

PATENT LEGISLATIONS COMBATING BIOPIRACY OF TRADITIONAL KNOWLEDGE OF INDIGENOUS COMMUNITY IN INDIA: A CRITICAL STUDY

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INTRODUCTION

India is regarded as a biodiversity economy as it has a rich cultural and biological diversity. India is said to be the home of various species of plants and animals. There are many ethnic tribes residing in India as compared to other countries who possess various traditional knowledge. Such traditional knowledge people in India have a vast amount of knowledge about the trees and their medicinal qualities. India is even regarded as one of the countries which has many traditional health care practices like Ayurveda and Unnai. There are still people in India depending upon the traditional medicines for treatments related to health.

India is also said to be the home of traditional or indigenous communities. These people or communities have a close relationship with the forests as well as the natural resources obtained from the forests. These people have a vast amount of traditional knowledge. The term traditional knowledge means the knowledge which has been passed on for centuries from one generation to another. These people preserve and conserve this knowledge for more than thousand years. These knowledges are said to be not owned or created by a single individual but has been evolved over time. There is an increase in the threat of misappropriation of traditional knowledge of indigenous communities. This act of misappropriation can also be termed as Biopiracy which has become a very common phenomenon. The developed nations often obtain intellectual property rights upon the goods or products produced by misappropriating their knowledge without giving adequate benefits to them who had preserved it for centuries. This commercialization of traditional knowledge give rise to Biopiracy and there is a grave need for protecting the same. Biopiracy and patenting of TK is a double theft because first it allows theft of creativity and innovation of indigenous communities, and secondly, the exclusive rights established by patents on pirated knowledge steal economic options of everyday survival on the basis of preservation of biological diversity and associated traditional knowledge. Biopiracy, in simple terms, is the modern version of the old approach of take-and-run. As the name suggests, it is the piracy of the various valuable elements in the biosphere or the biodiversity. Biopiracy is the stealing of nature and its knowledge. Biopiracy refers to an unauthorized use of biological resources or of traditional communities' knowledge of biological resources. It includes the use of plants, animals, organs, microorganisms, genes,

etc. The exploitation of biological and other resources and related traditional knowledge for commercial use without the consent of their customary holders or traditional communities is purely an assault on biodiversity. The existing laws or legislations are falling short in providing protection to the traditional knowledge of indigenous community. Even the increase in the scope of Intellectual Property Rights (“IPR”) have also been not able to provide adequate protection to the traditional knowledge. The Indian Patent Act, 1970 provide protection to the traditional knowledge by not granting patent on products invented out of traditional knowledge. The amendments made to the Indian Patent Act, 1970 in 2002 and 2005 helps in curbing the Biopiracy of traditional knowledge to some extent in the national scenario. However, in the international or global level India still lacks in protecting its traditional knowledge from getting exploited. The agreement on Trade Related Aspects on Intellectual Property Rights (“TRIPS”) is also silent as to the protection of traditional knowledge. At the international level there is no recognition for this knowledge. Due to this lacuna in the laws and policies, it is difficult for developing countries like India to protect the traditional knowledge of indigenous community from exploitation by the developed countries.

INDIAN PATENT ACT, 1970

The word or term Patent has been derived from the Latin word “Patere” which means “to lay open”. Originally it was called as the letters of Patent and was granted to the individuals and business. Patent is an ownership or proprietary right granted to the person for protecting his invention. A patent has been defined in **section 2 (1)(j)** of the Patents Act as, "**any new process or product that involves capable industrial application and inventive step**". The government grants the Patent right to the inventor for a limited period of time after which it becomes available in the public domain. The owner enjoys a monopoly right when the patent is given by the government to the inventor and hence no other person or individual can exploit the patented invention of the innovator without his prior approval or consent.

