CHAPTER IX

CONCLUSION

INTRODUCTION

Traditional knowledge associated with medicinal plants is easy to exploit. Biopiracy takes place through the process of patent. In this process, either by suppressing the 'prior art' or the 'existing traditional knowledge' in the patent application which is in public domain, patents are obtained or granted because there is no mandatory 'source disclosure clause' about the invention in the patent application. Patents are being granted on the so called invention by acknowledging it as novel and non-obvious and in a way legally refusing to accept the 'prior art' or 'existing traditional knowledge' as 'prior art' or 'existing knowledge'. This is due to this gap in the legal framework of those countries and their attitude to exploit traditional knowledge enriched weak third world countries. As a result, the holders of such traditional knowledge (either the country or the community) are not getting the legitimate share of royalty or benefit-sharing from those companies/the research institutes/the persons who have obtained wrongful patents and are commercially exploiting a new type of intellectual property of the society or the country. This type of biopiracy of Indian traditional knowledge through wrongful patents is very common.

There are rampant incidents of TK exploitation within India by the companies and trusts which manufacture and market the ayurvedic medicines. The main issue is that these companies and trusts have huge yearly turnovers and earning large profits from these products. Such companies obtain information relating to genetic and bio-chemical from the traditional knowledge system. This is also a form of biopiracy but it is yet to engage the attention of the law framers.

In a nutshell, it is clear that traditional knowledge of India associated with medicinal plants is not well protected. The present IPR regime to protect traditional knowledge of medicinal plants at the international level is weak. Further no legal framework exists in India as in the TRIPs. This gives rise to a need for a model sui-generis legal framework exclusively for traditional knowledge associated with medicinal plants or genetic resources of India which can offer a fair and appropriate protection everywhere in this world. This protection would be comprehensive and should take into account all matters of protection and scope of misappropriation, causes of destruction, so on and so forth. This can be a model law for other traditional knowledge enriched countries of the world to be enacted for the protection of their traditional knowledge.

Exploitation of traditional knowledge is an emerging method of violation of fundamental rights. It is the result of globalisation and not envisaged by the framers of

the Indian Constitution. The violations occur not because of the instrumentalities of the State is directly indulging in it, but because of its acceptance of some of the binding commitments. This is where the State is facilitating other countries to encroach upon the fundamental rights of the Indian people. The violations occur because as per the international obligation, the State is allowing foreign patent rights to be enforced in India. The State cannot just wash off its hands in this regard. Though there is no need to have a legislation to implement an international treaty; it can be done through an executive action. Such executive action resulting in violation of fundamental right is liable to be struck down under Article 13 of the Constitution. Such action has not yet taken place-neither has a Writ Petition being filed nor has the apex court taken any suo-moto cognition of the situation.

Take for example, patents on Indian traditional knowledge associated with medicinal plants granted by the foreign countries-USA and others. Though no patent can be granted on traditional knowledge in India, but due to international obligations, U.S and other medicinal companies do business in India with their patents granted on Indian traditional knowledge associated with medicinal plants and genetic materials. India is unable to remedy this situation. Though the national laws of U.S or other countries fulfil the minimum criterion of WTO-TRIPs, but there are other areas where there is no unanimity and these diversities are allowed by WTO-TRIPs. Patenting on traditional knowledge associated with medicinal plants and genetic materials is one such thing. Being fully aware that this type of patenting is with the permission of the WTO-TRIPs and as a result fundamental rights are going to be violated, India signed the WTO agreement. This amounts to violation of fundamental rights by the State. And these violations are occurring in India when the patent is operative in India and it is being violated when patents are operative in foreign countries and other foreign countries. As Constitution of India does not have any extra-territorial operation, there is no extra-territorial protection or remedy.

Individuals, families and communities in possession of traditional knowledge use it as their livelihood which is a named fundamental right in the Constitution and is also covered under right to life under Article 21 of the Constitution. Thus it is also the human right of these communities and as such is national assets.

The traditional knowledge associated with medicinal plants and genetic materials of India- the method and the medicine which the Indians preserved either orally or by written description for centuries and applied in their day to day lives to cure ailments and to prevent diseases. In fact, it has been an integral part of unique Indian culture, tradition and heritage. As a result of patents granted on the traditional knowledge by the foreign countries, this property is being stolen and misappropriated. As the right to protect and preserve own tradition, culture and heritage is so important for an individual's live, it is also equally important for a nation's life. Similarly, right to protect and preserve one's right to property individually and collectively is also very important. Traditional knowledge associated with Indian medicinal plants as

intellectual property comes within the purview of 'property'. This right to property of the Indians (collectively) is being violated in India. This is because of WTO-TRIPs and its subsequent endorsement by Government of India.

It may be noted that in the foregoing chapters of this research, problems and issues have been discussed, analysed and critiqued in detail. A brief summary of the findings are mentioned below.

CHAPTER I deals with traditional knowledge digital library: a rich scientific heritage of India and it has been concluded that TKDL documents the written description of the TK of medicinal plants only. It states the names and medicinal values of Indian plants, which can be utilized for the treatment of various diseases. The significant thing is that those above mentioned medicinal values were in the written descriptions in centuries old and modern Indian books. The TKDL states the names, verbatim transcription and translation of those scripts narrating the medicinal values of those books written in different Indian languages. It signifies that there was 'prior art', about the medicinal plants of those Indian plants. Though very few documents regarding the written descriptions i.e. for each medicinal plant only two or one, are pointed out, written descriptions from many more books of same or different authors are there. TKDL documentation shows that India has rich store of traditional knowledge associated with medicinal plants. It also further proves that how much advanced India was in science i.e. medicinal science, hundreds and centuries before.

CHAPTER II deals with patents on medicinal properties of Indian plants associated with traditional knowledge, in India and foreign countries and the researcher arrived at a conclusion that the patent documents of U.S.A., EPO and India, regarding the topic and abstract of the patents show that there is traditional knowledge of India on this subject, if judged against TKDL documents and informal traditional knowledge base public use in India. It reveals and makes it clear that there was "prior art" or "existing knowledge" on the subject matter of the patents. In spite of that the patents were granted by accepting the inventions as novelty and non-obvious. But actually there is no novelty and non-obviousness. It is known to Indians and are in common use. The patents were granted either by violating law of patent of the patent granting countries or these countries do not consider them as violation as such. Sometimes by suppressing the facts that there exists common knowledge in the public domain or sometimes by not accepting the fact that it is not a subject matter of granting of patents, patents are granted and commercialisation of the others property start giving huge profits to the others. The latter is due to the reason that informal 'prior art' or foreign public use is not a bar for USPTO to grant patents. The patent documents which are shown are just tips of the iceberg. If the patent documents of the medicines of U.S.A., EPO, India and other countries are analysed, it will be found out that there are thousands of wrongful patents on the traditional knowledge associated with medicinal plants. These patents are examples of biopiracy, for which India's traditional knowledge is misappropriated. The aim to have a biopiracy-free world

would remain elusive if existing laws are not amended or new laws enacted to ensure no grant of patent on traditional knowledge. One glaring fact is that patents are granted to researchers and companies in India. Even CSIR has so many traditional knowledge based patents. When India is fighting the traditional knowledge based patents dubbing them as examples of bio-piracy, the incidents of granting of Indian patents of the medicinal properties or processes on herbal and biological resources is definitely to weaken the fight. It would be literarily impossible to convince the international community to accept Indians suggestions to amend the laws or to make laws to fight against bio-piracy. Hence it is suggested that initiative should be taken to find out that how many of the patents are genuine inventions and how many of them are the incidences of bio-piracy. It is also recommended that initiative should also be taken to start the process of their revocation. Same is true regarding innovative patents or petty patents. At the time of struggling with biopiracy through patents, another form of biopiracy has arisen for India and other TK enriched countries. This problem is a new challenge to be dealt with same seriousness.

CHAPTER III has specifically dealt with misappropriation of traditional knowledge in India without obtaining patent and was concluded that the ayurvedic medicines produced by various companies and trust, which are shown, contain only very few medicinal products. There are thousands and thousands of the ayurvedic medicines are being produced, which are not listed. These companies and trust are commercialising the traditional knowledge without actually paying for the use of this intellectual property of the society. They are earning huge profits every year. This is a new form of misappropriation of traditional knowledge and biopiracy, which has not been attracted the attention of those who advocate for TK protection. The trust and pharmaceutical companies are producing and selling the ayurvedic medicines under Drugs and Cosmetics Act. The authority under this Act, does not provide any safeguard to the traditional knowledge, from being misappropriated and commercially exploited without paying for the use of TK. Moreover, there is a scope to offer sufficient safeguards, but it is not being explored out by the authority. Hence it is suggested that the aforesaid practice has to be declared as biopiracy and illegal. It is also recommended that this type of business only can be allowed if it is ensured that they pay for the commercial use of traditional knowledge.

