J. Phytol. Res. **31**(1 & 2) :71-83, 2018 **ISSN 0970-5767**

REVIEW ON IPR ASPECTS FOR USE OF PLANT BASED BIO-RESOURCES AND THE ASSOCIATED TRADITIONAL KNOWLEDGE

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Intellectual property rights in bio-diversity are a significant part of the economic and policy landscape. During the past few decades the link of biodiversity and plant based traditional knowledge to Intellectual property protection is noted as one of the very contentious issues globally. Traditional knowledge is considered a form of IP as well a part of public domain and so not protected under the system of IPR. Further, bio-diversity which includes genetic resources is generally not considered IP as being considered as the gift of nature. In view of immense value of traditional knowledge, numerous commercial entities have misappropriated traditional knowledge without the consent of its original holder and the traditional society maintaining the traditional knowledge, since a long time. This paper reviews such plant based cases and norms on IPR issues on biological traditional knowledge internationally. This spot out the, concern norms pointing the IPR regime as existing can be used to protect TK, particularly the Geographical Indications and trade secret by mean of prior informed consent and sharing of benefits. Although, the TK is considered IP but internationally, it yet to be protected under IPR or any other related tools.

Key words: Intellectual property, Plant bio-resources, Traditional knowledge.

Introduction

Traditional knowledge (TK) related to plants, whether should be considered for Intellectual property rights (IPR) protection or open access in free public domain has always been a question of debate. It is squabbled by some that use of TK should not be for exclusive control and ought to be allowed to use making it free from obligation of burden of prior consent and benefit sharing. IPR are like any other property rights, allows the author, inventor, designer or other creative and innovative person to get benefits from his or her creativity and innovation. IPR is a well-established formal system of legal protection of IP system which facilitates various forms of IPR as per the kind of IP. The 'public domain' as defined in the context of IPR may not be accepted by indigenous peoples having traditional knowledge related to plants or any other form. Further, the Tulalip Tribes of Washington state has commented that the open sharing does not automatically confer a right to use the knowledge of indigenous people[1]. TK can be defined as know-how, knowledge, practices and skills and that are gradually developed, sustained and passed on from one generation to next generation inside a community, frequently

creating part of its own cultural or religious uniqueness. It is the knowledge which is continually developed, acquired, used, practiced, transmitted and sustained by the communities or individuals through generations[2]. TK means practices, knowledge and innovations of local indigenous communities having long-established life-styles. It is the knowledge that has urbanized over many generations of holistic conventional logical utilization of the lands, bio and natural resources and environment. It is generally moved down by word of mouth, from generation to generation and is mostly not documented. TK is legitimate and essential and anticipate its currently relevant broader application for human welfare. Its living nature also means that TK is difficult to define[3].

End use of bio-resources particularly plant species provide a variety of products like food, medicines and raw materials which proved subject of commercial utilization like drugs, industrial enzymes, food flavors, fragrance, cosmetics, emulsifiers, oleoresins, colors, extracts and genes used for improving crops and livestock through genetic intervention and the similar meaning has been cited for 'commercial utilization' under section 2(f) of the Biological Diversity Act, 2002. Some plant extracts are used in the manufacture of glue, soaps, cosmetics, dyes, lubricants, polishes, source of renewable energy etc[4]. It is noted that numerous bio-products have been developed and ongoing developments based on traditional knowledge have huge bio-prospecting.

There is doubtful condition of the plant bio-resource indigenous knowledge that embody many generations of experience and problem solving capability of ethnic groups across the world. A small fraction of this valuable information has been recorded till now and has proved a source of inspiration for further scientific research and value added products[5]. If bio-diversity and the associated TK are utilized fully, then it can play a major role in enabling all those countries having biological TK especially the applications of their medicinal aspects which certainly help such countries to greatly improve their economies through exploitation of their own wealth of plant resource TK.

