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INTELLECTUAL PROPERTY RIGHTS FOR TRADITIONAL HEALERS: INDIAN PERCEPTION

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Abstract

The patents and intellectual property rights (IPRs) associated with the development of new crops and other products are often critical to trade. Yet there is no unified international framework for a fair IPR regime in genetic resources. At this multi-faceted interface, complex ethical questions arise. This article provides an overview and discussion of key issues, dilemmas and challenges. It points to possible modifications and at ways to devise new forms of intellectual property ownership that may better suit the needs of those who seek to protect traditional medicine. It sets out to establish an equitable IPR regime for biodiversity taking into account: environmental and social impacts; technology transfer; and the relation between traditional knowledge and IPRs.

Key words: Traditional medicine; Intellectual property rights
JEL classification: O34

Traditional Medicine & IPR

World Health Organization (WHO) defines 'Traditional Medicine' as "The sum total of all knowledge and practices, whether explicable or not, used in diagnosis, prevention and elimination of physical mental or social imbalance and relying exclusively on practical experience and observation handed down from generation to generation, whether verbally or in writing".

What makes Traditional medicine a special case study is the fact that usually it is passed among community members through verbal communication, which they are practicing since centuries. This renders it unsuitable for protection under modern framework where everything is based on documentation and is applied to all countries uniformly.[1]

Traditional medicine[2] is a part of the country's own tradition and is in use for centuries but lacks documented evidence of safety, efficacy and quality. A fair distinction can be made between condified and non-codified medicinal know-how[3] Codified medicine systems include well established structures like Chiness system, Ayurvedic and Unani system found in India and Homeopathy in Europe. Non-condified medicine system is knowledge possessed by Tribes and Indigenous people and is being used since centuries. A distinction can be made as procedure-based therapy and medication-based therapy. Procedure-based

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therapies are osteopathy, chiropractic therapy, acupuncture and spiritual therapy. Medicine based therapies use minerals, animal parts, medicinal parts and herbs to treat diseases.[3]

The importance of traditional medicine stands renewed due to recent high profile cases of misappropriation of knowledge without consent and sharing of benefits with the community. For any invention to be patentable it has to satisfy three criteria, i.e., novelty, inventiveness and industrial applicability (utility). Traditional Medicine does not satisfy any of these criteria thus making it unique and a special case of study.[4]

Traditional Medicine can be seen as a subset of Traditional knowledge. A multifaceted concept, Traditional knowledge embraces every walk of life from genetic resources, farm produce, personal and spiritual aspects like yogic practices to Traditional Medicine. Traditional Medicine is the knowledge possessed by local and indigenous community relating to medicine.

TRIPS standards are based on models existing in developed countries for their Pharmaceutical Industry, making it inadequate for developing countries where industry is still growing or is in nascent stage. Besides TRIPS does not provide a clear guidance for Traditional Medicine which is a strength of developing countries.[5]

To obtain patents under existing framework awareness among indigenous community is needed and services of qualified professionals are required which is not possible on most of the occasions. The hurdle[6] is not only in obtaining patent, but in maintaining them. First of all community may not be aware of such infringement and even if they are aware, fighting a suit against powerful companies can be a very costly exercise for them.

Paragraph 19[7] of the 2001 Doha Declaration says, "TRIPS Council should also look into relationship between the TRIPS Agreement and the UN Convention on Biological Diversity (CBD) and protection of traditional knowledge and folklore". Most recently discussed are proposals on disclosing the source of biological material and associated traditional knowledge.

Paragraph 19 reviews Article 27.3(b) and 71.1 of TRIPS, which deals with relationship between TRIPS and CBD and its impact on protection of Traditional Knowledge .

Article 27 of the TRIPS Agreement defines for which inventions government has to provide patent protection and options for exclusions from the patent law. Inventions that can be patented include both products and processes, and should generally cover all fields of technology.

The inventions which are based on Traditional knowledge of local community or country pose a significant issue for justification. The two major conventions i.e. TRIPS and CBD need to coordinate[8] so as to give a, meaningful protection to all traditional forms of medicines. There are significant grey areas to application of TRIPS provisions for plants and animals. Due consideration and revision is required if moral and ethical issues are involved as in case of patenting invented life form. Need is felt for clarity about meaning of effective protection for new plant varieties.