CHAPTER IV dealing with an analytical study of the IPR law regime in U.S.A., U.K., Germany, Australia, Japan, India and some other countries for protection of traditional knowledge of medicinal plants, comes to conclude as follows (A). The patent laws of India, USA, UK, Germany and Japan have some of the very basic shortcomings of each of the legal frameworks. These shortcomings are some of the major constraints in the way of making of a fair and just intellectual property laws about patent aiming at protection of traditional knowledge of medicinal plants. Some of them are common in nature and present in all legal systems. Some of them are peculiar to a particular system different from others. The cumulative effect is that

these are all leading towards the negation of the positive protection of existing public domain knowledge either for one reason or the other; or granting of patents disregarding the existence of 'prior art' in the subject; or no expressed or implied exclusion clause for written or unwritten traditional knowledge; or by non recognizing 'the written or oral description' as prior art; or though not granting IPR protection but allowing commercialization of existing public domain knowledge. As a result these laws are endorsing biopiracy in different ways.

(B). There is a point needs to be explained to a new type of bio-piracy which was not considered as bio-piracy as such in any of the countries. Inventions based on any existing knowledge either traditional or non-traditional are still patentable as long as they are novel and non-obvious in view of prior art. There would still be no requirement in patent law that inventors compensate the TK holders and non-TK holders or share benefits equally for sharing the existing knowledge to carry on research on and building something new or non-obvious. It is the utilization of knowledge which is in public domain and accessible to everyone. This is also an improved and sophisticated form of bio-piracy, is allowed all the countries including in India. This form of bio-piracy would continue as long as the ownership issue of traditional knowledge which is in public domain is settled (more specifically if ownership is not conferred on it) by going against the present concept of its free and easy availability and accessibility. But the patent laws which were analyzed in some of the foregoing paragraphs do not accept the present concept of 'public domain knowledge' as something objectionable and unjustified. There is no protection of the existing knowledge which is in public domain in the present intellectual property regime. Hence, there is a need to regulate original or non-original invention derived from existing knowledge. As long as public domain knowledge is used by anyone for the welfare of mankind without any profit motive, there must not be any restriction on its accessibility and utilization. But the moment inventors want to commercialize the invention, based on 'prior art' or 'public domain knowledge', the inventors have to pay for the use of existing knowledge.

(C). There should be mass revocation of all patents where there are written or oral traditional knowledge-prior art, compensation, punishment, and refund of profit, moratorium on future grants etc because it is a clear case of appropriation and bio-piracy-and for non-original inventions as the result of the use of public domain knowledge, either sharing of benefits or offering joint ownership.

(D).If doctrine of 'public trust doctrine" of environmental law-a common law principle is applied in traditional knowledge protection, it will give a new direction and dimension. Like some of the natural resources of a country, century old oral or documented traditional knowledge of the medicinal values of Indian plants is the intellectual property of the society. The public authorities or the state are the trustees of this traditional knowledge. This doctrine imposes the three restrictions on government, first, the property must not only be used for a public purpose, but it must be held available for use by the general public; second, the property may not

be sold, even for a fair cash equivalent, but it can be done for the greater benefit of the society or the people and third, property must be maintained in particular types of uses. With this jurisprudential approach, it would be easier to strongly protect, preserve and augment this TK oriented intellectual property. There is a paradigm shift to look at TK from two perspectives. First, there is no farther question of ownership over TK, rather it is a intellectual property under trust. Second, the custodians of TK may be indigenous community or society-they have to follow inter-generational equity, to preserve them for future generations. The governments would be under strict legal scrutiny for all its decisions about traditional knowledge. This is one of the viable ways to offer comprehensive positive and negative protection to the existing public domain traditional knowledge which has become the target of actual and imminent threat from the western new knowledge oriented IPR regime. This approach has the answer of all questions-conservation, augmentation of resources, development, sustainable use, taking action against biopiracy, regulating non-original inventions and innovations etc., regarding existing public domain traditional knowledge.

(E). The definition of "invention", as given by TRIPs and developed countries is not properly applied by those countries. Those countries and TRIPS have changed the meaning of the term 'discovery' into 'invention' and creating all sorts of problems to the advantage of them. What they do in the name of 'invention', it is not 'invention' as such, but actually is 'discovery'. The bio-pirators are compelling to accept the discovery as an invention or rather by manipulating the legal framework get the 'discovery' accepted as invention. If there is prior knowledge and information in different forms traditionally with the society or community or practice in the society, either documented or non-documented, how can it be 'invention'? Whatever they are doing it is just discovery, not invention.

CHAPTER V is on the international legal framework relating to traditional knowledge of medicines from biological resources. The analysis of the relevant international laws in the field related with traditional knowledge protection, it can be reasonably inferred that international laws i.e. TRIPs, CBD, WIPO and EPO, are not mutually supplementary and complementary to each other. On all the major areas where there are serious concerns for the TK protection, these laws are conflicting with each other. This is so because, the international laws which pursue the policy of sufficient safeguards for the traditional knowledge associated with medicinal plants like CBD and WIPO are not comparatively binding in nature and there is no strong consensus among the developed and powerful countries to stop biopiracy or commercialisation of the TK, according to the CBD or WIPO recommendations. Ultimate success of CBO lies in its acceptance by USA and other developed countries, where biopiracy is taking place and reshaping or remodelling their legal frameworks with an object to stop biopiracy in any form. Moreover, its success lies also in the revocation of all existing wrongful patents on which there is 'prior art' of Indian traditional knowledge associated with medicinal plants and enforcing benefit-

sharing formula with the holders of such traditional knowledge. The role of WIPO is very encouraging in protecting the traditional knowledge of Indian herbal medicine. There are numbers of declarations and recommendations of WIPO which strongly advocates the protection of traditional knowledge. But actually it does not have any binding force unlikely to WTO. WIPO recommendations are just moral values in nature without any sanction worldwide. WIPO is striving very hard to have an international legal framework to protect traditional knowledge, but it is in its nascent stage and yet to take a binding legal shape throughout the world. EPC's role is also very encouraging for TK protection. This is because EPC recognises both formal and informal, both documented and non-documented i.e., foreign public use, as 'prior art'. Other international instrument like WTO-TRIPs is not in any way protects traditional knowledge related with medicinal plants. WTO-TRIPs is binding in nature and mandates so many do's and don'ts about IPR but it is silent on the issue of TK. It does not recognise the traditional knowledge as another form of intellectual property. Even if there is traditional knowledge either formal or informal, the so called invention TRIPs allows the developed countries to consider it as novel and non-obvious. In this way, TRIPs encourages the developed countries to misappropriate the traditional knowledge with the help of patent. Hence, TRIPs is not fair, just, good or reasonable in this matter of TK protection and if this goes on, international law i.e. WTO-TRIPs will lose the faith and confidence of international community very soon.

CHAPTER VI deals with a case study of turmeric and neem patent revocation and thereafter and concludes the following: (A). Turmeric and neem patent revocation cases are no doubt great and significant achievement but actually these are nothing. There are hundreds and thousands of traditional knowledge based patents are still operative all over the world-USA. Germany, Japan, Canada etc. The industrial houses-national and multinational corporations are commercialising TK and earning without paying substantial amount to the knowledge holders. Unless those patents are revoked, profits are returned, exemplary punishments are given, compensations are awarded, the object to have bio-piracy world cannot be achieved.

(B). Unless it is ensured that any claim of invention; may be novel or non-obvious in nature, derived from traditional knowledge related biological resources in any form and in any manner, is not a subject matter of patent, the object will not be fulfilled. It means that knowledge in any form in public domain can be utilised for academic or research purposes but inventing something and its subsequent commercialisation cannot be allowed. Intellectual property law of all countries does not grant patent on public domain knowledge, it is good. But exploiting the present knowledge to get clues to build upon something, even if novel or non-obvious and commercialisation is allowed. It means paving the way for exploitation of PDK for personal gain. But if it is used for the benefit of the society, there should not be any objection. This is the correct approach to protect public domain knowledge.