In India, the Indian Patent and Designs Act was first enacted or enforced in the year 1911 by the British during the colonization phase. The Patent Act has undergone many changes and modifications since then. Even though India obtained independence in the year 1947, the British imposed the patent laws which favours the foreign multinational companies. In the year 1949 and in the year 1957, the Indian government constituted committees to look into or review the existing Patent laws. The recommendations of the committee formed in the year 1957 acted as a catalyst for changing the Indian

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Patent Act. This eventually led to the evolution of the Indian Patent Act 1970. During the 1990s India had undergone a rapid economic growth and that necessitated India to become a member of international trade agreements. Around 1995 the TRIPS agreement was enacted by the World Trade Organisation (“WTO”) for providing protection to the member countries in case of Intellectual Property Rights. However, at first India feared to implement the TRIPS laws as it assumed that it would again benefit the foreign multinational companies. India in the year 1995 became a member of WTO and thereby was obligated to modify the domestic intellectual property laws in order to comply with the TRIPS agreement. To comply with the TRIPS agreement, India had gradually and stepwise reformed the domestic patent laws. Therefore, there took place three amendments to the Indian Patent Act, 1970 in the years 1999, 2002 and 2005 for India to fully comply with the TRIPS obligations.

If looked at from the national scenario, India with the help of domestic patent laws has been able to provide considerable protection to the traditional knowledge of indigenous communities. The chapter 2 of the Indian Patent Act deals exclusively with the list of inventions that are not granted patent protection. Section 3 and 4 declare certain inventions that are not granted protection under the act. Section 3(p) of the Indian Patent Act, 1970 excludes those inventions from granting patent which in effect is traditional knowledge or which is an aggregation or duplication of known properties of traditional knowledge. In the 2002 amendment upon the Indian Patent Act, 1970, India had introduced a new provision as well as an obligation under Section 10(4) of the act to disclose the source and geographical origin of the biological material used in the invention by the inventor while applying for patent protection. This obligation helps in determining whether the invention is made out of misappropriating the traditional knowledge or not. Section 25(1)(d) and 25(2)(d) of the act states that a protection given under the patent act can be opposed if the subject matter of claim does not come under the meaning of invention within the act or if the patent is granted then before the expiry of one year from the date of granting protection. Even Section 64(e) of the act helps in revoking the patent already granted if any claim is made that the invention is not new or novel, if it is either known to the public or is used publicly in India before the date of claim or was published in India or elsewhere in any of the document referred to under Section 13 of the act. Apart from this India has also enacted Biological Diversity Act, 2002 by complying to the provisions of Convention on Biological Diversity, 1993 for providing protection to the biological resources as well as to the traditional knowledge of the indigenous community from misappropriation by the foreigners. The act provides that if any person has been seeking for any Intellectual Property Rights protection within India or outside India upon an invention which is based upon any biological resources or information/knowledge on the resources available from

India then an obligation is cast upon the inventor to obtain a prior informed consent from the National Biodiversity Authority ("NBA"). The NBA will after be looking into all the factors will determine whether to give consent for utilizing the resources as well as the knowledge. In case if the consent is given to utilize the biological resources as well as the knowledge then they determine the benefit sharing fees or royalty to be awarded to the indigenous community for commercializing their resources as well as the knowledge.

While examining traditional knowledge in the light of patent requirements, it is evident that almost all categories of traditional knowledge are in the public domain. The condition of novelty has defeated in as much as the common public is aware of the information. At least a particular segment of the local or indigenous community is mindful of the information regarding traditional knowledge. In most cases, the knowledge is in the community's continuous use. Based on the novelty's statutory requirement, one can categorically argue that most of the existing products and processes based on traditional knowledge will not satisfy the test of originality. The lack of novelty will disqualify the products based on the knowledge treated as an invention for patent protection.

From the above analysis, it is apparent that traditional knowledge does not fulfill patentability conditions. Moreover, it is excluded expressly under section 3 of the Patent Act from granting patent protection. Therefore, traditional knowledge, traditional innovations, and traditional practices are not patentable subject matters in the Patent Act's scheme, 1970. Issues of patentability mostly arise concerning traditional or folk medicines. Folk medicines include the medicinal practices of indigenous people and their knowledge of traditional cures, the curing properties of herbs, leaves, and other treatments unknown to the rest of the world. It also includes the genetic makeup of people who are immune to diseases thus far considered incurable. Unfortunately, most traditional medicines in their natural form often do not qualify for patent protection. Although traditional medicines have many uses, they often fail to meet patent applications' novelty and inventiveness requirements.

