CHAPTER V

INTERNATIONAL LEGAL FRAMEWORK RELATING TO TRADITIONAL KNOWLEDFE OF MEDICINE FROM BIOLOGICAL RESOURCES

INTRODUCTION

Globalisation is an inevitable process. WTO mandates for globalisation. It is the process of relegation of States' political boundaries. This new world order is diminishing the borders of the countries. It emphasises the withdrawal of State activities from the economic affairs of the countries. There will be easy inflow and outflow of goods and services in all the countries of the world. Everything will be decided by the market forces and markets are expanded all over the world. The markets are open and without any tariff and non-tariff State barriers. Each and every major incident has global ramifications or the cause of any international incident-legal, social, political and economic.

In this backdrop, biopiracy is not only a national phenomenon, when the patent is granted on the herbal medicine associated with traditional knowledge. It is not only a legal incident of a particular country for which that country's national law only is to be blamed or appreciated. International law has also some contributions, which just cannot be denied. There is a strong allegation that International law has been encouraging and legalising the legal frameworks of some developed countries to grant patents on the medicines derived from traditional knowledge by using the active bio-chemical ingredients of the medicinal plants of some countries including India in spite of some international attempts against this. Without the active support of superior international law, biopiracy could not have happened. Its effect is felt globally, in every corner of this world including in India and few other countries. This is because the patent laws of some of the developed countries which have granted patents or may grant patents in future on the bio-medicines (both products and processes) look to them as matters of inventions with novelty and non-obviousness and also because some procedural matters are according to the minimum standards prescribed by the international laws. Yet there are laws either in the form of intellectual property rights or in other fields in the international arena which do not approve any national law allowing legal incident of claiming and owning others' intellectual properties. Even if, it is not approved, umpteen numbers of biopiracy cases have taken place and so many countries and societies have become the victims. So the world body is divided with different kinds of sanctions and mandates which can be ignored by some countries and cannot be avoided by some other countries. As a result, it has different legal implications and ramifications in different parts of the world.

There are various types of international laws for different purposes with different natures and consequences. To understand the dynamics of international intellectual property laws or some other laws which prescribe and proscribe patents on non-original inventions where there are centuries old written or oral traditional knowledge of the societies and indigenous communities, it is very important to analyse and compare these various laws. This analysis will be helpful to suggest a viable and strong legal protection of medicinal plants related with traditional knowledge of India and other countries. With these objectives, here is an attempt to do the analysis and comparison with the international laws in this field to shed some lights regarding the protection of the traditional knowledge of medicinal plants of India. Moreover, it is also to ascertain the legal instruments which international law permits or declines patent on traditional knowledge associated with medicinal plants. The international laws which will be analysed are: WTO-Trade Related Intellectual Property Rights (TRIPs), Resolutions of the Convention on Biological Diversity (CBD), Guidelines of the World Intellectual Property Organisation (WIPO) through Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore) and Resolutions of the European Patent Convention (EPC).

AGREEMENTON ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS

LEGAL FRAMEWORK OF TRIPS: A BRIEF OVERVIEW

The final defining international legal event, in trade matters after long negotiations over decades at different levels and under huge protest all over the world is the formation of the Agreement on Trade Related aspects of Intellectual Property Rights agreement within World Trade Organization. This has now created internationally accepted standards for intellectual property law for various kinds of intellectual properties and obligated all the member states to commit to meeting these standards subject to the accepted exceptions. The agreement on patent law has a direct and indirect impact on the centuries old associated traditional knowledge of Indians about the medicinal values of thousands and thousands of herbs and plants. The TRIPS Agreement is Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 April 1994.

PREAMBLE TO TRIPS

Desiring to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade;

Recognizing, to this end, the need for new rules and disciplines concerning:

(a) the applicability of the basic principles of GATT 1994 and of relevant international intellectual property agreements or conventions; (b) the provision of adequate standards and principles concerning the availability, scope and use of trade-related intellectual property rights; (c) the provision of effective and appropriate means for the enforcement of trade-related intellectual property rights, taking into account differences in national legal systems; (d) the provision of effective and expeditious procedures for the multilateral prevention and settlement of disputes between governments; and (e) transitional arrangements aiming at the fullest participation in the results of the negotiations;

Recognizing the need for a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods;

Recognizing that intellectual property rights are private rights;

Recognizing the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives;

Recognizing also the special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base;

Emphasizing the importance of reducing tensions by reaching strengthened commitments to resolve disputes on trade-related intellectual property issues through multilateral procedures;

Desiring to establish a mutually supportive relationship between the WTO and the World Intellectual Property Organization (WIPO) as well as other relevant international organizations;

PART 1-GENERAL PROVISIONS AND BASIC PRINCIPLES

Nature and Scope of Obligations[1]

1. Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

[1] Article 1, TRIPs.