Article 71.1 of TRIPS provides a detailed procedure for its review and amendment in view of experience gained in its implementation and new developments. New insights and inadequacy in protecting Traditional Medicine call for an urgent reconsideration and amendment to TRIPS agreement.[9]

In 1987, a medicine named JEEVANI[10] was developed from Trichopus zaylanicus (Argoyapacha) plant found in tropical forest of southwestern India. Jeevani is derived from Arogya paacha plant and is traditional knowledge used by Kani tribe of Thiruvanthapuram district in Kerela, India. It helps in improving athletic performance, mentel alertness, and

work out put. Scientists at Tropical Botanic Garden and Research Institute (TBGRI) kerela, India undertook research to isolate active elements in the Arogyapaacha plant. They filed a patent application in India and not in other countries.

In 1995, TBGRI negotiated technology transfer agreement to other interested parties on payment of license fees which was to be shared in a fifty-fifty proportion with the tribe. Now this tonic is manufactured by major Ayurvedic drug companies in Kerela. With money earned and assistance of TBGRI 'Kani Samudaya Kshema Trust' was created to promote welfare of the Kanis in Kerela and to ensure sustaible use and conservation of biological resources. The trust is successfully run and regularly funded with the royalities received by TBGRI for transfer of Agogyapacha related technology.

Patent of Jeevani and sharing of result was possible because basic principles and requirements were observed and honored by all parties involved. Any patent system must ensure at least three things.[11]

Industry should be seen as scientific parks where discoveries are confirmed and inventions made using advanced tools. They spend million of dollars to make this knowledge suitable for use in contemporary times, so they need to be promoted.

There have been cases of authorities granting patents for inventions which are neither novel nor inventive. The barometer for the criteria is with regard to traditional knowledge available in public domain. This can happen due to two reasons:

- Knowledge is written down but is not accessible to patent examiner.
- Knowledge is not written and is passed from generation to generation orally.
- It is relevant to quote a famous patent dispute related to grant of patent for Turmeric.

Documentation

TKDL is an initiative by India to digitize and document knowledge available in public domain to facilitate systematic arrangement, dissemination and retrieval of information.[12] While granting patents, authorities check invention to prior art in public domain. Documentation of knowledge helps trace invention in public domain and to know whether it is eligible for patents, preventing misappropriation of Traditional knowledge. Documentation helps in tracing indigenous community with whom commercialization benefits are to be shared. This documentation process has to start at community level in the form of 'People Biodiversity Register' or 'Community Biodiversity Register.[13]

Access and Benefit Sharing

The indigenous community saves valuable time, money and investment by providing valuable leads and cutting down R&D resources. This makes a significant point as benefit is shared with indigenous communities and Prior Informed Consent has be obtained for accessing their Traditional Knowledge.[14] The fact that claim of patent can be made outside the country holding knowledge makes it important that the user country creates legislative environment, to ensure legislations of the other countries are respected. This is the way that will lead to equitable sharing of benefits. One suggestion world over is that in patent applications, the applicants should identity source of these resources and furnish proof that

prior informed consent of the country holding knowledge has been taken. Incorporation of these two requirements will ensure benefits are shared with local communities.

Sui Generis

It is a widely felt need that countries make legislation based on national priorities to ensure protection of their unique national knowledge, benefits to indigenous communities and prevent misappropriation of their knowledge. This is a legal way to recognize ownership of knowledge and reward communities rights to indigenous community.[15] This legislation provides for Prior Informed Consent, access and benefit sharing and protecting their rights. It envisages free exchange of information among local community. On similar lines Indian Bio-Diversity Bill was introduced in 2002.

Protection of Plant Varieties and Plant Breeders Rights

Intellectual property protection has been conferred around the world in relation to plant materials in a number of ways. Intellectual property rights were applied primarily to mechanical inventions or artistic creations. Application of intellectual property rights to living things is of recent origin. Vegetatively propagated plants were first made patentable in United States in the 1930s. Protection of plant varieties in the form of plant breeders' rights evolved in second half of 20th century. US model of plant patents is distinct from normal as utility patents. Normal patents on plants or parts thereof, such as cells are allowed. One can patent plant varieties as in US and other countries. State can allow parents of deoxyribonucleic acid (DNA) sequences. Actual form of legislation a nation uses for its plant protection depends upon its state of development and strategies that the nation uses to protect its national interests.

The key issue in this context is related to ways and means of recognizing contribution of farmers to the conservation and development of plant genetic resources. Giving recognition to farmers for their contributions to conservation and innovation and ensuring increased spending on agricultural R&D, are essential ingredients for meeting the food requirements of the growing world population expected to be in the region of 8 billion by the year 2020.