TRADITIONAL KNOWLEDGE DIGITAL LIBRARY (TKDL)

To prevent the issue over biopiracy of the traditional knowledge, India had devised the Traditional Knowledge Digital Library ('TKDL' or 'the Digital Library') as a tool for combating misappropriation of such knowledge. The TKDL was principally developed by Council of Scientific and Industrial Research ('CSIR') as a mechanism to prevent the Indian traditional knowledge from getting commercially exploited. It is essentially a database of traditional knowledge that has been collected by researchers through various sources, and provided to Patent Offices on an agreement. The information in the database helps the Patent Officers to reject the patent products based on it. TKDL received enormous resources from the Government since it was developed with the idea of benefiting indigenous communities. As promising as it may sound, it presently functions as merely a protective tool, because it does not perform the other functions of an IPR regime. An IPR regime typically performs a dual function wherein it acts as a protectorate of the intellectual work and provides monetary benefits towards it. The present TKDL framework merely performs one of the functions of providing protection to the knowledge, but does not accrue benefits to its holders.

In order to ensure the traditional knowledge is not misappropriated, CSIR under the chairmanship of Dr. V.K. Gupta entered into a MoU with the Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy ('AYUSH') under the Ministry of Health and Family Welfare of the Govt. of India. According to the Eleventh Five Year Plan, CSIR has been given the responsibility of systematically documenting traditional knowledge using books on Unani, Ayurveda and other medicine systems available in the public domain in the form of existing literature. CSIR has begun work and a major portion of the traditional knowledge has been meticulously compiled into a digital library in five popular languages including Arabic, English, Spanish, Japanese and German.

For digitisation, CSIR uses a system called Traditional Knowledge Resource Classification ('TKRC'), which includes around 5000 subgroups pertaining to medicinal plants. This information is structured under section, class, subclass, group and subgroup according to the International Patent Classification ('IPC'). Each verse of the ancient text is translated into the selected languages before being classified, using the TKRC. CSIR thereafter enters into MoUs with the patent offices of various nations in order to give them access to the digital library. Subsequently, when patents are applied for in the foreign patent offices, they get screened through the TKDL. Patent examiners use TKDL to ensure that the applications that use the same information are not granted patents. Thus, attempts at biopiracy whether deliberate or otherwise, are curbed. Therefore, if the patent so applied for is already part of traditional knowledge in the TKDL or in other words considered to be prior art, the patent application is rejected. All applications are run through the TKDL in order to ensure that they do not misappropriate traditional knowledge of India, in any fashion.

Despite these successes, several scholars have criticised the current functioning of the MoUs as well as the Library itself. These criticisms include the inefficiency in the functioning of the

library, its availability (or lack thereof) to the public, as well as the free access agreements signed by the patent offices of various countries. According to some, the TKDL ought to be made public and accessible to all, in order to prevent the of used defence of ignorance of a particular formulation's 'prior art' status. In some instances, the defence has argued that the literature used by TKDL was unavailable in the public domain, and therefore the application ought not be rejected. The concern that emerges out of such arguments is the lack of awareness about traditional knowledge systems of India. In order to prevent patent applications in the first place instead of fighting each one of them, these indigenous knowledge systems need to be so publicised, that patents cannot possibly be applied for the conspicuous lack of novelty. The databases created by China for instance are available to the public at the payment of a fee and therefore prevents biopiracy. This essentially ensures that the idea of such usurpation does not mature into a patent application in the first place. Admittedly, there is scope for improvement in the implementation of the MoUs signed by CSIR. The biggest defect in the functioning of TKDL has been the concept of 'free access' agreements, which essentially allows international patent offices to exploit the database created by CSIR without paying. Provided with extensive databases of what constitutes traditional knowledge, patent offices across the world can now easily reject unworthy patent applications, and thus reward the truly deserving claimants. The other important factor for consideration is the financial burden on the Government of India in creating this database. The Government has spent close to seven crore rupees (as of 2010) to establish this library and therefore, logically must expect some returns to this investment.

TKDL's success therefore is yet to be measured in real terms. It needs to be swiftly improved upon, after a careful scrutiny of the critiques provided by academicians and users alike. It holds vast potential to improve the lives of many and if used appropriately, may in fact possibly solve the tragedy of the commons.