(C). Whatever India lost, it could have been substantially reduced, had Government's role been positive, had TKDL been established decades before. In spite all such unfairness in the legal frameworks of TRIPs and of other foreign countries, India could have challenged and got cancelled many bio-pirated patents by the legal use of very limited scopes of 'novelty' and 'non-obviousness' criterion. India failed to utilise those very limited opportunities. Moreover, after getting the leads from the traditional knowledge massive research works should have been started and completed, so that India could have documentation of the medicinal plants. Had the results of the medicinal values of plants i.e. non-original inventions been printed and published, the country could have protected the TK comparatively in a better way.

CHAPTER VII's subject matter is march to evolve a legal framework for the protection of traditional knowledge associated with medicinal plants and it concludes that there are some common concerns of these countries for traditional knowledge protection, as day by day, their traditional knowledge is being taken away by foreign countries and companies. It is good that at least these countries have enacted special laws for traditional knowledge protection. It is really appreciable that these countries have come up with their own set of special laws to deal with biopiracy. There are so many good ideas in these laws. Yet there are some drawbacks and the laws vary from each other in various respects. This is due to the reason that either laws are the reflections of particular situations and special needs of those countries, a country's traditional knowledge may have some unique features different from others or the laws are in furtherance of the national policies of these countries, which were adopted after due consideration. Vision of the political establishments might be different from each other along with the standard and availability of legal expertise, hence is reflected in these laws. Aiming at the traditional knowledge protection, these countries thought it right to set various types of objectives to achieve that goal and conditioned their national laws also accordingly. These diverse aims and objects get reflected in their legal provisions. These laws have some persuasive values to persuade India to have a law on TK and shape its law. Some good provisions can be incorporated into the Indian legal framework. It is hoped that all TK enriched countries would be joining with this group. Its presence would be felt in the international forum; its voice would be stronger enough that cannot be ignored by the developed countries. They can work as a block and would be able to exert pressure on the world body to just strike down the biased laws. India does not feel any necessity to have such a law. In this context, at present there is no comprehensive positive law especially for traditional knowledge protection, preservation and its utilisation. Biological Diversity Act offers a very limited protection. Hence, it is suggested that India must have a sui generis effective law to safeguard and utilisation of its vast traditional knowledge. To make a model law for India, new, innovative, radical and comprehensive thinking are necessary.

There is a necessity to have a uniform standard with some flexibility to suit the special needs of a particular country. This is because though TK per se has some

common characteristics, face same types of challenges but each country has its own socio-cultural and economic environments which are different from others. Apart from those common grounds which have to be uniform in nature in all the national laws of each and every country, laws must be uniform. But in other matters there can be diversity. There must have some flexibility and relaxation to adjust and adapt with the particular social, scientific, economical and cultural environments of India.

CHAPTER VIII deals with medicinal plants of Cooch Behar. The conclusions are:

(A). TKDL documents show that only some medicinal plants of Cooch Behar find their mention in TKDL. It means that TKDL documentation process is not complete. If all the medicinal plants associated with traditional common knowledge are left out of TKDL documentation, only consequence is that there would be bio-piracy incidences. Hence, it is suggested that as early as possible documentation of all traditional knowledge associated with medicinal plants of Cooch Behar, must be completed.

(B). It is also found that most of the medicinal plants of Cooch Behar associated with traditional knowledge, which people of this region have been applying for different treatment purposes, do not have any written description in any book or in any other printed material. As TKDL is basically deals with the documentation of the medicinal plants, where there are written descriptions, hence informal TK of Cooch Behar, is obviously left out. When people around the world are fighting to protect this huge informal knowledge of medicinal plants as part of IPR protection, there is no justification for not including this knowledge for documentation. TKDL should look into the matter and takes up for documentation of the informal traditional knowledge of Cooch Behar. Otherwise this treasure of vast knowledge either would be lost one day or it would be misappropriated in different ways. A thorough micro survey should be initiated to find out all unwritten informal common traditional knowledge from every corner of this country including Cooch Behar.

(C). There are village kabirajs i.e. ayurvedic practitioners, who do not want to disclose their knowledge about the medicinal values of the plants. They keep this knowledge very secretly only within their family members or within close confidants, who do not disclose to others. Take for example, at Nishiganj village of Cooch Behar some kabiraj do the treatment of broken bones. They use some medicinal plants, either leaf or root or whole part, no one knows that. The combinations of the parts or whole of the medicinal plants and method of preparing the herbal medicine are still not known. The researcher after a painstaking effort of several years got the information of one medicinal plant i.e. Harjor (Cissus quadrangularis) which is used as one important (probably the main element) item to treat broken bones. It has an inherent miraculous medicinal property to re-set the broken bones. There is no document about the medicinal value of this plant in TKDL. There have to be some special packages to encourage these knowledge holders to transfer their knowledge

for further research and development which not only will benefit the whole mankind but also can document the knowledge to protect it strongly from bio-piracy. There has to be massive awareness campaign to dispel the fear from their minds. Otherwise, this vast knowledge will remain inaccessible for India.

(d). Some plants of Cooch Behar become endangered. If immediately in-situ or ex-situ preservation measures are not taken, very soon these plants will not be available.

(E). The traditional and common practices of applying any medicinal plant to treat some diseases, are not clinically tested in modern scientific laboratory by the researchers of various educational institutions. These results of the clinical trials would have been accepted and recognised by the foreign patent offices as conclusive proofs of 'prior art' i.e. existing knowledge and would have been considered before granting patents in their countries as well.

(F). Finally, There is no such systematic study from the preliminary level up to documentation on each and every species of a particular medicinal plant, where a group is assigned to do the work with complete devotion only for that particular plant.

Based on the above finding this research work arrives at a conclusion that the existing IPR regime is inadequate to offer protection to traditional knowledge, particularly medicinal plants. The national and international laws also conflict. Moreover international laws are in conflict with each other. Though at the macro level, there is conformity between national laws of two countries, but at the micro level, there is no uniformity. These situations have affected the right of equality, right to trade and right to life of those communities' (including the country) which possess the traditional knowledge and makes the following remarks.

CHAPTER IX: CONCLUSION

I.NEED FOR A SUI-GENERIS COMPREHENSIVE LAW FOR THE PROTECTION OF TRADITIONAL KNOWLEDGE RIGHTS

Law is a living subject. It is dynamic in nature. If the law does not respond to the qualitative and quantitative changes of the society positively or the reasonable expectations and the serious concerns of the society in this tends-to-be-globalised world, it would frustrate the society and would lose its necessity as well. Law is either a tool to initiate and bring changes or a mechanism to command the changes in the society. There might be new problems, new demands in the society which are quite natural. Law should keep pace with the changing contours of time and space. Without confining the TRIPS within a narrow limit and further preventing the natural development of international IPR law, to address the basic concerns of the traditional knowledge enriched developing countries, a new and dynamic IPR law has to be framed. This is the need and demand of the hour.

A paradigm shift of perspective is required for addressing the issue of protection of traditional knowledge. New models and new thinking on IP will have to be envisioned to accomplish this. The issue of 'protection' of traditional knowledge needs to be looked at from two perspectives, the 'protection' may be granted to exclude the unauthorized use by third parties of the protected information. On the other hand, the 'protection' also means to preserve traditional knowledge from uses that may erode it. Time has come to think about the protection methods radically and according to new pedagogy. This research work with a missionary's zeal emphasises the need to have a comprehensive positive IPR protection of traditional knowledge of Indian medicinal plants which also takes into account the defensive or negative measures. There is some other purpose of positive IPR for traditional knowledge of medicinal plants. This kind of positive IPR is more important in a knowledge based economy. What is the use of this traditional knowledge-a gift of the earlier generations to the present and future generations, if it does not utilise for the economic benefit of the country? What is the use of this knowledge if it does not bring development in the lives of the people of the country? What is the use of such knowledge if it is not preserved and further development through systematic research? Without denying the importance of other laws, there is no alternative way other than a separate and special law on the subject itself, to have more specificity and clarity which would focus the uniqueness associated with the intellectual property of the community or the country. Dr. Vandana Shiva in her book 'Patents: Myths and Reality' demands that "this diversity of knowledge needs to be recognised and respected and a pluralistic IPR regime needs to be evolved which makes it possible to recognise and respect indigenous knowledge and protect the indigenous knowledge systems and practices and livelihood based on it. We, therefore, need diverse legal regimes to protect the diverse knowledge systems and the diverse communities."[1]

Time has come to think about the protection methods radically and according to new pedagogy. This research work with a missionary's zeal emphasises the need to have a comprehensive positive IPR protection of traditional knowledge of Indian medicinal plants which also takes into account the defensive or negative measures for the first time. There is some other purpose of positive IPR for traditional knowledge of medicinal plants. This kind of positive IPR is more important in a knowledge based economy. What is the use of this traditional knowledge-a gift of the earlier generations to the present and future generations, if it does not utilise for the economic benefit of the country? What is the use of this knowledge if it does not bring development in the lives of the people of the country? What is the use of such knowledge if it is not preserved and further development through systematic research?