2. For the purposes of this Agreement, the term "intellectual property" refers to all categories of intellectual property that are the subject of Sections 1 through 7 of Part II.

3. Members shall accord the treatment provided for in this Agreement to the nationals of other Members. (1) In respect of the relevant intellectual property right, the nationals of other Members shall be understood as those natural or legal persons that would meet the criteria for eligibility for protection provided for in the Paris Convention (1967), the Berne Convention (1971), the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits, were all Members of the WTO members of those conventions. (2) Any Member availing itself of the possibilities provided in paragraph 3 of Article 5 or paragraph 2 of Article 6 of the Rome Convention shall make a notification as foreseen in those provisions to the Council for Trade-Related Aspects of Intellectual Property Rights.

Intellectual Property Conventions[2]

1. In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967).

2. Nothing in Parts I to IV of this Agreement shall derogate from existing obligations that Members may have to each other under the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits.

National Treatment[3]

1. Each Member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection (3) of intellectual property, subject to the exceptions already provided in, respectively, the Paris Convention (1967), the Berne Convention (1971), the Rome Convention or the Treaty on Intellectual Property in Respect of Integrated Circuits. In respect of performers, producers of phonograms and broadcasting organizations, this obligation only applies in respect of the rights provided under this Agreement. Any Member availing itself of the possibilities provided in Article 6 of the Berne Convention (1971) or paragraph 1(b) of Article 16 of the Rome Convention shall make a notification as foreseen in those provisions to the Council for TRIPS.

2. Members may avail themselves of the exceptions permitted under paragraph 1 in relation to judicial and administrative procedures, including the designation of an address for service or the appointment of an agent within the jurisdiction of a Member, only where such exceptions are necessary to secure compliance with laws

[2] Article 2, TRIPs.
[3] Article 3, TRIPs.

and regulations which are not inconsistent with the provisions of this Agreement and where such practices are not applied in a manner which would constitute a disguised restriction on trade.

Most-Favoured-Nation Treatment[4]

With regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members. Exempted from this obligation are any advantage, favour, privilege or immunity accorded by a Member:

(a) deriving from international agreements on judicial assistance or law enforcement of a general nature and not particularly confined to the protection of intellectual property;

(b) granted in accordance with the provisions of the Berne Convention (1971) or the Rome Convention authorizing that the treatment accorded be a function not of national treatment but of the treatment accorded in another country;

(c) in respect of the rights of performers, producers of phonograms and broadcasting organizations not provided under this Agreement;

(d) deriving from international agreements related to the protection of intellectual property which entered into force prior to the entry into force of the WTO Agreement, provided that such agreements are notified to the Council for TRIPS and do not constitute an arbitrary or unjustifiable discrimination against nationals of other Members.

Multilateral Agreements on Acquisition or Maintenance of Protection[5]

The obligations under Articles 3 and 4 do not apply to procedures provided in multilateral agreements concluded under the auspices of WIPO relating to the acquisition or maintenance of intellectual property rights.

Exhaustion[6]

For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

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[4] Article 4, TRIPs.
[5] Article 5, TRIPs.
[6] Article 6, TRIPs.

Objectives[7]

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Principles[8]

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

PART II-STANDARDS CONCERNING THE AVAILABILITY, SCOPE AND USE OF INTELLECTUAL PROPERTY RIGHTS

PATENTABLE SUBJECT MATTER[9]

Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect order public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

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[7] Article 7, TRIPs.
[8] Article 8, TRIPs.
[9] SECTION 5: PATENTS, Article 27, TRIPs.

Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

RIGHTS CONFERRED ON INVERTOR[10]

A patent shall confer on its owner the following exclusive rights: (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product; b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

EXCEPTIONS TO THE RIGHTS CONFERRED[11]

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

REVOCATION OR FORFEITURE[12]

An opportunity for judicial review of any decision to revoke or forfeit a patent shall be available.