The system of protection of new varieties of plants is dealt with by the Ministry of Agriculture, and in recent years it has acquired importance, and policy makers are becoming increasingly aware of its value in the development of agriculture and in the protection of food, fiber, and renewable raw materials. This awareness is fostered by a trend towards privatization of plant variety and seed sector.

New varieties of plants giving a higher harvested yield or providing resistance to plant pests, diseases, are essential factor in increasing productivity and product quality. It is important to identity a system that is suitable to the particular agricultural or socio-economic circumstances of a given country.

Breeding new varieties of plants requires investment in terms of skill, labor, material resources and funds, and may take many years. A new variety, once released, may in many cases be readily reproduced by others and deprive its breeder of the opportunity to profit adequately from investment. Granting to a breeder of a new variety, the exclusive right to

exploit his variety, encourages him to invest in plant breeding and contributes to development of agriculture, horticulture and forestry.

To be eligible for protection, a plant variety must fulfill certain conditions. It must be distinguishable from any other variety whose existence, at the time of application, is a matter of common knowledge. It must be sufficiently uniform, subject to variation that may be expected from particular features of its reproduction by seeds or vegetative propagation. It must be stable in characteristics, and remain unchanged after repeated reproduction by seeds or vegetative propagation; it must be stable in characteristics, and remain unchanged after repeated reproduction or propagation and case of particular cycle of reproduction or propagation, at the end of each such cycle; it must be new in the sense and must not have been commercialized prior to certain dates established by reference to the date of application. It must be given a variety denomination, or, a name whose use will be mandatory in commercial transactions of the variety, even after termination of protection. This right rarely implies that the breeder enjoys a monopoly, for it is in the nature of agricultural production that varieties must be used by many farmers. The right could, therefore, be considered as one to assist in establishing partnership.

The right granted to the breeder is subject to important limitations. Most countries provide an exception to the breeder's right under which farmers may freely produce seed for use on their own farm("farmer's privilege".) like most other intellectual property rights, the breeder's right does not extend to activities done privately and for non-commercial purposes. This exclusive right includes only production for commercial marketing; it does not extend to production of propagating material that is not for commercial marketing. Hence, production of seed, by a farmer for subsequent sowing on his own farm falls outside the breeder's protection.[16]

Initiatives were taken in the year 2001, for realizing of farmers' rights in relation to breeding of new varieties of crops, and were included in FAO's International Treaty on Plant Genetic Resources for Food and Agriculture, adopted by its General Conference in November 2001. It contains a specific clause concerning operatinalisation of farmer's rights.[17] In 2001, the protection of Plant Varieties and Farmers' Rights Act of India, gives simultaneous rights of farmers, breeders, and researchers, and the protection of the public interest.

Agro-Bio-Diversity & IPR

Agro biodiversity is backbone of nation's food security and basis of economic development. Over the years this diversity in India is under pressure due to massive commercialization of agriculture leading to almost extinction of traditional farming systems. In top-down system of agricultural research, farmers are seen merely as recipients of research rather than as participants in it. It has contributed to an increased dependence on relatively few plant varieties. [18] This trend and increasing industrialization of agriculture are key factors, in what can only be called "genetic erosion". The term refers to loss of species and the reduction of variety. Behind this commercialization there lies interest of breeders for obtaining intellectual property rights. It has a complicated relationship with this diversity.[19]

India is an agriculture-based country where more than 70% people are living in villages and their main sources of subsistence is agriculture. Majority of Indian farmers are poor and they live on subsistence farming. Traditionally Indian agriculture has been characterized by the use of extremely diverse crops and cropping patterns/methods. They are

the original curators of agro biodiversity. More specifically farmer women had the greatest contribution towards maintaining this diversity. A traditional rice field provided not just rice, but also fish, crabs, frogs and other important elements of the rural diet. Traditional farming also provided for fuel, fodder, and other rituals, cultural needs of the community, and was intimately connected to social relations, festivals, and other aspects of rural life.[20]

When farmers look to increase their sale they often sow different and commercially more viable seeds. Sometimes, government schemes force them to adapt specific seeds or new plant varieties. Commercial agriculture tends to increase genetic uniformity and this, in turn, leads to genetic erosion. IP system encourages commercial agriculture that accelerates genetic erosion.

The criteria for awarding PVC (Plant Variety Protection) certificate to the breeder (PBR) involve lower thresholds than the standards required for patents. There are requirements for novelty and distinctiveness, but there is no equivalent of non-obviousness (inventive step) or industrial application or utility. Thus, PVC laws allow breeders to protect the varieties with very similar characteristics, which mean the system tends to be driven by commercial considerations of product differentiation and planned obsolescence, rather than genuine improvements in agronomic traits.

