CHAPTER VIII

CONCLUSIONS AND SUGGESTIONS

Very few countries in the world can boast of the variety and vastness of TK especially traditional medicinal knowledge that India has. As the global economy has taken more firm root, however, this knowledge has increasingly been available to non-Indians as well. And in research laboratories and patent offices around the world, this knowledge has been exploited and claimed exclusively by foreigners, both individuals and corporations\(^1\).

At the beginning of the third millennium, TRM invites us to an essential appointment with our future, in spite of the obstacles from the dominating western system. TRM functions as the repressed of this system and reveals the epistemological and institutional obstacles within it\(^2\).

If earth is a negligible element of the universe, lost in a kind of large suburb of a very ordinary galaxy, it owes to the solar system, of which it is an element, all manifestations of the life which animates it; and man is subjected inexorably to rhythms which are fortunately not yet in his power to modify. An event which occurs in the cosmos starts vibration of electromagnetic waves which travel through space and arrive by resonance at a point on the surface of the earth which has the same natural frequency.

Traditional Medicine appears as a science that is no longer possible to be treated with contempt, and that soon will be impossible to be unaware of. From prohibition to tolerance, and soon to respect, the current status of TRM is dependent, without any doubt, upon a qualitative and quantitative uneasiness with western medicine and in the search for a global and natural medicine which modern medicine seems not to be able to bring\(^3\).
Traditional Medicine has received increasing attention on the international agenda over the past decade. This is due to a number of factors, including the recognition of its importance in the lives of the majority of the world’s population and in the conservation of biodiversity\textsuperscript{4}. The era of globalization has allowed the blatant misuse of TRM and granting of monopolistic rights to a few in spite of the fact that the TRM has been well known and used for centuries by indigenous groups\textsuperscript{5}.

Documentation activities undertaken by developed countries like India are worth recognition. In India an exercise has been initiated to prepare easily navigable computerized database of documented TK relating to use of medicinal and other plants (which is already under public domain) known as TKDL. Such digital database would enable Patent Offices all over the world to search and examine any prevalent use/prior art, and thereby prevent grant of such patents and bio-piracy\textsuperscript{6}.

Documentation of TRM knowledge is one means of giving recognition to knowledge holders. But mere documentation may not enable sharing of benefits arising out of the use of such knowledge, unless it is backed by some kind of mechanism for protecting the knowledge\textsuperscript{7}. Documentation of TRM may only serve a defensive purpose, namely that of preventing the patenting of this knowledge in the form in which it exists.

However, unless there is awareness and strict measures about respecting and valuing TRM, corporations can always find a way to commercially exploit the TRM to their advantage\textsuperscript{8}. The main concern of protecting TRM should include;

- equitable distribution of benefits,
- conservation concerns,
- preservation of traditional practices and culture,
- the prevention of misuse by unauthorized parties of TRM, and
- promotion of its use and its importance in development.
Many countries and communities worldwide are currently grappling with how to best address this issue at national, regional and international levels. As apparent from the wide range of interests and concerns, TRM is a complex and multi-faceted issue. It is thus being discussed in a range of forums, each from its own perspective and within its own area of competence and expertise. This is useful and necessary. However, focusing on one part of the problematic and ignoring all the other aspects runs the risk of yielding a patchwork of particular solutions that in the end do not fit seamlessly together, and may in some cases partially or wholly cancel out each other’s’ well-intended effect. There is need, therefore, for a holistic approach.

In this work the researcher tried to critically analyse on concerns raised in the context of existing legal measures and its effectiveness to protect the knowledge of TRM both at national and international level, the extent of bio-piracy and misappropriation of knowledge of TRM and the effectiveness of existing legal provisions in combating the same, the contemporary ABS Mechanisms for fair and equitable sharing of benefits and also the protection afforded by IPR for TRM knowledge.

Over the past few years, the patent system has come under considerable criticism for its failure to prevent the misappropriation of TRM. It has been observed that discussions on the challenges of the digital era tends to focus on the ownership rights of companies and individuals but far more daunting to the poor in developing societies are the challenges raised from waves of legislative changes to copyright and patenting law that are led by multinational companies seeking to define ownership of knowledge and to a large extent what knowledge is.