A true globalised world needs a strong IPR law for TK enriched countries including India, to protect traditional knowledge of medicinal plants, where no country should

[1] Dr. Vandana Shiva, 'Patents: Myths and Reality' in "Biopiracy" Penguin Books, New Delhi, 2001, Page-51.

benefit at the cost of others. Without denying the importance of other laws, there is no alternative way other than a separate and special law on the subject itself, to have more specificity and clarity which would focus the uniqueness associated with the intellectual property of the community or the country. Dr. Vandana Shiva in her book 'Patents: Myths and Reality' demands that "this diversity of knowledge needs to be recognised and respected and a pluralistic IPR regime needs to be evolved which makes it possible to recognise and respect indigenous knowledge and protect the indigenous knowledge systems and practices and livelihood based on it. We, therefore, need diverse legal regimes to protect the diverse knowledge systems and the diverse communities."[2]

Keeping in mind these, apart from those common concerns which India shares with these TK enriched countries and expects to be combated jointly with similar approaches, India has some special needs to get special protection in some areas. As its problems are different it needs to be addressed separately, have some prospects needs to be explored adequately. At present there is no such special law to protect traditional knowledge associated with medicinal plants in India. There are different legislations which could offer some sort of protection, but these are very limited in nature. India's traditional knowledge of medicinal plants must get a sui-generis and comprehensive positive and defensive or negative IPR protection which takes into account the society oriented knowledge and where 'prior art'-either within public domain or non-public domain, is fully protected. With this it will be ensured that knowledge be utilised for economic benefits of the society without the vulnerability of being misappropriated. Moreover, the contents of 'positive protection' would also be manifold. Moreover, from the standpoint of this research work, there has to be some more new and extra considerations on theoretical and practical matters to be incorporated while framing a model law on this subject. As was emphasised in earlier discussions, there are some fundamental premises for a model law of traditional knowledge to be build upon for India. This is not to say that there cannot be any further criticism and improvement of these ideas and suggestions. Actual test of an effective system lies in its proper and speedy application and how much it is contributing to knowledge based economy. The concept of protection has very broad connotations. There should be some kind of positive IPR as well to cover a comprehensive protection formula. This kind of positive IPR is more important in a knowledge based economy and preservation, improvement perspectives. If this broad concept is not accepted, protection of medicinal plants would lose its purpose and the protection would be incomplete. Revoking patents and revoking petty patents or withdrawal of patent applications after challenge, are defensive or negative in nature. Comprehensive protection should not include this negative approach. It is very limited in nature. Followings are the facets of comprehensive positive protection of traditional knowledge associated with medicinal plants.

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[2] Ibid, Page 51.

II. RECOMMENDATIONS FOR A MODEL LAW TO PROTECT TRADITIONAL KNOWLEDGE OF MEDICINAL PLANTS

A.RECOGNITION OF VARIOUS KINDS OF POSITIVE AND PRO-ACTIVE INTELLECTUAL PROPERTY RIGHTS TO THE COMMUNITY OR THE SOCIETY

(I). DEFINITION OF TRADITIONAL KNOWLEDGE OF SOCIETY OR COMMUNTY

No definition has been given to this traditional knowledge associated with medicinal plants India. The very object of the definition is to correctly show the perfect nature and essential characteristics of any particular thing-tangible or intangible. Keeping in mind this, it is suggested that 'intellectual property rights' be divided in to two categories; first is 'individual intellectual property rights' and the second is 'collective intellectual property rights'. The traditional knowledge of medicinal values of Indian plants can come within the purview of the second category of intellectual property rights. 'Collective Intellectual Property Right' is appropriate to name this unique property and right over it. This new definition of 'collective intellectual property' reflects the unique nature and characteristics of such traditional knowledge.

(II). EXPLORING CRITERION FOR THIS SUI GENERIS COLLECTIVE INTELLECTUAL PROPERTY

If traditional knowledge of medicinal plants or genetic resources does not fit in present legal framework of patent, what is wrong in it to create another new IPR to give traditional knowledge an appropriate legal protection? The fact is that present conventional criterion of novelty or non-obviousness cannot positively depict the unique collective knowledge of the society. If it does not fit in the present legal framework, it does not necessarily mean that it cannot get protection. If it does not fulfil the criteria of novelty, non-obviousness, it is better not to try it to avoid a misfit. Just another new law is to be created to give a match to this new 'collective intellectual property.' As it has its own name, it will have its own definition, exceptions, essential elements and extent of protection, cause and consequence of violation. This is the way law develops to cater the needs of the changing time and space. This is the way a new law is enacted to give justice to the people. Next task is to determine the criterion of this second category of intellectual property rights. The proposed criterion to find and determine the 'collective intellectual property rights' about medicinal values of the plants: (1). There is a knowledge about the proved medicinal value of a plant; (2). The knowledge is unique to the world; (3). This knowledge is the result of research and experience in different ways; (4). The knowledge is held, preserved and identified by a tribal community, village community or the society of the country in general; or (5). The knowledge is distinctively associated with the above mentioned societies and transmitted in a traditional and

intergenerational context ; (6). In both the cases the knowledge by the tribal or village community and the society in general, is held since time immemorial or is innovated on the centuries old TK; (7). The knowledge is transcribed in the ancient books and scriptures in any Indian languages; or, (8). People are well aware or apply the knowledge through the natural use of the extracts of one or more parts of the medicinal plants in their day to day lives to cure ailments or to have resistance power i.e. the knowledge is in public use, though undocumented.

(III). COMMERCIAL UTILISATION OF TRADITIONAL KNOWLEDGE

Knowledge is and will be produced in order to be sold, it is and will be consumed in order to be valorized in a new production: in both cases, the goal is exchange. Knowledge ceases to be an end itself, it loses its 'use-value.'[3] There is a need for fair commercialisation of the all the traditional knowledge related herbal medicines. It is for the sake of economic development of the country or society and welfare of the people. Community based or society based traditional knowledge of medicinal plants should be utilised commercially. This positive IPR law would be granted in favour of the state i.e. government or the community. Accordingly, state or community should have an exclusive right over the traditional knowledge of the medicinal value of a plant. There has to be an institutionalised system where the state through its instrumentalities can commercially use and utilise that knowledge. The state on its own can manufacture the herbal medicine in the state-run factories; can sell the herbal medicines in the national and international markets. It can allow others to commercially utilise the knowledge who are interested in doing that. They also can encourage the national and multinational companies to commercially utilise the knowledge in different ways. In that case, whosoever wants to do business or are doing business in any form, either production of medicine from extracts of medicinal plants or selling, have to pay for that. This is not only for foreign multi-national companies but also for national companies as well. For all these matters, the responsibilities will be with the traditional knowledge protection authorities. Commercialisation of it through a benefit sharing arrangement with the holders of the traditional knowledge and entrepreneur is one of the ways to do that. But best way is to commercialise the traditional knowledge of herbal medicine in different ways- production of the herbal medicine and market them, on its own by the government of India or the state governments by forming and incorporating companies. It would be the responsibility and function of the government, to establish manufacturing units for production and spreading network for marketing. Instead of depending upon others, state should come forward for the utilisation of the traditional knowledge and generate

[3] Lyotard. J.F as referred by Johanna Gibson, "Emerging Issues in Intellectual Property, Trade, Technology and Market Freedom: Essays in Honour of Herchel Smith", in 'Knowlegde and Other Values-Intellectual property and the limitations for traditional knowledge', edited by O. Westkamp, published by Edward Elgar Publishing Ltd., U.K., 2007.

income. If fruits of the traditional knowledge associated with medicinal plants are not enjoyed by the society or the country, then intellectual property right is for what? As in case of 'individual intellectual property' i.e. patent, the patentee has the sole owner, has the power to commercialise and he does it and gets the income, similarly, in case of 'collective intellectual property' state will have to do the same thing. This is protection i.e. positive protection in the knowledge based economy of India. As CBD empowers the state to have the sovereign right over the biological resources associated with traditional knowledge, it can commercialise the 'collective intellectual property' of the tribal or village community over their traditional knowledge if they agree or if are not in a position to do so. The point is that recognition of this sui-generis collective IPR, subsequent grant of IPR and then not commercialising, will not be allowed. If it is not possible, only then by entering a benefit sharing arrangement, the traditional knowledge can be utilised by others.