INSTITUTIONAL ARRANGEMENTS: FINAL PROVISIONS

Review and Amendment[13]

1. The Council for TRIPS shall review the implementation of this Agreement after the expiration of the transitional period referred to in paragraph 2 of Article 65. The Council shall, having regard to the experience gained in its implementation, review it

[10] Article 28, TRIPs.
[11] Article 30, TRIPs.
[12] Article 32, TRIPs.
[13] Article 71, TRIPs.

two years after that date, and at identical intervals thereafter. The Council may also undertake reviews in the light of any relevant new developments which might warrant modification or amendment of this Agreement.

2. Amendments merely serving the purpose of adjusting to higher levels of protection of intellectual property rights achieved, and in force, in other multilateral agreements and accepted under those agreements by all Members of the WTO may be referred to the Ministerial Conference for action in accordance with paragraph 6 of Article X of the WTO Agreement on the basis of a consensus proposal from the Council for TRIPS.

ANALYSIS OF TRIPS

In 1994, countries adopted the Agreement on the Trade Related Aspects of Intellectual Property (TRIPS) under the Uruguay Round of the General Agreement on Tariffs and Trade (GATT). TRIPs agreement is a key international agreement promoting the harmonisation of national IPR legal frameworks. The effect of this harmonisation is to provide minimum standards at the international level and to make national IPR laws more similar to each other. Most important aspect of TRIPs is that unlike some other international laws in this field of intellectual property rights, this international trade law is mandatory and binding in nature all over the world and for non performance or violation of the agreed commitments by one or more countries, other country or a group of them can go for international dispute settlement forum against that country or group of countries.

Although TRIPS agreement covers various types of IPRS, namely, patents, trademark, geographical indications, undisclosed information etc., it does not acknowledge society or indigenous community based knowledge and makes no reference to the protection of traditional knowledge of medicine from the plants. TRIPs does not appreciate the elements of the collective knowledge of societies and the right of the communities over their knowledge. They recognise intellectual property rights are merely private and individual rights. It is due to the reason that the basic principle of western culture and civilisation are reflected in the national and international legal framework for IPR. There may be some other reasons like urbanisation, commercialisation and neglect of community movement from status to contract. Basically western civilisation is based on individualism. Accordingly, present patent system is centred on the concept of individual rights. Western countries do not understand the importance of community oriented concepts because of different cultural values and attitudes, where community knowledge is alien to the western philosophy. This kind of exclusivity of attitude is a hindrance to the smooth process of globalisation. Hence, there is no recognition of collective knowledge and community right of IPR in TRIPs.

According to Rajshree Chandra, it is due to the "ownership patterns of traditional indigenous knowledge prevent rights claims over it within any framework of individual rights, such as the TRIPs. Political philosophers Anthony Stenson and Trim Gray argue that because TIK is primary common knowledge and the product of collective experience without an act of individual creation, it gets precluded from being seen from the point of entitlement theory as intellectual property. The entire idiom of western legal practices and the vocabulary protection law carves out exclusive rights to an individual either natural person or legal one, to exploit particular creations of human ingenuity. Generally, these forms of intellectual property protection do not provide the necessary protection for traditional indigenous knowledge, innovations and rights of indigenous and local people. One of the prime reasons is that locus of ownership cannot be clearly identified for knowledge systems that are essentially inter-generational of products of community endeavour."[14] Ownership here does not lead to standard exclusionary implications of the property language. These features imply important differences between the meaning of individual property in Western culture and knowledge held by individuals within a non-Western community context. The distinction between 'knowledge of communities' and 'of individuals within communities' does not get subsumed under the standard divide of private and public property. Privately held knowledge in traditional or indigenous communities is not 'private' in the exclusionary sense. The residential connotations may not be implied here at all. In most cases of traditional and indigenous communities, a strong sharing ethos prevails, leading to an uneasy fit of any form of individualistic Western style appropriation as recognised and rewarded by the IPR regime.[15] It is due to the nature of possession also in the present trade related international legal framework. Possession is probably the single most important basis of an intellectual property rights claim. A property is that which is capable of being delineated with an identifiable author or inventor and is capable of being possessed or owned. Propertization is thus predicted on the divisibility of the object such that it can be delineated to an owner and on the location of the legitimate owner. on the basis of location, that is, who possesses it, knowledge may be categorised as individual knowledge, distributed knowledge or community knowledge. According to, Kibet. A. Ng'etich's analysis, knowledge can exist in either of a combination of these forms in all societies, including traditional societies. However, we also need to understand the peculiar nature of individually held knowledge in traditional societies 'the possession of knowledge by individuals does not mean that such knowledge is perceived by communities as not belonging to them. Although at any one time, knowledge may only be held by a handful of people with special roles in the community, in the course of the history of that community it becomes essentially community held knowledge. This is because those with the special knowledge do not 'own' it as such, and many have obligations to share the