The connection of biodiversity and TK to IP protection is noted as a very controversial issue internationally during the past decade. Traditional knowledge is like geographical indications (GI) that is generally held collectively and may not be exclusively and individually appropriated. Some of the major subjects of biological TK resources are herbal medicine, cosmetics, personal care items etc. It is understood that present intellectual property mechanisms including patents, copyrights, trademarks, trade secrets etc cannot protect traditional knowledge but novel forms of intellectual property law like sui generis right[6]. If there is a substantial improvement in the existing TK and if it can fulfill the criteria of patentability, a patent application may be considered for legal protection of such invention no matter whether based on TK. 'Novelty' is one of the criteria for patent and so the subject invention must be new in its particular field and in order to establish the novelty, it needed to be tested against the existing body of knowledge in that field (Prior-art). It is surprising that over the past few years, the United States and some other developed countries have granted patents over products or processes which were new in such countries but already known in other parts of the world[7].

TK as such by its nature seems cannot be protected appropriately under any of the IPR; rather, a sui-generis system may help to protect, manage and commercialized it. Traditional knowledge is considered intellectual property but there is no any recognized system of protection which exists for other kinds of intellectual

property. Almost every kind of IP policy raises the concern on various IP including industrial property and copyright but hardly on TK and any concern to enforce protection of biological TK based products is visible.

Plant based case studies

Hoodia Case

Worldwide, *Hoodia gordonii* belonging to family- Apocynaceae, is commonly known as Bushman's hat. It is a cactus like, leafless, spiny succulent plant having therapeutic properties and popular as an appetite-suppressant. The plant is widely used as a therapeutic remedy and since generations, also as a food and water substitute for local native people of the Kalahari desert. Natural habitats of this plant are Botswana, South Africa and Namibia[8]. The South African Council for Scientific and Industrial Research (CSIR) patented use of the active constituents of the plant responsible for suppressing appetite, without the consent of the San (South African Patent No. 983170. This was followed by the granting of international patents in 1998, GB2338235 and WO9846243). CSIR proceeded in 1998 to grant a license to the U.K.-based company Phytopharm for the patent. CSIR for permission to develop a bio-prospecting agreement made request to the Department of Environmental Affairs and Tourism (DEAT) and the response from DEAT was to acknowledge the lack of legislation in place to govern it. Phytopharm lead to a license and royalty agreement with Pfizer. In 2004 a joint development agreement was negotiated between Phytopharm and the consumer giant Unilever. The global value of functional foods is estimated at US $65 billion. The market value for the dietary control of obesity is over US $3 billion per annum in the United States alone[9]. The prices commanded for the dry product of up to US $200 per kilogram and there are hardly any benefits to the San people. It was insisted that the organizational policy on bio-prospecting was to eventually share benefits of research on plant based traditional knowledge. The CSIR and Phytopharm argued that, could the real owners of traditional knowledge be identified, and what if one group had historically stolen the knowledge from another group. In 2001, a South Africa-based NGO Biowatch along with the international NGO Action Aid alerted the media on the matter and consequently highlights of the story. Such highlights pressurized the CSIR to enter into negotiations with the San people. During negotiations, the San were faced with a difficult choice. Should they oppose or even challenge the patent, based on ethical considerations and lack of novelty, or should they adopt a more practical approach and become active partners in negotiating a share of royalties from the patent- this was a critical dilemma. At last, it was decided that benefits will be shared by the San people. The main features of the agreement included commitment, on the part of both the San and CSIR, to a progression of negotiating with one another in good confidence, in a view to arrive at a complete benefit-sharing agreement.

It was also agreed that both parties would provide each other with full disclosure of any 'matters of significance' relating to the agreement, and that all relevant disclosable information held by the CSIR relating to the P57 patent and subsequent licensing agreements would be made available to the San people. The absence of legislation to protect holders of traditional and indigenous knowledge presented a major stumbling block, requiring the San people to negotiate in the absence of any legal requirement for benefit-sharing agreements to be developed with owners of knowledge and biological resources.

Money received by the San would be extracted from royalty and milestone payments obtained by the CSIR, whereas profits received by Phytopharm and Pfizer

would remain unchanged. Overall, therefore, the San would receive less than 0.03% of net sales of the product although if successful this would still translate into millions of dollars[10]. The Trust started engaging with them and the first income, a total of Rs. 560,000 was received from the CSIR, at that time.