The study involved the analysis of the definition and the scope of the TRM on the one hand and evolution of IPR and its scope in protecting TRM on the other, and arrived at the conclusion that positive protection of TRM cannot be successively accomplished through the IPRs.

These IPRs regimes are calculated to reward those who are in a position to patent certain kinds of innovation, but do not recognize the originators of the innovations. It is quite clear
that the existing forms of IPR protection do not adequately recognize the rights of TRM holders. Application of IPR to TRM is not only economically detrimental to developing nations but also capable of eroding local knowledge\(^{13}\).

A patent system which is supposed to reward inventiveness and creativity in real now rewards piracy. If a patent system fails to honesty apply criteria of novelty and non-obviousness in granting of patents related to TRM, 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 bio-piracy, to a great extent is a result of Western style IPR systems\(^{14}\).

Increased commercial interest in TRM 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\(^{15}\).

In fact, there exists a vacuum in the overall framework that can provide comprehensive protection to traditional medical knowledge\(^{16}\). In most of the cases, patents are granted outside country that holds knowledge. In such a situation the interests of the nation’s cannot be protected unless presence of international framework that recognizes and respects national laws\(^{17}\). Besides international action, there is a need for nations to protect their communities by making national laws\(^{18}\) and addressing relevant issues like Documentation of knowledge\(^{19}\), ABS\(^{20}\) and PIC\(^{21}\). A need of the hour is that nations should show mutual respect for national legislations, for the benefit of mankind\(^{22}\).

Work on TK/TRM is undertaken in various inter-governmental bodies like CBD, WIPO, FAO and UNCTD. The efforts of these bodies are in stage of discussion and a comprehensive framework has yet to evolve urgent action is needed by all concerned\(^{23}\).

The harmonization process of IPR system\(^{24}\) by international treaties and agreement was evaluated during the study\(^{25}\). The CBD was the first international agreement to acknowledge the role and contribution of indigenous and local communities in the preservation and sustainable use of
biodiversity\textsuperscript{26}. It was observed that though the importance of preserving TK as well as TRM was emphasized in CBD, there was no provision to protect TRM or safeguard the rights of its possessors. CBD recognizes nation’s right to make laws; it does not set any minimum standards to protect them. Continued dialogue and information exchange between users and providers of genetic and biologic resources is vital, which is not properly addressed in CBD. This has been in part due to what some perceive as the frustrating nature of the policy making discussions in the CBD process\textsuperscript{27}.

Appropriate ways to seek PIC, negotiate MAT, and share benefits associated with the use of TRM remain unclear in CBD policy\textsuperscript{28}. Basic questions remain unanswered, such as:

- Is all knowledge, including that which is widely known, subject to ABS regulations? Who should provide PIC, enter into an agreement, and receive benefits?
- How are the owners of TRM identified?
- And what if knowledge is shared by a number of communities?

These and related questions have been raised since the CBD entered into force, but developing effective ways to address them within ABS agreements and partnerships is still in the early stages. Because of these difficulties, many companies have adopted a ‘hands off’ approach to the use of TK and TRM, whilst others have little awareness of the need to enter into ABS arrangements when using TRM\textsuperscript{29}. In cases where TRM is used, there is typically strong reliance by companies on the use of intermediary institutions such as research institutions, NGOs or governments, to resolve difficult issues\textsuperscript{30}. The variety of terms and definitions used by different sectors to describe genetic resources and related products has led to a lack of clarity in the terms and concepts used in ABS measures. Resolving these definitional issues would enhance understanding and agreement about the scope of proposals to regulate ABS\textsuperscript{31}.

The ABS agreements seldom involve a single, framework agreement but instead are characterized by an interlocking web of agreements between multiple parties which may or may not
be divided into research and commercialization phases. Governments in both user and provider countries should build capacity within national focal points, and ensure their mandate, scope, roles and responsibilities are clear. Expertise in the scientific, commercial, and legal areas that make up ABS should be found within these focal points. The process for granting access should be transparent, minimally bureaucratic, and should promote communication and collaboration, rather than suspicion and frustration.

Let us put a few words on TRIPS Agreement of WTO, which was designed to promote effective and adequate protection of IPR, covered a broad range of IPRs, including Copyright, Trademark, GI, Trade Secret and Patents.

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 TRM.