(IV). EQUITABLE BENEFIT SHARING

The idea of an equitable balancing of interests is common to many legal systems. In IP law, this is often phrased in terms of a balancing of the interests of right holders and the general public. Benefit sharing formula is a form of equitable balancing of interests. According to this principle, the TK holders would receive an equitable share of the benefits that arise from the use of the TK, which may be expressed in terms of a compensatory payment, or other non-monetary benefits. An entitlement to equitable benefit-sharing may be particularly appropriate in situations where exclusive property rights are considered inappropriate. The issue of benefit sharing needs to be assessed and calculated in a systemic way, both at the level of taking indigenous knowledge for utilisation and at the level of later pushing it out through aggressive marketing of medicinal products throughout the world. In case of utilisation of traditional knowledge, the users have to follow a benefit sharing formula with the holders of the traditional knowledge or in case of state, with the state out of the incomes and profits, generated from the use of medicinal plants as medicines.

According to this new and positive IPR protection system, no one should be allowed to utilise the traditional knowledge about medicinal plants for profit making without sharing at least 50% of the profits with the holders of the knowledge. At present there is no such system of benefit-sharing with the government, by the business and industrial houses, for the use of the medicinal plants though they have got a lead from the traditional knowledge. There is only one exception to 'Jeevani' drug and benefit-sharing formula with the community. While transferring the technology for production of the drug to the pharmaceutical firm, TBGRI agreed to share the license fee and royalty with the "Kani" tribe of western-ghat in Thiruvananthapuram of Kerala, on a fifty-fifty basis.

BENEFIT SHARING FORMULA: THE 'JEEVANI' AND 'KANI TRIBES'[4]

The Kani tribals belong to a traditionally nomadic community, who now lead a primarily settled life in the forests of the Agasthyamalai hills of the Western Ghats (a mountain range along south-western India) in the Thiruvananthapuram district of Kerala. The Kanis, numbering around 16,000, live in several tribal hamlets, each consisting of 10 to 20 families dispersed in and around the forest areas of Thiruvananthapuram district. These Kanis do not constitute a cohesive unit, although they do share certain common characteristics and practices. Kanis are the traditional collectors of non-timber forest products from the forest. Living close to nature, the Kanis have acquired unique knowledge about the use of the resources, particularly the biological resources around them.

In December 1987, a team of Scientists working on the All India Co-ordinated Research Project on Ethnobiology (AICRPE) led by Dr. P. Pushpangadan was trekking through the tropical forests of Agasthyar hills. They were surveying the 'Kani' tribal settlements and got exhausted after a while. This team was accompanied by a few 'Kani' tribesmen as guides, who surprisingly remained energetic and agile. They occasionally would munch some small blackish fruits. One of them offered a few of these fruits to the team pointing out that if they ate those, they could go on trekking without fatigue. And that is what happened to the AICRPE team, after they had followed their advice. It was later that the 'Kani' tribesmen introduced the 'magical' plant, which was subsequently identified as *Trichopus zeylanicus ssp. travancoricus.*

Detailed chemical and pharmacological investigations showed that the leaf of the plant contained various glycolipids and some other non-steroidal compounds with profound adaptogenic and immuno-enhancing properties. The fruits showed mainly anti-fatigue properties. Tropical Botanical Garden Research Institute (TBGRI), was successful in developing a scientifically validated and standardized herbal drug, based on the tribal lead. The drug was named as 'Jeevani' and it was released for commercial production in 1995 in Arya Vaidya Pharmacy. While transferring the technology for production of the drug to the pharmaceutical firm, TBGRI agreed to share the license fee and royalty with the tribal community on a fifty-fifty basis.

The prime concern of the tribals in the beginning was to evolve a viable mechanism for receiving such funds. With the help of TBGRI, some government officials and NGOs, the tribals formed a registered trust. About 60% of the Kani families of Kerala are members of this trust. From February 99, the amount due to them has been

[4] A verbatim transcription from Prof. Mashelkar's article-R.A.Mashelkar, "Intellectual Property Rights and the Third World" Vol. 7, No.4, Journal of Intellectual Property Rights, Page 312, July 2002.

transferred to this Trust with an understanding that the interest accrued from this amount alone can be used for the welfare activities of the Kani tribe.

TBGRI has trained 25 tribal families to cultivate the plant in around their dwellings in the forest. In the first year itself, each family earned about Rs.8, 000 on sale of leaves from cultivation of T-*zeylanicus* in half-hectare area by each family. But unfortunately the forest department objected to the cultivation with the plea that the tribals may remove the plants from the natural population of this species in the forests and thereby make it endangered. It is understood that this problem has now been resolved and the Forest department has recently approved the cultivation of this plant. It is significant to note that while the issue of material transfer and benefit sharing was discussed and debated after convention of Biological Diversity (CBD), India has already pioneered one of the first models.

(V). SUSTAINABLE USE OF THE RESOURCES

At the time of commercial utilisation or non-commercialisation of the traditional knowledge associated with medicinal plants, it is to be kept in mind that the biological resources which are being used for the preparation of herbal medicines, are very limited or might be exhausted if not used quite sustainably, keeping a part for the future generations. These genetic materials or the biological resources will be exhausted one day if simultaneous augmentation through plantation does not take place to compensate the earlier uses and to meet the future needs of the herbal medicines. So, sustainable use is such a mechanism which ensures preserving, augmenting and keeping the resources for the future generations and future needs, without destroying and damaging the environment. There has to be a restriction on the indiscriminate use of the biological resources by anybody. Otherwise traditional knowledge would remain, but there would not be any medicinal plants in India.

(VI). ENLARGEMENT OF 'PRIOR ART' CONCEPT WHICH INCLUDES FORMAL AND NON-FORMAL DOCUMENTS

It is also true that in the present legislative framework, sometimes a patent can be cancelled if there exists well documented prior art. But Informal 'prior art' cannot lead to a patent revocation in all the countries. According to Indian law, anyone either Indian or foreigner including the Government of India or any state government itself, cannot obtain an Indian patent on medicinal property of a plant if there is traditional knowledge existing prior to patenting, either formal or non-formal. Patent is not granted in favour of the community also, who are the holders of TK of a particular medicinal plant. This is due to the reason that they are not the inventers of that; they are just preservers of that knowledge. They have not added some new and novel value to the existing knowledge in the world. Hence it is suggested that 'prior art' concept to be widened to include informal and non-documented 'prior art' which are in public use.

(VII). GRANTING OF COLLECTIVE INTELLECTUAL PROPERTY RIGHT TO THE COMMUNITY OR THE STATE

The traditional community or the society in general must have an intellectual property right over traditional knowledge. Accordingly, state or community should have an exclusive right over the traditional knowledge about the medicinal values of the plants. This can be achieved if the IPR in the form and name of 'collective intellectual property rights' is granted to the tribal or village community if the traditional knowledge is exclusively identified with that community. In other cases, where the traditional knowledge is not identified with the communities, for its general nature, 'collective intellectual property rights' is to be granted to the country or the society at large. With this, there will be seen a paradigm shift in the ownership pattern of the intellectual property right for the first time. With this also, for the first time, collective ownership over the century old traditional knowledge related intellectual property rights, on the herbal medicine, will be recognised.