Kani's Case

Herbal medicinal plant *Trichopus zeylanicus,* family- Dioscoreaceae is widely known as Arogyapaacha. It is used by the Kani tribals, inhabitants of Agasthyarkoodam mountain ranges in Kerala, India. They use it as traditional medicine, being restorative, immuno-enhancing, anti-stress and anti-fatigue agent. The TK was divulged by Kani tribal members to the team of scientists at TBGRI who isolated 12 active bio-compounds from Arogyappacha and developed the drug 'Jeevani'. The patent was licensed to an Indian pharmaceutical manufacturer AryaVaidya Pharmacy Ltd. Benefit sharing arrangements between Kani tribals of Kerala and Tropical Botanical Garden and Research Institute (TBGRI) for the development of a drug called 'Jeevani'. A Trust Fund was established to share the benefits arising from such natural plant drug commercialization[1].

Novartis and UZACHI case

The UZACHI are indigenous people who had self help by establishing a laboratory and a capacity to capitalize on the vast range of local fungal species. This was intended to use microfungi and mycorrhizae for the discovery of drugs, study of wild mushrooms for their consumption, edible mushrooms for export etc. The beginning of the facility was with the Novartis-UZACHI agreement[12]. The agreement for bio-prospecting contained an up-front payment, royalty, training and capacity building and was for duration from 1995 to 1998. The UZACHI have been channelling the limited funds of upfront payment and the capacity building exchange that took place between the two parties to establish the Mycological Facility: Oaxaca (hereafter, the MFO). There was no plant based traditional knowledge in the agreement since UZACHI wished so, but the conservation of biodiversity using the funds generated by the agreement employs traditional knowledge[13]. There were 120 new bio-chemical compounds identified during initial collections by Novartis. The collections ended in 1998 and until now, the UZACHI have not heard back from Novartis. They also had extreme difficulty in tracing their partners in Novartis since the three main people who were responsible for the BIOLEAD project at Novartis and had originally contracted with the UZACHI have either changed jobs or have been transferred to other positions within the company. The UZACHI themselves understand the difficulty of keeping tabs on the company's R & D when their main contacts are no longer in place[14].

Sangre grado case

Croton lechleri is a flowering plant, native to northwestern South America belonging to family- Euphorbiaceae. It is commonly known as 'Sangre de grado' or 'Sangre de drago' both of which mean dragon's blood due to presence of red latex. The Amazonian tree sap has been used to cover cuts, abrasions, blisters, scratches, blisters, animal bites and insect stings to prevent bleeding, reduce inflammation, close wounds, injuries and to protect from infection. Shaman Pharmaceutical entered a deal with one Amazonian community for Sangre grado and payed to the concern Amazonian community some salaries, gave them a cow, and promised some royalties. However, the company dissolved it some years later and the promises could not be kept. Although a human Sangre grado pharmaceutical has recently come onto market, it appears that Shaman's corporate heir, Napo Pharmaceuticals, no longer controls the drug. The Napo's erstwhile business

partners Salix and Glenmark inherited Shaman's benefit sharing commitments; to the extent they were ever made. Later, Jaguar Animal Health launched its first product in year 2014, an anti-diarrhoea pill for calves that is derived from the Sangre grado. Even after 25 years of Shaman foundation and with over $200 million and counting spent to commercialize Sangre grado, the outlook for benefit sharing for Amazonian indigenous peoples remains miserable[15].

Teff grain case

Eragrostis tef, commonly known as teff, bunch grass and William's love grass is an annual species of grass native to Ethiopia and Eritrea. It belongs to family- Poaceae and its edible seeds are known as teff. It is a multi-use crop which has great importance for the Ethiopian diet and culture. In Ethiopia it is used for human nutrition as a flatbread, fodder for livestock, building material and to prepare alcoholic drinks. An incidence published by APA News that "Ethiopia is considering suing the Dutch company called Health and Performance Food International, to nullify the patent rights over Teff grain that the company registered in Italy, England, Germany and Austria[16]. Ethiopia claims that it is the first to domesticate the Teff grain across its highlands, which was believed to be the origin of the grain between 4000 BC and 1000 BC.