Another concern is the criteria for uniformity. While proponents argue that Plant Variety, by stimulating the production of new varieties, actually increases biodiversity, In reality requirement for uniformity, and the certification of essentially similar varieties of crops, will add to uniformity of crops and loss of biodiversity. Similar concerns have arisen in respect of greater uniformity arising from success of Green Revolution Varieties, leading to greater susceptibility to disease and loss of on-field biodiversity. In addition, the privatization of genetic resources that have been engineered and patented. accelerates the trend towards monoculture cropping. An engineered organism may produce unanticipated harmful impact on other species in its new environment that may cause further erosion and ecological degradation.[21]

Improved seeds require more fertilizer and pesticide consumption, which has tremendous contribution towards biodiversity loss, and have direct impact on floral, faunal and microbial population. Substantial royalty's payment to the developed countries and multinational seed companies will greatly increase the debt burden that could further intensify environmental and social disruption if we consider debt repayment such as the export of natural products.

Despite emphasis on value of traditional farming system, prevailing belief among most agricultural scientists is improved agricultural systems should replace those traditional systems that are not capable of producing sufficient food and income. The Protection of Plant Varieties and Farmer's Rights Act, 2001 (Act 53 Of 2001) of India claims to protect the farmer's right. It has a distinct inclination towards breeders' right. Traditional farming community of India know how to preserve biodiversity, have been doing it for centuries, and do not need a great deal of outside direct assistance to get the job done. They cannot continue to preserve essential agro biodiversity solely for the sake of conservation if there is no compensation for their labor or access and control over their ancestral resources. There are many factors like intellectual property rights for the farmers, community rights, and true encouragement for traditional farming systems through various institutional means from government front, proper local in-situ management and conservation of plant genetic resources, current public distribution system of the government are needed to be restructured and reexamined on a war footing. Agro biodiversity of India cannot be preserved in-situ

unless local communities see it in their best interest to do so. Marginality and poverty are great impediments towards conservation of agro biodiversity in India. Intellectual property rights and its various forms like patents, trademarks, geographical indications and trade secrets will benefit local communities if government allows income from these legal arrangements to reach local population. These are the factors, which need to be restructured in order to see a better and sustainable tomorrow.[22]

Bio piracy Based Perceptions

Some conflicts have arisen from perception that knowledge-rich companies and researchers from developed world have been attracted to wealth that lesser developed countries have in their traditional knowledge systems. The rich nations argue that access to such biodiversity and community knowledge by the developed nations is necessary for larger welfare of mankind, as this advances knowledge and leads to new products, and contributes to well-being of global consumers. Those who guard interests of the lesser developed, argue that this access to the resources of developing countries does not benefit them, while their natural resources and intellectual property continues to be appropriated and exploited.

Conflicts further deepens, as many researchers from the developed world have obtained knowledge about biodiversity and its uses from local innovators, communities and institutions, but they have not even acknowledged their contributions, let alone sharing of benefits from such knowledge.

It has been argued that the communities have a storehouse of knowledge about their flora and fauna, their habits, their habitats, their seasonal behaviour and the like-and it is only logical and in consonance with natural justice that they are given a greater say in all matters regarding study, extraction and commercialization of biodiversity. Conflicts vanish when a policy is developed that does not obstruct the advancement of knowledge, and provides for valid and sustainable uses and intellectual property protection with just benefit sharing.

It is true that many indigenous cultures appear to develop and transmit knowledge from generation to generation within a system, individuals in local or indigenous communities can distinguish themselves as informal creators or inventors, separate from the community. Some indigenous or traditional societies are reported to recognize various types of intellectual property rights over knowledge, which may be held by individuals, families, lineages or communities. IPRs and traditional knowledge should draw more on the diversity and creativity of indigenous approaches to IPR issues. There are power divisions as well as knowledge divisions among people in many communities, and sharing of benefits with a community as a whole is no guarantee that the people who are really conserving traditional knowledge and associated biodiversity will gain the rewards they deserve for their efforts, since it provides the much needed financial support for the first time for such endeavors.

Conflict resolution can take place, when it is realized that there is a deep philosophical divide on the issue of IPR. The existing IPR systems are oriented around private ownership and individual creativity or invention. They are at odds with indigenous cultures that emphasize collective creation and ownership of knowledge. There is a concern that IPR systems encourage the appropriation of traditional knowledge for commercial use without fair sharing of benefits, and they violate indigenous cultural percepts by encouraging commoditization of knowledge.[23]

Long considered a technical issue, intellectual property has entered the political arena and is often held up to public scrutiny, obliging its defenders to justify it. This is due to increasing economic importance of intellectual property, which has made it an important issue in trade relations between states.