[14] Rajshree Chandra, "Knowledge as Property", in 'Indigenous Knowledge Rights', Oxford University Press, New Delhi, 2010, Page 294.
[15] Ibid, Page 293.

knowledge within the community. There may exist community standards for when the information must be passed. They may hold the knowledge as trustees of the community.[16]

"One of the crucial issues that came up for consideration in these agreements was the question of how to deal with 'knowledge'. It is needless to emphasize the role played by the transnational corporations during the last two decades in commercialization of knowledge in the name of intellectual property rights. In this process they disregarded the traditional knowledge systems, destroyed the existing knowledge systems, culture and practices and tried to homogenize the newly generated knowledge for commercial gains. They deliberately and constantly undermined the knowledge and culture of the traditional and indigenous people. These were considered by them as common property for exploitation. On the contrary, the results based on their exploitation of the 'common knowledge' are considered as private property for further exploitation. These big corporations thus become the owners of the new knowledge. They use it exclusively with profit motive and in the process the majority of humankind is kept outside the benefit of the new knowledge"[17]. In general, the TRIPS agreement does not even mention traditional knowledge relating to medicinal properties of the plants. "This has two main consequences. On the one hand, if traditional knowledge innovations fulfil the criteria for protection under existing categories of intellectual property rights they are not excluded from the purview of the agreement. On the other hand, there is no recognition of a special nature of traditional knowledge under TRIPS."[18]

As the TRIPs is silent on the protection of traditional knowledge, it does not necessarily mean that it is against the protection of traditional knowledge. There is scope for further development of TRIPs by including a new type of IPR for the protection of traditional knowledge, which can offer viable protection for medicinal properties of plants of India or any other countries. By incorporating this, TRIPs can enhance the minimum standards laid out in Parts II and III, which the member States are obliged to respect other members' IPR commitments or in case of non-compliance, to face trade sanctions by the WTO Dispute Settlement Mechanism. In general, WTO makes it clear that whilst members are required to implement the provisions of the TRIPs agreement, more extensive forms of protection and enforcement are not precluded. In their national legislations, the countries may add

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[16] Ibid, Page 293.

[17] Dr. Darrell Posey, "Intellectual Property Rights-An Indigenous Affair", *Anthropology Today* (August 1990) as referred by Prof. N.S Gopalakrishnan in "Diversity Related Intellectual Property Rights: GATT Final Act, The Convention on Biological Diversity and the Challenges", Academy Law Review, Vol. XVIII 1994, Page 263.

[18] Philippe Cullel, "Intellectual Property Protection and Sustainable Development", in 'Traditional Knowledge Protection', Lexis Nexis-Butterworths, New Delhi, 2005, Page 291.

extra categories of intellectual property or higher levels of protection. The absence of any mention of TIK does not disallow a member from enacting legislation to protect such a category of knowledge. However, what is drawback of TRIPs is that other WTO members are not required to recognise rights of other countries that go beyond the minimum standards established by TRIPs legal framework. The protection also must not contravene the provisions of WTO. Does this not create problem? Should this not become part of minimum standard of TRIPs?

TRIPs also has introduced the concept of sui generis system of protection for plant varieties, which could be interpreted in different ways. It means that countries can develop their own system of plant variety protection that is appropriate in their respective contexts, to suit their own interests for the special protection of medicinal plants. The rationale behind the sui generis provision is that the claims of traditional knowledge holders are based on completely different socio-cultural norms and values. Therefore, a system that is unique and rooted in local specificities should be used for the protection of traditional knowledge. To develop *sui generis* system of protection is based on the logic that if innovators in the 'formal' system of innovation receive compensation and licence fees through IPRs, holders and innovators of traditional knowledge should be similarly treated. For traditional knowledge, the focal point has been the terms of Article 27.3(b), initially to look for space for national level traditional knowledge initiatives to be taken without breaching the requirements of TRIPs.