The TRIPS is based on the assumption that the U.S. style IPR systems are ‘strong’ and should be implemented worldwide. In reality U.S. System is inherently flawed in dealing with TK and is ‘weak’ in the context of bio-piracy, the review and amendment of TRIPS should begin with an examination of the deficiencies and weakness of Western style IPR systems.

Western concept of Intellectual Property is ill-suited for TK and TRM. Attempt to apply Western concept of IPR to protect and preserve TRM will not be economically beneficial to developing countries. Because of their continuing unequal status, developing countries bear the greater share of misappropriation of TRM. Their true loss is not the pennies which their indigenous population might earn selling herbs and local seeds but rather the true price is the induction into a system of trade where the deck is already stacked in favour of existing and highly developed proprietary interest. Long range economic value cannot be achieved by artificially monetizing shared traditions through patenting, copyrighting or trademarking components like medicine or genetic materials or other processes and structures of nature incorporated into the common heritage within developing countries.
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 legalises monopolistic exclusive rights by granting of patents based on every day, 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. It is also submitted that the implementation of TRIPs, which is based on the U.S style patent regimes, be immediately stopped and its review undertaken. No country can achieve the objective of protecting its TRM by changing its IPR related laws alone. The problem needs to be tackled under the auspices of TRIPS. Not only TRIPS should prohibit patenting of TRM but also prevail upon the member nations to recognize ‘unpublished foreign art’ as ‘prior art’ under their IPR laws.

The international community is debating the consequences of globalisation in its various dimensions in various forums. It is the responsibility of the same international community to debate the means of protecting and preserving TRM. The global community has acknowledged the role and importance of TRM and that for the TRM to be maintained, the social and economic context in which it developed has to be maintained. In this regard, it is necessary to recognize and respect the rights of holders of TRM. Misappropriation of TRM and bio-piracy erodes the rights of the TRM holders and adversely affect conservation and sustainable use of bio-diversity and associated TK. Though complex issue of protecting TRM cannot be solved overnight, the process to initiate legal effort in this direction must not be delayed.

To protect TRM, new approaches are required at the national and international levels. At the national level, measures must be developed in light of national priorities, and the needs of indigenous and local communities. A national legislative approach alone cannot ensure that citizens from other countries do not misappropriate the genetic resources of the source countries. At the international level, some minimum frame work will be required to protect against misappropriation, and to ensure
fair benefit sharing. No international system has yet been developed to adequately preserve TRM, protect the rights of knowledge holders, and compensate them equitably for its use\textsuperscript{43}.

Indigenous peoples have always had their own laws and procedures for protecting their heritage and for determining when and with whom their heritage can be shared. Many traditional societies have their own custom-based ‘Intellectual Property’ systems which can be very complex, vary greatly among different indigenous peoples, and often differ considerably from western concepts of Intellectual Property. Rather than developing a uniform system for protection of TRM, which imposes uniformity on diverse Customary Law systems and does not fit the values or laws of any one indigenous society, countries should recognise that TRM should be acquired and used in conformity with the Customary Laws of the people concerned. Formal law needs to recognise the supremacy of Customary Law in matters relating to TRM, not only within ancestral territories, but at country-wide and international levels\textsuperscript{44}.

An important issue that needs to be considered is the international dimension of \textit{Sui Generis}\textsuperscript{45} model for protection of TRM. TRM is a rather culture specific concept and the kind of protection required would also depend on the cultural context of that region. Therefore, the countries should be left free to decide the regime that best suits the socio-cultural context of their country.

The use of current systems of national, international level legislations and IPRs for TRM will not do justice to the concerns and rights of the traditional community. However, the rights of the traditional community have to be balanced with other interests such as need for public access, innovation etc. there is a need for a model that can ensure that the traditional communities benefit from their knowledge and maintain control over it without sacrificing public interest in TRM.

Yet, in order to rectify some major defects in protection of knowledge of TRM and to make ABS more effective and meaningful, the researcher has summarized certain recommendations and suggestions which is furnished below:
Actions to be Taken at International Level:

➢ To ensure realisation of the CBD’s goals, Parties should consider about the insisting on permanent observer status in the Council for TRIPS.

➢ Remove Article 27.3.b from the TRIPS Agreement. To start with, the demand for patents on life forms should be withdrawn.