(VIII). LINKAGE OF TRADITIONAL KNOWLEDGE WITH MODERN SCIENCE

The methods of diagnosis and treatment either preventive or precautionary have been developed for the last and this century. The main reason for such tremendous success of modern allopathic system is its reliance on modern science-physics, chemistry, biology, bio-technology etc. and taking of assistance from these subjects. Just opposite has happened in India regarding ayurveda and herbal medicine i.e. traditional knowledge. Modern sciences such as physics, chemistry, biology or bio-technology do not have much place for the diagnosis, treatment and use of medicine and the continuous development of the subject itself. This is the main reason that western medical science is so developed and Indian traditional knowledge with medical science is lagging behind and cannot compete with. In spite of all its potentialities to have a science base and medicine being without side effects which can offer complete curative and preventive methods of treatment, it is not as popular as western medical science worldwide and preferred as the first option the way it should have been. So, there has to have a linkage of traditional knowledge with modern science. Traditional knowledge of India associated with medical science and the use of whole or various parts of medicinal plants must take assistance for research and development from modern sciences. Prof. R.A.Mashelkar has also echoed the same thing in one of his articles recently. He has observed that "20th Century has revealed some of the greatest insights into our understanding of life at increasingly higher levels of organization – molecular, sub cellular, organelles, cells, tissues, organs, organisms, species and ecosystems –the most remarkable feature of modern medicine is its close integration with the basic sciences – physics, chemistry and biology. For example, we would not have had 'gene therapy' a new frontier of modern medicine, if the structure of DNA was not known, which itself has been possible due to the structural elucidation achieved X-ray diffraction, the contribution of the modern physics advances whereas

the connection between modern medicine and modern science was always strong, the connection between modern science and traditional medicine, including Ayurveda has been poor. And so has been there a poor connection between modern medicine and traditional medicine. India can benefit enormously, if it can build a golden triangle between traditional medicine, modern medicine and modern science. In this lecture, I will make a case for this golden triangle. [5]

(IX). PRIOR INFORMED AND FAIR CONCENT

According to the principle of prior informed consent (PIC), TK holders should be fully consulted before their knowledge is accessed or used by third parties and an agreement should be reached on appropriate terms; they should also be fully informed about the consequences of the intended use. The agreed scope of use may be set out in contracts, licenses or agreements, which would also specify how benefits arising from the use of the TK should be shared. In this context, the right to information is very much pertinent and significant. This right to information is the sine-qua-non for valid and fair consent of the holders of the traditional knowledge. That is why, right to information is stressed upon with so much of importance. Unless the holders of the traditional knowledge know all the terms and conditions about the utilisation of the traditional knowledge by any person or company, it is impossible to give a valid consent for commercial arrangement with traditional knowledge of medicinal plants. Likely to this, the terms and conditions of such an arrangement must be fair and reasonable which will benefit both the parties or in any way will not deprive the holders of the traditional knowledge. It will not be seen that the persons or the companies with their money power and with the strong support of their governments, in the name of 'prior informed consent' uses it as a mechanism of exploitation and thrust their terms and conditions upon the traditional knowledge holders. Hence, fairness and reasonableness are to be brought in the terms and conditions, where informed consent is to be exercised. It is suggested that a standard set of terms and condition has to be evolved, which will be followed at the time of negotiations and giving of consent by the traditional knowledge holders. It also should take into account the consequence of violation of the terms and conditions by any party. This is very important for the enforcement of such contract.

(X). DURATION OF THE RIGHT AND EXCEPTIONS

Duration of this benefit-sharing agreement is another issue which needs to be looked into differently. In general the IPR protection is available for some years. After that it

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[5] Prof. R.A Mashelkar, "On Building a Golden Traingle between Traditional Medicine, Modern Medicine and Modern Science", a speech delivered on 25th May, 2003. Available at http://www.csir.res.in/External/Heads/aboutcsir/leaders/DG/DG%20speech%201.htm. Visited on 21st June, 2011, at 4.15 PM.

becomes public domain knowledge; thereafter no question of further giving of royalty does arise. Without giving royalty profit making out of the invention of somebody is allowed. But as the traditional knowledge per se is not the invention of a particular individual, benefit sharing either with the community or with the society, cannot be limited for twenty years or thirty years. It should continue as long as there is a commercial use of the medicinal plants to produce and sale herbal medicines by anyone. Moreover, if the commercial utilisation of the biological resources associated with traditional knowledge, if done by the state through its instrumentalities directly, profit making out of the traditional knowledge for the general public will continue forever, without any kind of time limit. As long as there would be commercial exploitation of the existing traditional knowledge by others, the benefit sharing would continue and as long as the holders of the knowledge can do, profit making would be allowed. This is one exception to the general rule of conventional IPR protection.

(XI). PROTECTION OF EXISTING KNOWLEDGE IN PUBLIC DOMAIN

One of the serious shortcomings of the existing legal framework of the IPR, is that it does not protect of the existing knowledge i.e. prior art, which are in the public domain and not in the public domain. Moreover, it is also not providing incentives for conserving existing knowledge which is in the so-called public domain. Rather, it is encouraging to commercial exploitation of the existing knowledge without paying anything for the use of the same. Actually 'existing knowledge' by whatever name it can be termed, does not have any protection in the existing IPR legal framework. There cannot be any problem if it is used for the benefit and welfare of the people without any monetary consideration by anyone, anywhere in the world which is to be accepted. Upto invention level, anyone can utilise the existing knowledge which is in public domain, for research purposes, there should not be any restriction. But the moment he wants to have an IPR protection over his invention even if there is complete and absolute novelty and non-obviousness in his invention. Though the invention may be an original invention, he has to pay for the utilisation of existing knowledge-either traditional or individual. This is because the original invention was built upon the existing knowledge. This is the only one way, a model IPR law has to protect the existing public domain knowledge. This is completely a new dimension to the present legal frameworks of IPR of all the countries including India. Profit-making, has to be stopped in the name of public domain. The whole concept of public domain knowledge which everyone can experiment, use, commercialise according to TRIPS agreement, must be revisited. Public domain knowledge is for public charity, not for profit. The entire notion of intellectual property has been framed all over the world in such way, so that the developed countries get more mileage for their advanced technology and all the countries in the world have fallen in their trap by accepting those fundamental principles as fundamental and eternal. To get the lead to invent something from 'a pre-existing knowledge in public domain' must to valued and recognised. Public domain knowledge may be for public use for public purpose not for individual use for profit making. Knowledge of thousands and thousand years

gathered from experiment and research is just robbed in a fraction of seconds. 'Public domain knowledge' has become an instrument of exploitation; to exploit the developing worlds. Moreover, what is the extent of 'public domain knowledge'? How does 'public domain knowledge' of a country become 'public domain knowledge' of another country like America or Japan etc. If it is 'public domain knowledge', it must have a country of origin of its own and it is the knowledge of that country. This does not have any logic, any rationality. Whole gamut of the issues about the "public domain knowledge" has to be changed and modified. This is the strong demand of the time to make the IPR law, reasonable and intelligible. There is a group of people who actually conserved and developed the knowledge just do not get anything and have to sacrifice their knowledge for others and there is another group of blessed people who would make huge profit out of it. This is a wholly non-sensical law. It means that "public domain knowledge' is not protected at the national and international level by the accepted IPR jurisprudence. It is a long, deliberate plan and sinister design of the developed countries to get it planted in the IPR legal frameworks of all the countries. Though same kind provision about 'public domain knowledge' is in the IPR laws of all the developed countries, but it is the developed countries can take advantage of it. The developing countries will bite the dusts and fruits of their research works will be eaten by the developed countries. Due to their technological advancements, the developed countries can do more research and find something novel and non-obvious subject matter out of the public domain existing knowledge, which is not possible for the developing countries in that extent. The very object of 'public domain knowledge' is that the fruits of the intellectual property when it becomes the property of the society after some years of commercialisation would be enjoyed by everybody. No further commercialisation would be allowed by anybody. If that is the objective, by utilising the 'prior art' after it becomes 'public domain knowledge', if somebody invents something and wants to commercialise it for profit, how can it be allowed? That would frustrate the very object of such type of arrangement. As was said earlier, if it is used for non-profit motive, there is nothing wrong to allow it. Hence it is recommended that this existing 'public domain knowledge' and 'non-public domain knowledge' and its use for commercial purposes have to be relooked into with this type of amendments in the proposed IPR law for the traditional knowledge associated with Indian medicinal plants.