As there is mention of sui generis form of protection in the TRIPS agreement, it can be exploited to stop biopiracy in a country. With this permission, in bio-diversity rich countries, there can have a special legislation to protect traditional knowledge and medicinal plants. The sui generis protection will be of no sense unless there is an obligation on other countries to honour the same. Thus even when the countries do undertake sui generis legislation to protect a category of knowledge it very often fails to get protected at the global level as there are no global commitments to these legislations outside the boundaries of the legislating country. But it is left to the choice of the individual countries to enact and follow as their national legislation, which is in no way made obligatory to the other countries to respect and follow them in their countries. This is one most remarkable weakness of TRIPs to protect traditional knowledge and medicinal plants from being bio-pirated from the hands of the countries of origin or indigenous communities, in spite of sui generis legal protection in these countries.

Another point of view is that though there is no reason why such categories of rights may not apply to various expressions of traditional knowledge, there are several characteristics of traditional knowledge that create barriers to protection through the use of existing norms of TRIPs. The conventional type of intellectual property right is inadequate to protect traditional knowledge primarily because it is based on protection of individual property rights, whereas various forms of traditional

knowledge are collective in nature and characteristic-entirely different paradigm. This knowledge presents other difficulties in being recognized for the purpose of IP protection, even from the perspective of convention type of IP. The pre-requisites of intellectual property are that it must have non-obviousness and novelty etc. Traditional knowledge of the society or indigenous community may fall short of these requisites as traditional knowledge is often orally transmitted, developed over a period of time, evolves gradually by experience, research, study of so many people from so many generations, little by little by adding value to the existing level of knowledge in a span of centuries and finally comes out with the invention. Here time factor and individual factor are very important. It is difficult to prove at what point of time and by whom the ultimate invention occurred with the quality of novelty and to determine that it was non-obvious to the others especially when entire group or community is involved in it. As a matter of fact the present generations and society is not the inventers, they are just the bearers, holders or preservers of that great knowledge. Moreover, it does not actively endeavour to be 'novel' or distinct from nature or natural resource. This is an impediment for intellectual property claims. Unless a product is substantially different from what is found in nature and is thus the result of a 'non-obvious' human invention, the product or its knowledge cannot be considered as intellectual property. An invention that the one or some active bio-chemical products of plants can do wonders as natural medicines is somehow impossible to prove as novel invention. Moreover, there is no proof of prior 'existing knowledge' or 'prior art' which does not form part of the medicinal value of plant and to prove or disprove the present invention as a matter of novelty and non-obviousness becomes difficult due to this procedural requirements. There appears to be nothing. Moreover, on the 'new' or 'novel' criteria, the invention may fail because this knowledge is known to all members of the entire society or the community, may be even the outside world. The issue of 'non-obviousness' or 'inventive step' may also fail due to the reason that it is known and science has developed so much that any person (who have knowledge about it) knows it. Again to determine that there is novelty and inventive step, there have to have the existence of prior art. Without prior art how is it possible to prove that the so-called invention is novel and it is with an inventive step? That is why, the matter is a bit complicated to analyse these claims according to present internationally accepted standard criteria and procedural requirements. Apart from this, it is also difficult to prove that this is the invention of the community or the whole society. This is due to the reason that it was not an invention of the present generations. The fact remains that the holders of the existing knowledge is not the inventors of this traditional knowledge. But definitely, it is the invention, but not of present day society. Centuries before, it was invented by someone or a large group in the society. Then little by little, as because of social practice or tradition, the knowledge became the intellectual property of the society and through socialisation process, most of the people of the society were enlightened and educated about this knowledge. This knowledge evolved and developed over the centuries, little by little by the small contribution as addition of values from each succeeding generations through experiment, observation, study and research and finally came to this shape.

Now it has become the property of the society-no one is the owner but every one is the owner. Now, they are merely the holders of such knowledge and have possession of the knowledge as such. This knowledge is also not new or novel as such; it is the existing knowledge so far. So there are sufficient arguments also not to accept the traditional knowledge as novelty and non-obviousness as two basic requirements of invention for patent protection. Hence, it is suggested that new criteria and new procedural requirements must be adopted to give traditional knowledge a distinct category of intellectual property right.