➢ Implement strictly, Article 29 of the TRIPS Agreement, which requires disclosure in the case of patent applications, to genetic resources and TK used in inventions for which IPR are claimed.

➢ Invoke Articles 8(j), 15, 16, 20 and 21 of the CBD in all discussions relating to access to bio-resources.

➢ At the international level, both procedural and substantive steps should be taken by the CBD and the WTO that would enhance the ability of the agreements to be implemented in a mutually supportive way.

➢ In the CBD, give primacy to conservation, since that is what will conserve the TRM base and continue to provide livelihoods and opportunities for value addition to communities.

➢ Implement the relevant provisions of international commitments such as the ILO Convention, the International Undertaking on Plant Genetic Resources, the Guidelines for Protection of Folklore issued by UNESCO and the WIPO, the United Nations Draft Declaration on the Rights of Indigenous Peoples, and the CBD.
- Maintain countries’ flexibility to draft their own *Sui Generis* legislation by insisting on compliance with the conventions of The International Union for the Protection of New Varieties of Plants (UPOV).

- Develop strong guidelines for ABS. Parties should consider encouraging the Ad Hoc Open-ended Working Group to develop guidelines that suggest minimum binding requirements for ABS for implementation in national law and emphasize the need to permit in national legislation.

- Conservation of TRM and bio-resources has to be taken up on a priority basis. Strategy for protection should take into account the fact that genetic resources and TRM are inextricably linked.

- The herbal drug industry should be allowed to use plants only from cultivated sources. Collections from nature should only be permissible for local communities and traditional healers and monitored for sustainability.

- Ensure that any agreement on databases recognizes the ownership of communities and includes provisions for PIC, multilevel trade agreements, and benefit sharing when access is granted.
Actions to Be Taken at National Level:

- National legislation is needed specifically to protect TRM. This should be followed by negotiations at the international level for an international agreement to protect TRM and the rights of local communities.

- National policy and legal framework is to be urgently formulated appropriately to prevent its misappropriation.

- It is important to develop an indigenous paradigm to discuss the issues related to TRM, identify the problematic areas and develop solutions. The debate and its content must be generated indigenously.

- Efforts of the knowledge of TRM holders, who are often poor and marginal tribals, and village communities, should be recognized and care should be taken by the researchers not to disclose vital and crucial information in academic publications.

- Basic knowledge on IPR may be included in under-graduation and post-graduation academic curricula.

- It is important to develop an indigenous paradigm to discuss the issues related to Traditional Medicine, identify the problematic areas and develop solutions. The debate and its content must be generated indigenously.

- Developing procedures for PIC. These procedures should be developed in cooperation with local and indigenous communities.
Define core IP concepts carefully in national legislation. For example what is ‘novel’ or an ‘invention’, must be carefully defined to ensure that the resources are not removed from the public domain. Careful definition of core concepts will avoid strengthening IPRs further than required by the TRIPS Agreement, and reduce its potential to undermine the CBD.

Ensuring indigenous and traditional local community representatives have full participation in the development of strategies on the preservation and protection of TRM. Governments should consider taking steps to ensure that indigenous and traditional local community leaders have full participation in the development of strategy on IPRs and the preservation and protection of TRM. National delegations to any international forums discussing TRM should seek to include representatives of indigenous and traditional local communities.

Considering the development of registries of TRM. The development of registries of TRM at the national level or international levels and the sharing of this information with patent offices throughout the world, may contribute to preventing the misappropriation of TRM. The inclusion of TRM in such registries is appropriate only with the PIC of the community in question.

Ensuring that national IP offices are adequately resourced. They must have sufficient resources to complete a thorough search of ‘Prior Art’ and to avoid granting overly broad and otherwise inappropriate patents.
- Develop a *Sui Generis* system to protect the IP of communities in the field of TRM.

- Ensure an effective *Sui Generis* system, which should be consistent with the provisions of the CBD, and respect national priorities regarding protection of TRM, and ABS.

- To conserve TRM, it is crucial to accord its prestige and value. Integrate the indigenous systems of medicine into the mainstream health and veterinary care system on par with the conventional system. Involve local communities in policy formulation and decisions.

- Disclosure, informed consent and equitable benefit sharing should be mandatory for any commercial use of TRM and genetic resources. Concrete and specific methods of sharing benefits should be worked out in the event of commercialization. Develop a Community-Industry National Authority interface to work out these modalities. Concrete and specific methods of sharing benefits in the case of commercialisation should be worked out in favour of communities.