Issues related to traditional knowledge protection

There is a huge market for plant bio-resources and the associated traditional knowledge and so there are various commercialization activities by monopolizing it either by IPR or without IPR. So far many such bio-inventions based on TK have been granted and commercialized too while hardly any benefits shared with the concern holder of the TK out of the profit earned by the commercial entity using their local biodiversity and the associated knowledge. The increased market demand for such biological resources and the associated plant based TK would certainly help to increase earning and benefit sharing with the concern TK society peoples. However**,** mostly the commercialization of such resources is by other commercial entities and so hardly with prior informed consent of such indigenous people. Such misappropriation like unauthorized commercialization and so without sharing the benefit is considered bio-piracy. It is observed that there is hardly any prior informed consent or the sharing of the profits with the concern society maintain such bio-diversity and the associated traditional knowledge. Numerous applications filed for patent based on bio-inventions developed on TK filed in many countries including international filings. So far many such bio-inventions based on TK have been granted and commercialized too. Unfortunately, hardly any benefits arise to the concern holder of the TK as no sharing with the profit by the commercial entity using the TK of the indigenous society[16].

Biodiversity and genetic resources are not creations of the human mind and thus cannot be claim as such under IP system. However, it is noted that numerous applications for patent for bio-inventions based on TK have been granted and commercialized and so hardly sharing with the profit with the stakeholder i.e. the indigenous society. Further, with the development projects and the bio-prospecting activities, this diversity declining at a fast pace. Further, extinction of animals from the forest and grazing lands has added to the frailty of ecosystem and wearing of biodiversity. The TK, except those in secret use, are considered part of free public domain and may be treated like common property without anyone ownership and so enabling any person interested to use it for scientific analysis and bring out new inventions. Such inventions if granted patent may deprive the custodians of such TK

without any share in the profits and in some cases may force to go out of their traditional occupation. It seems very unfortunate that the labor and efforts taken by the generations to keep TK alive and use it for social benefit is taken away without any share or recognition[17]. Mostly the TK found undocumented and therefore mistakenly granted patent. TK is considered like IP but like other IP, there is lack of adequate protection to such IP i.e. TK and it reflects that TK had been over looked in the IPR system. In view of commercial utilization and industrial usage of the biodiversity and plant related traditional knowledge, both by mean of generic and patenting the goods developed based on such bio-resources, sustainable development and the interest of the stack-holders need to be maintained which is hardly attained by any such commercial entities. Now it has been well noticed that the demand of goods based on TK is continuous increasing and in view of its economical value, there is huge bio-prospecting and so the threats of bio-piracy too[18].

In recent years, indigenous communities have demanded protection for their traditional knowledge (TK) of bio-diversity. The present intellectual property rights (IPR) system does not entertain the challenges that indigenous peoples and local communities face as to their TK misappropriated by someone else with or without the IPR therein. The present legal framework both nationally and internationally to provide legal protection have gaps and so far, no any strong system of TK protection developed internationally or nationally[19-20].

Rationale for protecting traditional knowledge and biodiversity

In recent years, indigenous communities have demanded protection for their local bio-diversity and the associated TK. The vital requirement to ensure the conservation of biological diversity is now extensively recognized. In addition, there is an urgent need to know the conservers of bio-resources, knowledge and information holders relating to the use of such bio-resources and the protection of their interest, the bio-diversity and indigenous knowledge as well[21]. The TK is the IP either of traditional communities and sometimes societies in general, as being the expressions of idea. This is owing to the reason that it is the outcome of so much of labor, study, hard work, research, observation, success and failure- a cognitive and intellectual work out of brain. It is completely a learned behavior of a group of people i.e. the tradition of the people, and the same vary from members of one society from another[22]. The TK associated with bio-resources is an intangible constituent of the bio-resource itself: This TK on biological resources of the plants, especially about medicinal plants is also an inalienable part of the culture of the particular community or society in general. Therefore the TK should not be permitted to monopolize by other without involving the concern community for due consent and sharing in the profits[23]. The rationale for protecting traditional knowledge centres on questions of fundamental justice and the ability to protect, preserve and control one's cultural heritage.