Rajshree Chandra is of the opinion that "the TRIPs regime has at least two far reaching consequences in relation to the knowledge and resources of indigenous people. First, the agreement greatly altered how biodiversity was to be used and controlled. There was a shift in the ways and norms according to which nature was intercepted. Paul Rabinow remarks, 'Biotechnology's hallmark lies in its potential to get away from nature, to construct artificial conditions in which specific variable can be known in such a way that they can be manipulated. This knowledge then forms the basis for remaking nature according to norms'. By conferring a property right to the biotechnological innovators, the tacit rights that local communities had over generations to their local environment and resources were transferred to a legal right that bio-prospectors could hold by freely accessing unprotected commons. Secondly, the agreement greatly exacerbated the debate already raging between developed and developing countries over trade-related issues. It brought to fore the assumptions behind intellectual property rights and the dangers that it held for the food and ecological security of developing nations. Above all, it brought into focus the issue of the knowledge rights of indigenous people and the inquiry or absence of benefit-sharing mechanisms."[19] She continues to say that "ii is often argued that the rights of the indigenous people are being violated when their access to resources and benefits from their contributions to science and technology are ignored. This has been attributed, in a large measure, to the intellectual property protection sanctioned by the TRIPs regime which recognises and rewards innovative activity that is 'novel', 'non-obvious' and usually of some benefit to the society. It has been argued that what is regarded as innovation ignores the form and the kind of innovative activity undertaken by the traditional and indigenous communities. In doing so, the TRIPs regime becomes an international institution that fosters the intellectual dominance of the WMS and fails to acknowledge and grant epistemic parity to global intellectual pluralism. This has become the background for varying claims: for the knowledge rights of the indigenous communities to be given parity within the TRIPs framework; for the protection of traditional knowledge systems; for an end to bio-piracy and the one-way genetic resource flow (reminiscent of the mercantile capitalist era); for the development of equitable benefit-sharing mechanisms; for community property rights; These are the all rights which emanate from the central claim of knowledge rights of

[19] Rajshree Chandra, "Knowledge as Property", in 'Indigenous Knowledge Rights', Oxford University Press, New Delhi, 2010, Page 289.

the indigenous/traditional people which are as much aspects of their socio-economic rights as rights to food or health."[20]

WTO has succeeded in making the IPR law static by limiting the scope of TRIPs for further expansion. This is due to the reason that definition of intellectual property rights includes only those IPR are accepted that are the outcomes of the negotiation in which several power equations became the driving force of the negotiation.

Society is not static. It is changing rapidly. Law is either a tool to initiate change or a mechanism to command the changes which are taking place for different reasons such as scientific and technological advancement or social enlightenment and consciousness. Law needs to keep pace with changing contours of time for accommodating the changes. If law fails to adopt and adapt the changes, it would lose its efficacy and purpose. This has happened in case of free trade regime and process of globalisation. It could not fulfil its purpose. There has been a successful attempt by WTO to confine IPR within particular limit. The Paris Convention 1884 had very few matters for the deliberation. With the changes of time, from the Berne convention onwards, it kept on expanding and took within its ambit more and more subjects. Now is the need to include newer subjects into the international IPR regime. This expansion of IPR regime is hindered by the developed countries. All attempts by the bio-diversity and traditional knowledge rich developing countries to either amend the present provisions or include some other newer rights in the present legal framework is thwarted by them.

There are different systems of recognition of IPR in different countries in the world. A true globalisation process must accommodate at least some of the core concerns applicable to both developed and developing countries otherwise. TRIPs or WTO become the instrument of exploitation by the developed countries. The term itself denotes or conveys that any right resulting from intellectual activities of mind and brain through cognitive processes in the industrial, commercial, scientific, literary or artistic fields have to be considered as 'intellectual property'. Thus it is clear that "intellectual property" is a broad concept and can include products and processes not forming part of the existing categories of intellectual property, if it is the outcome of intellectual processes as just mentioned. In that line of thinking, not only the invention fulfilling the criterion of novelty or non-obviousness, but also the knowledge once invented by individual or a group (centuries before through research, experimentation and through other ways), its preservation, conservation, adaptation, value addition, applying for the benefit of human beings including other living creatures and for all other human activities, keeping the traditional knowledge lively, educating others and transmitting the knowledge in toto to the next generations through the socialisation process need tremendous intellectual exercise (might be something less than invention). It has to be considered as intellectual property. Hence this traditional

[20] Ibid, Page 280.

knowledge of the holding community or the society in general is not anything less than intellectual property. Non-acceptance of this is really disgusting from the part of TRIPS and by no stretch of common sense TRIPs rigid stand can be justified.

