daily misappropriation of traditional knowledge-based creativity and innovation is nothing other than the stealing of economic capabilities and options from the indigenous people, and thereby prevents them from making any economic progress based on their knowledge. No one makes the offer or the suggestion that the traditional knowledge holders receive fair and adequate compensation and equal benefits from those who are utilizing the traditional knowledge. Meanwhile they lose access to their biological resources and traditional knowledge since their usage is forbidden. Both the resources and the knowledge are liable to be destroyed or lost forever.

[29] TK will be presumed to be misappropriated not only when the knowledge is obtained by the third party through theft, coercion or fraud. It also involves the provision of misleading information when trying to acquire prior informed consent, unjust enrichment or provision of unfair compensation to TK holders for utilization of their knowledge. See WIPO (2004) "Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Protection of Traditional Knowledge: Overview of Policy Objectives and Core Principles, at 5, 7th Session", WIPO/GRTKF/IC/7/5 available at http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_7/wipo_grtkf_ic_7_5.pdf, accessed on 10th June, 2014.

[30] Suvarna Pandey Patent Attorney S Majundar & Co. Bio piracy Related to Traditional Knowledge and Patenting Issues, available at http://www.birac.nic.in/webcontent/dib.pdf, accessed on 3rd May, 2014.

Various cases concerning bio-piracy have been reported.[31] Examples of these cases are as explained below.

3.1 Neem Patent

Indian people used Neem seed trees for centuries to treat fungal diseases that attack agricultural crops. In 1994, the European Patent Office granted a patent to the United State Corporation W. R. Grace Company and United State Department of Agriculture for a method to prevent the growth of fungi on plants by the aid of hydrophobic Neem oil.[32] The Indians objected to the granting of the patent on the ground that the fungicidal properties of Neem seed trees were publicly known and used for centuries to protect crops from being attacked by fungal disease before even the patent application. Therefore, there were no grounds for granting a patent to the method because it was neither novel nor inventive. After approving the evidence that was presented to them, the officials in the European Patent Office revoked the patent.

3.2 Turmeric Patent

Indian people have used turmeric powder for many centuries as traditional medicine to heal wounds and rashes. However, in 1995 the United States granted patent No. 5,401,504 to Suman, K. Das and Hari Har, P. Cohly, expatriates from India, at the University of Mississippi Medical Centre for using turmeric for wound healing. The Council of Scientific and Industrial Research in India objected to the granting of the patent on the ground that turmeric powder has been used for centuries for the healing of wounds and rashes in India. Therefore its prior existence before the patent application meant that the turmeric medicine was neither novel nor inventive. Considering the truth of this argument, the United State Patent and Trade Office revoked the patent as it failed to meet the established requirements for patent protection.

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[31] These patent cases are cited from a power-point presentation now available in a pdf format, Suvarna Pandey Patent Attorney S Majundar & Co., Bio-piracy Related to Traditional Knowledge and Patenting Issues, available at http://www.birac.nic.in/webcontent/dib.pdf, 17-18, 23-24. Accessed on 3rd May, 2014.

[32] Bio-piracy Related to Traditional Knowledge, 17.

3.3 Ayahuasca Patent

The natives of the Amazon rain forest used Ayahuasca, a "wine for the soul" in religious and healing ceremonies to diagnose and treat illness, contact with spirits and divine the future of the Amazonians in generations to come. In 1986, an American scientist and entrepreneur known as Loren Miller obtained a United State patent on an Ayahuasca variety collected from Amazon Rain Forest which he analysed for potential medicinal properties. The Coordinating Body of Indigenous Organization of the Amazon Rain Forest objected the granted patent on the ground that Ayahuasca had been public known by the natives of Amazon Rain Forest and was used it for centuries as their traditional medicine and divine the future of Amazon generations. Failure of meeting the qualification grounds for patent protection made the United State Patent and Trade Office to revoke the patent on 1999.

3.4 Colgate Case

Indian activists are accusing Colgate for bio-piracy of a recipe for toothpaste that Indian people have been using for thousands of years. Colgate obtained the United State patent for the tooth powder composition comprised of a rust-like red iron oxide, clove oil camphor, black pepper and spearmint ingredients. Indian activists objected to this patent on the ground that the ingredients that constituted the patented tooth powder are publicly known and used by dozens of generations of Indians. Therefore the invention is not novel. India is now in the process of preparing the documentary evidence to prove that the ingredients were common knowledge.