Biodiversity and genetic resources are not creations of the human mind and thus cannot be claim as such under IP system. Innovations based on or developed using genetic resources may be protected by patent, geographical indications and plant breeders' right[24]. Traditional knowledge is like geographical indications that is generally held collectively and may not be appropriated exclusively individually. As the value and potential of TK is increasing, the challenge is to ensure that contribution of traditional communities is appropriately recognized. TK holding communities have frequent close linkage with the natural environment that indicates

TK can form the basis of a sustainable tool for locally-based development as well to benefit society and country economy[25].

Traditional knowledge as being important and having commercial viability, its misappropriation reported time to time. Therefore a policy needed for communities which is consisted of indigenous peoples contributing intellectual property like traditional knowledge so that their rights may distinct from the individual rights for such communities traditional resources. It is noted that numerous applications for patent for bio-inventions based on TK have been granted and commercialized and so hardly sharing with the profit with the stakeholder i.e. the indigenous society and therefore, in recent years, indigenous communities have demanded protection for their TK of Biodiversity and other related subjects like the IPR system[26]. The local bio-diversity or the associated TK misappropriated by the commercial entities without getting the prior-informed consent of the concern society maintaining such knowledge since time immemorial raises the concern of bio-piracy. Now days due to certain awareness however not the adequate, certain communities have sought some level of exclusivity[27].

After many incidents of bio-piracy and wrong patent on TK related inventions, the stakeholders of TK and genetic resources argued for some sort of legal rights like IPR to reward such indigenous society for maintaining the valuable resource of TK and genetic resources. It is essential to preserve the benefits of traditional knowledge for the entire mankind because it is culturally, socially and economically valuable. TK is an important lead to the developed countries for their new developments and manufacture of new products[28]. Apart from emerging international norm, which imply both legal and moral imperatives for protecting TK, there are number of reasons why TK sought to be protected. Some of reasons why TK sought to be protected are: (i) Improvement of Livelihoods of TK holders, (ii) Benefits to National Economy, (iii) Conservation of Environment, (iv) Prevention of Bio-piracy etc.

There are some of the issues like: whether TK may be treated like intellectual property or not; which IPR would be considered for TK if considered as IP; like new plant variety, whether TK may have a sui generis system of protection; whether the current legal framework may address to protect TK in the India; what options exist to protect TK subject matter; what learning from some successful case studies would be considered; how indigenous or local communities ensure control over there TK etc. and they need to be addressed. These issues addressed would offer a more adequate response to regulate the unauthorized use of it and protecting the interest of the concern society[29]. Consideration of such issues helps to create a framework where third parties cannot claim over such knowledge. International agreements on such objectives need to be rectified and implemented nationally ensuring rights of such TK custodians to manage its use commercially.

Need of international legal protection of traditional knowledge

There are some serious concerns to preserve, protect and fairly utilize the traditional knowledge on medicinal plants of India and some other countries. The laws which are there to give direct or indirect protection at the national level are insufficient and unfair. Thus there is a need for TK protection at national and international levels[30-31]. Very few countries have laws to protect traditional knowledge and have only a limited impact as there is territorial limit for the enforceability of the National and regional laws. Individual country are free to make policy to protect TK nationally but unable to implement over other countries and there is a need for such policy

internationally. Therefore, an international regime is needed that establishes minimum standards of protection of TK. Some countries have enacted the national legislation complying international obligations. However, there is no any official recognition of TK within the international IPR regime.

The effect of international negotiations would be a legally binding international treaty with well-defined policy objectives. Such treaties should leaves adequate space for national flexibility. Such a sufficiently balanced instrument may bind countries to ratify the same and legislate such law nationally. This would help to harmonize national laws and to provide protection internationally. It would also open up access to mines of TK which are hold by those communities[32].