TRADE RELATED ASPECTS ON INTELLECTUAL PROPERTY RIGHTS (TRIPS)

However, if looked at from the international perspective India has not been able to provide adequate protection to the traditional knowledge. This is because there is no specific provision under the TRIPS agreement which provide protection to the traditional knowledge of the indigenous communities. As there are no provisions under the TRIPS agreement the developed countries uses it as an opportunity to misappropriate the traditional knowledge of developing countries indigenous community without their consent. The TRIPS agreement does not even mention about the benefit sharing mechanism for inventing products by utilizing the traditional knowledge. The TRIPS agreement is silent as to th

definition of “Novelty” if compared with the Patent laws in India. For instance, the patent laws in United States of America consider an invention to be novel if it has been divulged outside United states by a non-written means. The United States Patent laws does not consider public use or sale of an invention in a foreign county as a prior art. If there exist a patent or even a written and published description of the invention then it can be considered as prior art or novel in the foreign country. India as such does not discriminate between the home country and the foreign country in case of novelty of an invention. For United States for rejecting a patent on the issue of biopiracy there has to be an evidence in the written form which shows that the invention is already in existence and cannot be considered as novel by granting patent. This also opens the door for developed countries like United States to misappropriate the traditional knowledge of indigenous community.

As TRIPS have failed to provide protection to the traditional knowledge, many countries are using this lacuna for misappropriating the knowledge. Hence, a revision of laws is needed to the existing TRIPS agreement. Article 27.3(b) of the TRIPS agreement needs to be reviewed to provide for sui generis protection of traditional knowledge, innovations and practices, as in the case of plant varieties. India along with some other developing countries have been fighting against the issue of Biopiracy with the World Trade Organisation (“WTO”) for a very long time. These developing countries have in various communications with the WTO emphasized the need to include in the TRIPS agreement certain provisions which could help the national country to protect their traditional knowledge from getting exploited or misappropriated. If the TRIPS agreement is not revised then the developed countries will continue to import the traditional knowledge and other resources from our country and will create a huge loss to our country. The developing countries like India and its allies have therefore proposed to the WTO that certain amendments are required to be made to the TRIPS agreement when a member applies for a patent which involves biological resources or traditional knowledge. The suggested amendments are as follows:-

- i. Disclosure of source or country of origin of biological resources or traditional knowledge used in the invention
- ii. Proof or evidence relating to the prior informed consent of the concerned national authorities for utilizing their resources or knowledge
- iii. Proof or evidence of granting fair and equitable benefit sharing to the specified people of country of origin

However, the United States of America and other developed countries who are members of WTO have not accepted the suggestions put forth by India and its allies in amending certain provisions of the TRIPS agreement. According to United States of America the provision as to disclosure of country of origin is not a proper solution in curbing the issue of Biopiracy. Till date this issue has not been resolved and still negotiations are carried out in the WTO. If the amendments suggested are included in the TRIPS then it would help the developing countries like India in protecting its biological resources as well as traditional knowledge from the issue of Biopiracy and misappropriation. It will help in reducing commercialization of products by the foreign multinational companies.

CONCLUSION

Biopiracy is an issue which threatens the everyday survival of indigenous community of India by exploiting their traditional knowledge. Our traditional knowledge will be lost if the issue of Biopiracy is not eliminated. If this traditional knowledge is not protected then there will be constant threats, misappropriation and patent by foreign multinational companies. The country is losing its unique traditional knowledge as there are no proper legislations enacted to protect the traditional knowledge. If we look at the past then many biological resources as well as traditional knowledge of the indigenous community have been used to patent products or commodities in the global trade. The Indian Government with the aid of Indian Patent Act, 1970 along with other legislations have been able to revoke certain patents. However, it is not possible for the government to always fight the legal battle of the indigenous community. Therefore, there is need for a sui generis law or legislation for traditional knowledge which would make it difficult for the foreign countries from patenting products based on traditional knowledge. As India has rich biological resources as well as traditional knowledge it should not lose any time in amending the TRIPS agreement. An international mechanism also gives a better protection for traditional knowledge by prohibiting the free import of knowledge from India. So, if there is a sui-generis or separate law protecting the traditional knowledge in every country along with the suggested amendments made to the TRIPS agreement at the global level then the developing countries like India can protect their traditional knowledge from the threat of Biopiracy.