The increasing integration of IP issues and concerns with broader international issues, and its emergence in many other fora as an issue of great interest, are the causes of increasing politicization of intellectual property. IP issue have been brought in to debates on the protection and exploitation of biodiversity resources, on the development and transfer of technology for environmental protection, on the protection of folklore and indigenous culture, and on other aspects of economic and social development.

IP is a techno-legal subject leading to economic growth of the society. In a democracy, policy issues pertain to technological and economic policies, and the technocracy implementing these, should ideally remain a priority despite change of ruling parties of the countries, whether developed, or developing. This is an ideal which is not practiced.

The need to continue efforts to build a greater awareness among all sectors of society, policy makers, government officials, business community and the general public, about relevance and role of intellectual property with regard to economic, social and cultural activities in society, is an imperative. The intellectual property system is a sophisticated system with legal, technical, economic, social, cultural and administrative dimensions. A collective effort to demystify would make it integrate in to development perspectives of developing and developed world.

Conclusion

Increased commercial interest in Traditional Medicine has made international and national communities to revise and amend their laws to protect unique systems and reward local indigenous communities to whom knowledge essentially belongs. CBD recognizes nation's right to make laws; it does not set any minimum standards to protect them. Provision in TRIPS allows countries to exclude some kind of plants, animals and biological process from patenting, but these measures do not give complete protection to traditional knowledge.

There exists a vacuum in the overall framework that can provide comprehensive protection to traditional medical knowledge. In most of the cases, patents are granted outside country that holds knowledge. In such a situation the interests of the nations cannot be protected unless presence of international framework that recognizes and respects national laws. Besides international action, there is a need for nations to protect their communities by making national laws and addressing relevant issues like Documentation of knowledge, access benefit sharing and Prior Informed Consent. A need of the hour is that nations should show mutual respect for national legislations, for the benefit of mankind.

Work on traditional knowledge is undertaken in various inter-governmental bodies like Convention on Biological Diversity (CBD), World Intellectual Property Organization (WIPO), Food and Agriculture Organization (FAO) and United Nations Conference on Trade and Development (UNCTD). The efforts of these bodies are in stage of discussion and a comprehensive frame work has yet to evolve urgent action is needed by all concerned.

Bio piracy and patenting of indigenous knowledge is a double theft because first it allows theft of creativity and innovation, and secondly, the exclusive rights established by patents on stolen knowledge and steal economic options of every day survival on the basis

of indigenous biodiversity and indigenous knowledge. The patents may be used to create monopolies and make everyday products highly priced. If there were only one or two cases of such claims to invention on the basis of biopiracy, they could be called an error. Biopiracy is an epidemic, 'Neem', 'haldi', 'allma', mustard, basmati, ginger, castor, 'jaramala, Amaltas' and now 'karela' and 'jamun'……The problem is not, as was made out to be in the case of turmeric, an error made by a patent clerk. The problem is deep and systemic. It calls for a systemic change, not a case by case challenge.[24]

A patent system which is supposed to reward inventiveness and creativity systematically rewards piracy. If a patent system fails to honesty apply criteria of novelty and non-obviousness in granting of patents related to indigenous knowledge, the system is flawed, and it needs to be changed. It cannot be a basis of granting patents or establishing exclusive marketing rights. The problem of biopiracy is a result of Western style IPR systems, not the absence of such IPR systems in India. Therefore, the implementation of TRIPs, which is based on the U.S style patent regimes, be immediately stopped and its review undertaken.

TRIPs is based on the assumption that the U.S. style IPR systems are ``strong'' and should be implemented worldwide. In reality V S System is inherently flawed in dealing with indigenous knowledge and is "weak" in the context of biopiracy, the review and amendment of TRIPs should begin with an examination of the deficiencies and weakness of Western style intellectual property rights systems. A globalised IPR regime, that denies the knowledge and innovations of the Third World, which allow such innovations be treated as inventions in the U.S, which legalizes monopolistic exclusive rights by granting of patents based on everyday, common place indigenous knowledge, is a regime that needs an overhaul and amendment.

Amending TRIPs and U.S. patent laws is a challenge which has to be taken up. The problem is not with Indian IPR systems but with the Western style IPR regimes which systematically enable piracy of indigenous knowledge and practices through patents.

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