The IPR aspects of use of genetic resources (GR) and the traditional knowledge always have been a part of discussion in several international organizations and in various international policy frameworks. The paramount international regime for the recognition and protection of TK are Convention on Bio-diversity (CBD) Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Protocol), WIPO Intergovernmental Committee (IGC) on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP) etc. The issues have been dealt and these organizations have cooperated with each other. The role of WIPO is the major one to protect the traditional knowledge and benefit sharing aspect[33]. Till yet, no international regime for the protection of TK has emerged, although some initiatives happened though is limited to access to genetic resources and benefit sharing by the FAO's International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and the CBD's Bonn Guidelines on ‘access to genetic resources and benefit sharing’. It is desired that international system acknowledge the IP of TK and the collective rights of the concern communities overhead to tackle the problem of illegal acquisition of GRs.

Recognizing the importance of international arrangements administered under separate mandates, and their objectives regarding conservation and safeguarding, the focal aspect of legal protection has been considered and particularly in IP policy making. Protection of biodiversity has been advocated during the UN Conference on Environment and Development held in 1992 in Rio de Janeiro. Such issues are the focused issues in discussion at various international forums including WIPO Intergovernmental Committee (IGC). Parallel discussions on such issues are also taking place in international forums like WIPO, WTO etc[34]. International frame-work on biodiversity and the associated knowledge includes: Convention on Biological Diversity (CBD), Cartagena Protocol on Bio-safety, Nagoya Protocol, 12 Principles under Economic Approach to CBD, Conference of the Parties to the Convention on Biological Diversity (COP) and its Decisions, Subsidiary Body on Scientific, Technical and Technological Advice, COP, CBD[35].

The biodiversity conservation has three main aims. The first is the conservation, the second is sustainable use and the third is fair and equitable benefit sharing. Nagoya Protocol of 2010 focuses on the third component (with which we are presently concerned), which is fair and equitable sharing of genetic material, including the traditional knowledge. At international level different organization like WIPO, WHO, WTO, UNESCO, UNCTADE are doing brainstorm for the protection of TK within the ambit of their international

frame-work. All member countries of WTO are trying to fulfill the minimum requirements of TRIPS and also trying to cover the traditional knowledge within the ambit of intellectual property laws[36]. WIPO is working on the issue yet to succeed to undertake a fresh analysis on the patentability aspects on the subject inventions applied by the member countries. This process is complex and there are many views. The TK stack-holders particularly the concerned communities now demand some sort of legal rights for their bio-resources and the associated knowledge. Law need to define where the line is to be drawn between fair usages not required prior informed consent and unauthorized appropriation[37].

Bio-resources and the associated knowledge

IPR system including patent, GI, rights in new plant variety and farmers/plant breeder rights may be used to directly protect traditional knowledge or may include tools preventing bio-piracy or wrong patenting in the subject. Bio-piracy or misappropriating on such subject may be prevented by enabling policy in the favor of the concern society of the bio-resource and the associated TK like prior informed consent or sharing the profits out of the commercialization of goods developed using their TK. The nature of IP protections sought for TK may be either defensive or positive protection. The indigenous society may have certain exclusive rights on use of the local bio-resources and the associated TK to prohibit others[38]. Government must protect their interest by preventing patent on inventions based on their TK without their prior consent. If the TK protection facilitated internationally, it would make possible to protect indigenous IP including traditional remedies and such legal monopoly certainly facilitate the communities sharing in the profits from commercial exploitation of such protected TK by authorized user(s). Wrong patenting in the subject may be restricted by making accessible some sort of database of such TK helping patent examiners finding relevant prior art. Further, such patent applications may disqualify if not comply with obligations as suggested by CBD and other such conventions. Some of such compliance are prior informed consent (PIC), mutually agreed terms, access and benefit-sharing (ABS), disclosure of origin etc.

Different approaches could be used within any legal instrument addressing the scope of protection of TK. Scope of IP protection of a product or process may be determined by its utility, newness and non-obviousness. It is noted that TK lacking such criteria particularly the newness and inventive step(s). In view of immense value and the potential of TK, sui generis system has developed for such intellectual property like IPR legal instrument for others. New plant varieties are protected under such sui generis system in some countries. Similarly, sui generis system may be developed for protecting TK. The nature of IP protections sought for TK may be either defensive or positive protection.