Conclusion

The denial of traditional protection on the ground of failure to meet the requirements of patentability leads to all-too-frequent bio-piracy actions by the multinational companies and the pharmaceutical companies. Such bio-piracy leads to a loss of biodiversity in the lands of the indigenous people: this loss is irreversible. This implies that TK holders' rights are not recognized; and their valuable knowledge fades into the past and so is lost to present and future generations. Patent holders unfairly

receive profits from patents which are illegally and unethically granted and continue to militate against the economic progress of indigenous people. To stop bio-piracy activity, effective mechanisms to grant protection to traditional knowledge holders should be devised. The establishment of that mechanism should also take into consideration the issue of fair and adequate compensation and equal benefits that should be allocated to the traditional knowledge holders when their knowledge has been proven to be utilized by the third parties.

4. Recommendations for Protection of Traditional Knowledge

The Trade Related Aspects of Intellectual Property Rights Agreement is an international legal binding instrument. Those who are authorized to amend it should make the necessary changes in order to grant effective protection to all forms of traditional knowledge as intellectual property. Such amendments will serve to remove the injustices perpetrated by third parties, such as the use of modern technology to transform the stolen traditional knowledge-based products into modern products and later patent them. The amendments should include a provision that requires disclosure of the origin of the genetic resources and the associated traditional knowledge used to develop the product for which entrepreneurs are seeking protection. It should also include the proof of free prior informed consent from the indigenous people who are either the traditional knowledge holders or the traditional cultivators of the relevant products before using the designated traditional knowledge-based materials. The entrepreneurs seeking to use traditional resources of indigenous people must furnish the proof that they are adhering to a method that is fair and equitable in the sharing of benefits derived from the utilization of traditional knowledge. The inclusion of these requirements in the mandatory rules of the TRIPS Agreement will empower state parties to refuse patents to entrepreneurs who seek protection of their products when these entrepreneurs utilise the genetic resources and associated traditional knowledge already in use among indigenous peoples in one or a number of countries and at the same time

neglect to seek permission from those countries where these resources and knowledge have originated.

On the other hand, upon amendment to the TRIPS Agreement, state parties should include the contractual agreement clauses which will regulate negotiation matters on access and equal benefit-sharing deriving from the use of genetic resources and associated traditional knowledge. These clauses will assist in the effort to remove the unfair exploitation of traditional knowledge.

As a practical implication of the conditions just summarized above, countries should adopt the *sui generis* system which obliges the third party users of genetic resources and associated traditional knowledge to disclose their origin, the proof of free prior informed consent as well as the proof of the method of fair and equitable sharing of benefits derived from the utilization of TK.[33] The adaptation of a *sui generis* protection regime should be in conformity with the customs, laws and cultural practices of traditional knowledge holders in order to protect their knowledge nationally and internationally. The failure of observing the stipulated requirements should empower the concerned country to prevent or seek invalidation of any granted intellectual property protection to entrepreneurs who made use of the genetic resources and associated traditional knowledge in the course of developing their products contrary to the laws where the resources and knowledge originated and contrary to international law.

Countries should also develop the traditional knowledge prior art database. The traditional knowledge prior art database is a compilation of information concerning traditional knowledge as a prior art, and thereafter, submit it to the public domain. The

[33] See article 8j, 15, and 19 of the Convention on Biological Diversity and article 13(d) of The FAO International Treaty on Plant Genetic Resources for Food and Agriculture, 2004. The enactment of domestic regulation to protect TK grants to nations the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts as per article 31 of The United Nations Draft Declaration on the Rights of Indigenous People, 2007.

compilation of traditional knowledge information would assist the prevention of misappropriation of traditional knowledge since such a database would immediately expose offenders who would attempt to use the traditional knowledge of other societies, cultures or nations without their permission. Hence countries and governments would be very slow to grant patents to those who are obviously engaged in bio-piracy.

The development of a traditional knowledge prior art database would enable the transmission of traditional knowledge from one generation to the next. It would identify the traditional knowledge holders' community or nation whose TK is incorporated into databases. At the same time if others were to utilize the compiled knowledge, the originators of the knowledge that others would try to utilise would become immediately public so that these indigenous originators of the traditional knowledge would now have the right to equal benefit sharing. [34]

Governments should provide the traditional knowledge holders with a thorough education concerning their rights to genetic resources, to traditional knowledge, and to the value that such knowledge generates on a global scale. The provision of such education will help them to negotiate economic issues effectively in order to enjoy their right to accessing the pertinent resources and to equal benefit sharing. These rights arise from the fact that there are people somewhere in the world who are making valuable use of their knowledge.

[34] See M. Alexander et al, "The Role of Registers and Databases in the Protection of Traditional Knowledge A Comparative Analysis", Institute of Advanced Studies, United Nations University, 2004, available at http://archive.ias.unu.edu/binaries/UNUIAS_TKRegistersReport.pdf, accessed on 4th June, 2014.