- Patents on genetic resources and TRM should not be allowed on ethical, social and economic grounds

- Developing and implementing ABS schemes. These should include minimum binding standards in national legislation.

- Policy-makers should consider excluding life patenting in order to implement their CBD obligations, including the development of
national measures to protect TRM, and to ensure fair and equitable ABS.

- Develop a system of rewards and recognition for creators and holders of TRM.

- The principles for ABS should be incorporated into benefit-sharing arrangements between stakeholders which should contain the following fundamental components:

  1. An ABS agreement shall cover the conditions, obligations, procedures, types, timing, distribution and mechanisms relating to the mechanism shared.

  2. Benefits should be shared, as is the case may be, among those who contribute resource management, scientific and/or commercial process, holders of associated Traditional Knowledge of medicine and poor people living in the geographical area of origin of the resource.

  3. Benefits should contribute to the conservation and sustainable use of biological resources as well as poverty alleviation. It should involve technology transfer and joint research. Priority in benefit sharing should be given to alleviating poverty, such as creation of income opportunities for local people and markets for products. Biological products should be cultivated in the areas of origin of the genetic resource. Benefits should include the empowerment of local people and the strengthening of self-governance, cultural identity and self-confidence.
4. Benefits should include advance and milestone payments sufficient to contribute to poverty alleviation in the short term and to create an incentive for the conservation and sustainable use of biodiversity. Appropriate institutions should be set up to ensure that payments are used efficiently (e.g. trust funds).

- Documentation of (oral) TK and TRM of communities and their legal protection is urgently needed in view of the rapid erosion of this knowledge base. Special attention needs to be paid to thousands of undeciphered manuscripts. Legally protected databases with suitable contractual agreements based on CBD principles should be set up.

- Efforts should be made to document the vast knowledge of TRM of all the ethnic groups/rural communities through involvement of various formal and non-formal institutions working in the areas.

- Keep transmission of TRM alive, both among the local people and outsiders, in a variety of ways and include TRM in all development programmes.

- In the emerging regime of international and national laws and policy regulations, it is necessary that the community level knowledge holders are appropriately educated so that they are made aware of their rights and responsibilities with regard to safeguarding their TRM knowledge.

- Create awareness at the local panchayat level, particularly among women and the youth, about the value of TRM, about the long-term sustainability of TRM and the attendant economic rewards. 

46
➢ TRM based on bio-resources, which are endangered and threatened are required to be conserved on war footing.

➢ There is a need for greater investment in research in TRM by both the government and the private sector. Investment is needed in the standardization and quality control of TRM derived products.

Hence this study concluded with a sense of optimism that all the measures suggested will be taken care of by the policy makers to enact new law and to amend the existing enactments accordingly.
See generally supra Chapter V, pp. 150-172
See supra Chapter IV, pp. 114-120
Ibid. at 115-118
See supra Chapter VI, pp. 173-181
See generally supra Chapter V, pp. 152-170
See supra Chapter VI, p. 194
Ibid
See supra Chapter VI, p. 203-204
See generally supra Chapter VI pp. 173-181
See supra Chapter I, p. 13
See supra Chapter VI, pp. 207-215
See supra Chapter VI, p. 227
Ibid
See supra Chapter VII, pp. 208-227
See supra Chapters VI
Ibid
Ibid
See supra Chapter VI, pp. 183-194
Ibid
See supra Chapter VII, p. 241
Ibid
See generally supra Chapters VI, p. 183-188
See supra Chapter III, pp. 84-88
See generally supra Chapter VII
Ibid
See supra Chapter II, p. 43-46
See supra Chapter VI
See supra Chapter VII, p. 244
See generally supra Chapter VII
Ibid
Ibid
See supra Chapter VII, p. 267
Ibid
Ibid
See supra Chapter VI, pp. 248
Ibid
Ibid
See generally supra Chapter VI
See supra Chapter VI, p. 173-181
See supra Chapter IV pp. 114-121
See supra Chapter II, pp. 19-40
See generally supra Chapter VI
43 See generally supra Chapter VI

44 See supra Chapter VI, pp. 224

45 See Ibid