Defensive protection aims to stop people outside the community from acquiring intellectual property rights over traditional knowledge[39]. It is to ensure that unauthorized person do not gain undue IPR over any creation based on TK. It has been noted that other countries mistakenly granted patent rights on subjects under TK in view of no prior-art found under search tools available to the patent examiners and later efforts have been applied for invalidity of such patents. It had realized that a defensive protection may be applied to such undocumented TK by well documentation of the same. Therefore, some measures had been taken including minimum documentation under Patent Cooperation Treaty (PCT). Some formal documentation

like providing a confidential or trade secret agreement and registries of TK supports sui-generis protection systems.

Traditional Knowledge Digital Library (TKDL) in India is one of the examples of such registries providing the Defensive protection to TK not in India but internationally prohibiting wrong grant of patents on such inventions. TKDL has been conceptualize and made accessible to all patent examiners round the world. After success of Indian TKDL, some nations are also developed and developing TK databases that may be used as search tools establishing novelty of the inventions related to TK. Such TK databases may be helpful as an evidence of prior art defeating claim(s) to a patent related to TK[40].

Two aspects of IPR protection are prohibiting unauthorized usage and exploitation of TK by the concern right-holder community itself. Positive protection in such matter is the granting of rights that empower such communities to promote their TK, control its uses and benefit from its commercialization. Regarding the patentability of inventions based on TK, as such TK is considered in public domain and lacking novelty and so it will not fulfill the requirements of patentability. When the society members innovate within the TK framework, they may protect their innovations by patent[41].

Conclusion

There are certain requirements to establish patentability of the inventions based on TK like whether it is considered obvious in view of the TK. There are some successful cases of non-consideration for patent, successful opposition and revocation of the granted patents.

Traditional Knowledge Digital Library (TKDL)

After the incident of some cases of bio-piracy of turmeric, neem, basmati etc. where patent has been wrongly granted in-spite of such knowledge being available in public domain, it was observed that such happened as such TK was not accessible by the patent examiners which lead to the grant of wrong patent. Further, it is noticed that many times TK is not well documented and passed orally generation to generation and prone to be misappropriated by such commercial entities. Therefore, it was felt the need of some sort of electronic database of such TK which may be accessible by the patent examiner to examine patentability criteria of the inventions applied for the patent. India took the initiatives and has developed a TKDL. Many developed countries using this TKDL and rejected numerous applications filed for patent in their countries on the ground that no novelty of the invention as being already cited in the TKDL and so considered part of the public domain[42]. Many granted patents were objected on the ground that no novelty of the patented invention in view of the information disclosed in the TKDL. The TKDL is well appreciated at World Intellectual property organization (WIPO) and it is recommended by WIPO that all such countries must developed such electronic database of their countries TK which later-on will be merged internationally helping to examine patentability of the invention applied for the patent.

To examine the patent applications, the examiners need to establish the novelty and inventiveness in view of the prior art. Therefore, TK databases like Indian TKDL are needed which help the examiners avoiding wrong patents. Thus TKDL needs to be created by all those countries which are having biodiversity and related TK.

Implementation of international obligations

Patent applications in the subject should disqualify if not comply with international obligations particularly CBD, Nagoya protocol etc. General compliances sought are prior informed consent, mutually agreed terms, fair and equitable benefit-sharing, disclosure of origin etc.

Provision of prior informed consent appropriating such TK

The prior informed consent (PIC) appropriating such TK may require certain agreement having terms conditions including benefits sharing clause. Even commercializing such TK by someone not from the concern society, with or without getting IPR need to be regulated and may attract provisions of PIC agreement having terms conditions including benefits sharing clause etc. In view of importance of TK and its misappropriation by the unauthorized person, some suggestions are: All nations should recognize TK as IP and may device some sort of IPR protection, The nations shall endeavor to pursue patent examination from TK perspectives too which required the training of patent examiners in the examination of patent applications related to plant based traditional knowledge. Now, some international patent offices are using TKDL during examining the application for the novelty criteria. The nations shall endeavor to cooperate through their respective government authority like IP authority, bio-diversity authority or other relevant authority to enhance the understanding of issues connected with TK.

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