(XII). NON-ORIGINAL INVENTION BASED ON EARLIER KNOWLEDGE SHOULD NOT GET PATENT PROTECTION

Existing knowledge is of two types; some of them are in the public domain and some of them are not. Likely to original invention based on study band research of existing knowledge, there is another type of non-original invention. In this type of invention, the researchers or so called inventers actually get the actual leads and basic informations from the existing traditional or non-traditional knowledge of various subject matters i.e. associated with century old herbal medicinal knowledge of Indians. After getting the actual leads or the basic informations that this particular

plant is with some confirmed medicinal values against some diseases, they confirm it again at the micro level bio-chemically in the modern state of the art scientific laboratories and through clinical trials, find the main genetic materials which have the capacity to cure and prevent the disease either from the leaf, or root or bark or stem or flower or shoot etc. They isolate those genetic materials and claim that it is the novel and non-obviousness invention. They do it sometimes suppressing the existing traditional knowledge and sometimes referring it as public domain knowledge, go for IPR protection i.e. patent. They start commercialising of it in national and international markets. This is not actually a novel and non-obvious invention rather unfair and unethical exploitation of 'existing knowledge' or 'prior art' which is in public domain for a couple of centuries. The general Indians and in some cases some specific communities know the use of these medicinal plants; some of them are written in ancient books or some of them are only in the public use since time immemorial. This type of unjustified and unreasonable use, exploitation and commercialisation of public domain knowledge i.e. traditional knowledge of medicinal plants somewhere has to be stopped in the name of exception to IPR. Hence it is suggested that the sui-generis law of traditional knowledge of medicinal plants must make it a point that above mentioned use of existing public domain or non-public domain traditional knowledge will not be allowed. It might be allowed if a fair benefit-sharing arrangement is reached between the holders of the traditional knowledge and the commercial users. But it is also to be ensured that study and research or even use for the benefit of general public without any kind of profit making will be allowed. The distinction between utilisation of existing knowledge and non-original invention is very important. The former is the using the existing knowledge to make a truly novel and non-obviousness invention. The latter is taking of information from the existing knowledge and subsequently confirming it. But in both the cases, it is utilisation of TK, hence to be paid for it.

(XIII). IN SITU AND EX SITU CONSERVATION OF THE MEDICINAL PLANTS TO PROTECT FROM EXTINCTION

Protection aspect of the medicinal plants is as important as the protection of traditional knowledge. The medicinal plants are grown in a particular environment-temperature, sunlight, humidity, rainfall, soil condition and they are grown with some special characteristics in their genetic materials. These genetic materials actually are the main reasons for the medicinal values of these plants which can cure ailments or are disease resistant in nature. The plants are conditioned with genetic materials in such a way that they must have the medicinal values; one of the reasons is that they are grown up in a particular type of environment. If they are grown up in a different environment, they might not have those medicinal values in themselves. Now the serious issue is that excessive and non-sustainable use of the medicinal plants to extract the genetic materials are posing a serious threat to their availability in nature, in expected quantity, keeping in mind the needs of the present and the future. People need medicinal plants and they need them in sufficient quantity for the treatment. As

the demands of the herbal and natural medicine are rising day by day all over the world because of their zero side-effects and their wonderful positive results on the patients, the demands of the medicinal plants will go up in near future. In this context, it is suggested that the model law on traditional knowledge must take into account the in-situ and ex-situ conservation of the endangered species of the medicinal plants together with the augmentation of the present quantity of all the Indian medicinal plants through different types of schemes at the grass root level. Otherwise what would happen that there would be traditional knowledge but no medicinal plants or less quantity of medicinal plants. The conservation aspect of medicinal plants must also take account the indiscriminate export of various medicinal plants in the international markets which are going on legally and illegally. This export business of medicinal plants is one of the threats to the availability of medicinal plants.

(XIV).CREATION OF TRADITIONAL KNOWLEDGE FUND AND ITS UTILISATION

The income generated by the commercial utilisation of the traditional knowledge associated with medicinal plants, either by the government or by others, has to be utilised for ensuring the basic needs of the people living below poverty line (BPL) i.e. health, pure drinking water, education, road, construction of the houses, sanitation, financial assistance for livelihood etc. The income generated by the communities themselves, will have to be utilised for the development of those communities only, which will be decided by themselves, according to the government guidelines.

(XV). DOCUMENTATION AND RESEARCH

First issue is complete documentation of traditional knowledge associated with medicinal plants. Without belittling the achievement and contribution of TKDL in preventing bio-piracy of Indian traditional knowledge about herbal medicine, it is suggested there is much scope for further improvement. It is because of TKDL, so many companies had to withdraw their patent applications. Patent offices of so many countries could not grant patents in recent past. Due to TKDL, India got the turmeric patent revoked by USPTO. What is lacking in TKDL is that it does not document the informal existing traditional knowledge regarding the public use of the medicinal plants in different remote areas of this country. Hence it is recommended that second phase of TKDL documentation should start. It must include the informal existing traditional knowledge within the documentation programme. This is very important because the second category of knowledge is more vulnerable than the first category of knowledge. Moreover, if it is counted properly, it would be found that approximately half of the traditional knowledge belongs to the informal existing traditional knowledge for which there is no written document; but everything is in public use. While going for the documentation of traditional knowledge, it has to face one serious problem. There are traditional or village communities or village ayurvedic practioners keep the informations about the use of medicinal plants and its method,

secret; they do not disclose these informations to anyone. This will be the uphill task for TKDL persons to get the information. For that reason, awareness programme, encouraging economic packages are very much essential to encourage and impress upon those people to disclose the informations.

Next issue is fundamental research. India needs serious research on traditional knowledge. Basically research serves two purposes. Firstly, getting the basic informations and leads about the medicinal value of a particular plant, a systematic research has to be started in the modern state of the art laboratories. It would find out the actual genetic materials which have the capacity to cure ailments, their DNA finger printings, their chemical components, chemical reasons for these types of medicinal values. It would experiment through clinical trials the results of applying the herbal medicines. Through this process, the research would confirm and reconfirm the medicinal values of these medicinal plants which can result in a very good documentation according to TRIPs method. This method of a fresh and modern research on the medicinal values of the Indian plants will also open up new areas of research. As a result some new informations about some other genetic materials with some more medicinal values might be found out; these new and novel findings in turn would enrich the existing traditional knowledge. It is suggested that it should be made mandatory as integral part of positive protection to initiate research in this way. Without research, there is no improvement of existing traditional knowledge; without improvement, there cannot be any positive protection of traditional knowledge. Through research outcomes, if values are not added to the existing level of traditional knowledge, then protection becomes meaningless. This dynamic part of traditional knowledge is pointed out by WIPO: "it is the relationship with the community that makes it "traditional". TK is being created every day, and evolves as individuals and communities respond to the challenges posed by their social environment. This contemporary aspect is further justification for legal protection. It is not only desirable to develop a protection policy that documents and preserves TK created in the past, which may be on the brink of disappearance; it is also important to consider how to respect and sustain the development and dissemination of further TK that arises from continuing use of TK systems."[6] Research is a method through which a new traditional knowledge is created or rather evolved to respond to the new challenges in the social environment.

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[6] Intellectual Property and Traditional Knowledge: Booklet No.2. This is one of a series of Booklets dealing with intellectual property and genetic resources, traditional knowledge, published by WIPO.
Available at http://www.wipo.int/freepublications/en/tk/920/wipo_pub_920.pdf. 14th July, 2011, at 6.35 PM.

(XVI). DUTIES OF THE CITIZENS

'Collective intellectual property rights' is a creation of a new right or recognition of a pre-existing right, whatever may be, for all the Indians and in some cases for specific communities. As rights and duties are co-related and right cannot be enjoyed without the concomitant duties with it, imply that people must perform some duties. It should be the duty of each and every Indian: (A). not to disclose the traditional knowledge related informations about any medicinal plant to the foreigners; (B). to disclose the traditional knowledge related secret informations to the government about the medicinal values of the plants which are not documented and in public use by the tribal and village communities, if it is for the protection and development of such knowledge; (C). not to indulge in unauthorised and illegal commercialisation of traditional knowledge of medicinal plants in any form.

(XVII). ESTABLISHING OF HOSPITALS-PUBLIC-PRIVATE PARTNERSHIP

Establishing hospitals and medical colleges in large numbers in this country is very necessary. It would serve three purposes. Firstly, the subjects will be taught, there would be further research on the medicinal plants and there can be experimentation through clinical trials on the patients (with their free consent only). Secondly, People can get good ayurvedic treatment and can avail of the fruits of traditional knowledge. Thirdly, as the ayurvedic treatment and medicine are very popular and going to be more popular in future in foreign countries, it can explore the new avenue of health tourism, which can generate job opportunities and generate national income The people from different countries will come to India for this less expensive and side-effect-less treatment and country can earn huge foreign money.

(XVIII). INTERNATIONAL CAMPAIGN AGAINST UNFAIR WTO-TRIPS

As all the powerful developed countries are in favour of the present form of WTO-TRIPs. They are not willing to change the present provisions to suit their own interest, so that traditional knowledge gets better protection. This is because they are the ultimate beneficiaries of the commercialisation of traditional knowledge. But India should join hands with other traditional knowledge enriched developing countries and start a vigorous and continuous international campaign at different levels against this type of unfair and irrational WTO-TRIPs provisions. This would exert tremendous pressure on those countries and a time will come when they have to change their attitude and make the WTO-TRIPs traditional knowledge friendly. Moreover, as India's market is enticing to all of them and they are facing a serious economic crisis i.e. recession, India should exploit the situation and take the advantage of this opportunity with the offer to open the markets further, subject to get the WTO-TRIPs amended.

B. DEFENSIVE OR NEGATIVE INTELLECTUAL PROPERTY RIGHTS

(I).EXAMPLARY PUNISHMENT AND COMPENSATION: VIOLATION AND SUFFICIENT PUNISHMENT-CIVIL AND CRIMINAL

Not only patent, there are other ways of unlawful commercialisation of TK in India. One of the serious shortcomings of the present legal framework is that the sanction or punishment under the existing laws of patent is not up to the mark. The sanction or punishment is either imprisonment or just cancellation and revocation of patents or just fine with a very meagre amount of money. Apart from the conventional types of civil and criminal punishments i.e. compensation, revocation of patents, non-granting of any patent for a particular period or imprisonment, it is recommended that the huge profit which was earned by an individual or a company with that wrongful patent or wrongful utilisation of traditional knowledge, to be returned to the holders of the traditional knowledge. Moreover, whatever the commercialisation or business took place, the continuance of the commercialisation or the business might be allowed only with the condition that a fair share of profitbut will be transferred to the holders of the knowledge. It means that to stop the practice of bio-piracy, the concept of civil and criminal punishment should be widened in this way, to make the punishment effective, functional, result oriented and successful.

(II). CANCELLATION OR REVOCATION OF WRONGFUL PATENTS OR ANY TYPE OF BIOPIRACY AND BIOPROSPECTING

The rate of the numbers of the revocation of the wrongful patents on Indian traditional knowledge is not satisfactory. Very few wrongful patents have been cancelled or revoked by the Patent Offices of various countries in the world at the initiative of government of India or by NGO. Huge and huge numbers of wrongful patents on traditional knowledge of herbal Indian medicine still remain in the IPR world. It is really an uphill task for the government of India and the NGOs working in this field, to get them cancelled or revoked. It is therefore suggested that a LEGAL CELL to be established to look after the above mentioned matters to initiate legal action against bio-piracy and bio-prospecting occurring in India and in other foreign countries.

(III). PROCESS PATENT

There has to be a relook on process patent. There are patents where there is no claim of the medicinal values of the plants as the invention of the person. It may be on the novel and non-obvious process of making the product. This process of making the herbal or non-herbal medicine is related to the medicinal values of the plants associated with TK. This is also a case of indirect utilisation and commercialisation of the traditional knowledge of India. It is suggested that this type of indirect commercialisation of TK should also be proscribed. It might be allowed if the users pay for the commercial use of the intellectual property of the society.

(IV). STRICT VIGIL ON THE PATENT APPLICATION

The way, CSIR foiled the UK firm's attempt to obtain a patent on ginger recently, the expectation is that CSIR would continue with their strict vigil of other similar attempts to obtain patents of Indian traditional knowledge anywhere in the world. For that reason, all the patent applications of all the countries of this world would be checked and necessary action should be taken without any delay.

(V). COMPLETE BAN ON NON-PATENT ORIENTED COMMERCIALISATION OF TRADITIONAL KNOWLEDGE AND LEGALISING OF EXISTING BUSINESS USING TRADITIONAL KNOWLEDGE

Amid worldwide concerns and debates that developed world and multinational corporations seek to benefit more and more from traditional knowledge associated with medicinal plants, especially for industrial or commercial advantage, by misappropriating the traditional knowledge through different ways of making unfair and unjustified national and international IPR laws, this research work found out another dimension of biopiracy in India. This type of misappropriation is taking place in India with the active support and approval of the government though it is losing huge amount of money. This misappropriation has been going on without any protest from the activist persons or NGOs who are concerned about the traditional knowledge protection. Problem is that when India will be vocal at the international forum against the IPR laws of developed countries and WTO-TIPs, they might counter India by raising finger on this type of misappropriation. It would be a loss of face of India and definitely would weaken its struggle against all forms of biopiracy. The issue is production of ayurvedic medicines by various companies and trusts-Divya Yoga Mandir Trust, Dabur, Baidyanath, Himalaya etc. They manufacture various types of ayurvedic medicines using various components of medicinal plants and sell them in national and international markets. Though they are actually utilising and commercialising the traditional knowledge i.e. the intellectual property of the society, but not paying for that-either royalty or any type of benefit sharing. The government is also not asking for the payment for the use of such traditional knowledge. Though Indian patent law does not allow patent on the so called invention which are in the traditional knowledge, but this type of commercialisation of traditional knowledge associated with medicinal plants, is allowed without having any patent. Whatever the trusts and the companies could not do under Patent Act, they are doing same thing without any patent. What they could not do directly, they are doing it indirectly. Hence it is suggested that the existing business of ayurvedic medicines, either be banned completely and the business be taken over by the government or be allowed with the condition that they pay for the utilisation of traditional knowledge along with the payment of dues from their earlier profits. But if is for charitable and philanthropic purposes, there may be some relaxation.

(VI). COMPLETE BAN ON INNOVATIVE OR SOFT PATENT

Nowadays some countries are granting petty patents. India is also contemplating for such types of patents. The inventions which do fulfill the criterion of novelty and inventive step are granted standard patent. But this type of patent is not required to fulfil the criterion of novelty or non-obviousness. Innovations, just short of invention suffice to get this soft type of IPR protection. Those claims where degree of difference between prior art and present new knowledge is little, these small claims are called innovations and are granted innovative patent as they are only innovations, cannot claimed as invention as such and cannot deserve full patent anywhere in any country in the world. As a result, though the claim is little bit different (the claim can never be new or novel) by a matter of small variation from the some earlier traditional knowledge of the medicinal values of the plants which may be possible but anyway there is no non-obviousness or inventive-step, is also entitled to have a new type of intellectual property rights. Hence the traditional knowledge is doubly susceptible to biopiracy. Where patent cannot be granted under the existing legal frameworks, a country can offer a new type of patent right in the name of innovative patent. This practice puts the traditional knowledge under a two pronged attack. Hence, it is recommended that initiative must be taken to start campaign against this sort of biopiracy and a new threat on TK and also to revoke these innovative patents.

C.ESTABLISHMENT OF TRADITIONAL KNOWLEDGE AUTHORITY AND OTHER SUBORDINATE AUTHORITIES

Hierarchy of authorities at the national, provincial and district levels have to be established as early as possible. Those authorities will be constituted with the members who have expertise in various fields of law including IPR, bio-technology, genetic, engineering, medical science and chemistry. To assist them there will be a group of researchers from all those fields. These authorities will have various powers and functions to look after the above mentioned protection measures-both positive and defensive or negative. With their various mandated functions, they will perform their duties to protect traditional knowledge. They can exercise all the powers to take all the decisions whatever is necessary.

The important functions of (TKA) Traditional Knowledge Authority are: (a) to prepare a national policy, strategy and action plan for ensuring the protection, continuum of use and practice of traditional knowledge and to ensure the sustainability of the resources including the human resources on which the TK is dependent, prevent biopiracy and other misuse of traditional knowledge and take preventive and/or punitive action if required (b) to ensure that any access to traditional knowledge is brought under the purview of the Authority and is fair by way of non-exclusive informed consent of the traditional communities; (c) to ensure through required instruments and proceedings that no Traditional Knowledge in the

country is the subject to any IPR application; (d) to provide the informed consent or prior informed consent as the case may be, to the Accessor, in case where a traditional community is not identifiable; (e) to help and facilitate the traditional communities to negotiate the terms and conditions of benefit sharing upon access to use the traditional knowledge; (f) to set up a watch cell to monitor the applications and/or use of traditional knowledge, both in the country or any part of the world, and to take appropriate corrective action if there is a violation of any provision under this Act, including taking measure on behalf of the Central Government for the opposition/revocation of grant of IPR on traditional knowledge in any part of the world; (g) to administer the traditional knowledge fund for protection of traditional communities and ensuring the continuum and sustainable use of traditional knowledge by traditional communities etc.

The legal framework to protect traditional knowledge is not appropriate and a new pro-TRIPs agreement is must to make an effective legal regime. A new and more effective legal regime is recommended in the present research work which will take care of the traditional knowledge associated with Indian medicinal plants.