Dr. Vandana Shiva says that "western reductionist method of study and analysis basically isolates chemicals and genes from the biological resources. Then this act of isolation is considered as an act of invention and creation intellectually and materially. But actually the indigenous knowledge gives the information and the leads for useful traits in biological organisms. Intellectually, the innovation has already been an integral part of indigenous knowledge systems. Materially, the medicinal properties for which the patent has been claimed already exist in nature. Hence how the act of isolation and separation can be claimed as invention? Treating these acts as acts of 'creation' and 'invention' is rooted in the philosophical assumptions of the Western industrialised society which defines non-Western cultures as inferior to the industrial west and perceives nature as inert and dead matter. The creativity of both nature and other cultures is negated and denied. "The legal regimes of IPRs have been universalised through TRIPs and WTO is restricted to Western IPR systems reflecting the interest of the dominant economic systems of the West-MNCs."[21]

Invention is of two types- original invention and non-original invention. There are patents, based on modern research which may have invented a new medicinal property which is invented for the first time in a plant and as such is novel and non-obvious. But the real concern is about the patents for non-original inventions in the traditional knowledge systems of the developing world. There are two systems of processes of invention. The former is formal and the latter is informal, that has evolved over time. Though as a usual practice, formal system of innovation gets legal recognition just to ensure clarity and specificity, but it cannot undermine the significance and contributions of informal systems of innovation to the world. There are enough of innovations which have already taken place, are taking place and would take place in future in an informal way. Many societies in the third world have nurtured and refined systems of knowledge of their own, relating to as diverse domains as geology, ecology, botany, agriculture, physiology and medicine. These informal innovators have, therefore, generated a rich store of traditional knowledge in those countries. This informal system of innovation has some similarity with common law concept. According to common law practice, law is either updated or a new law is added to the existing legal framework most of the time, without a formal process of legislation. It is a system where customary practices are valued and have the force of law. Traditional knowledge of medicinal plants is also customary in nature. That is why, it is quite surprising that U.K or U.S.A and other common law countries do not recognise the informal system of innovation, in TRIPs, in different areas including traditional knowledge of medicinal plants, by not taking them into account as part of

[21] Vandana Shiva, "Patents: Myths and Realities", in 'Bio-Piracy', Penguin Book s, New Delhi, 2001, Page 51.

prior art. Non-recognition of informal innovation of traditional knowledge is the fact of TRIPS, even accepted by common law countries, where the legal system is substantially informal and based on custom. This goes against the basic tenets of common law principle. Moreover, it is absolutely irrational if prior art includes only formal system of documented knowledge and exclude informal knowledge. In India and in other third world developing countries, patent law recognises informal and non-documented knowledge as part of prior art. As Article 27.3(b) prescribes a review of itself with regard to the optional exceptions to patentability, commencing in 1999, the review of Article 27.3(b) is an opportunity to pursue a dialogue about recognition and reward for traditional knowledge. This process of review should be initiated and completed immediately without wasting any more time.

There is also a similar observation of Prof. N.S.Gopalakrishnan, a renowned professor of IPR, "One of the crucial issues that came up for consideration in these agreements was the question of how to deal with 'knowledge'. It is needless to emphasize the role played by the transnational corporations during the last two decades in commercialization of knowledge in the name of intellectual property rights. In this process they disregarded the traditional knowledge systems, destroyed the existing knowledge systems, culture and practices and tried to homogenize the newly generated knowledge for commercial gains. They deliberately and constantly undermined the knowledge and culture of the traditional and indigenous people. These were considered by them as common property for exploitation. On the contrary, the results based on their exploitation of the 'common knowledge' are considered as private property for further exploitation. These big corporations thus become the owners of the new knowledge. They use it exclusively with profit motive and in the process the majority of humankind is kept outside the benefit of the new knowledge"[22]. In the area of this type of non-original invention-where it involves products and processes based on traditional knowledge, the present international patent system and the system of the follower countries shed light on the limitation of preventing the existing traditional knowledge of the genetic resources. It is very nicely explained by Prof. N.S.Gopalakrishnan: "The information given by the holders of the knowledge, acts as a lead for developing the new product. In this sense there is effective interaction between holders of two knowledge systems for the development of the new product to claim patent protection. It is true that in some cases the new product may be different from the one practiced by the community. But the important factor is that it is the basic information provided by the community that enabled the modern scientist to develop the new product. It is the sharing of this information that entitled the community the right to claim benefit deriving out of the patent system utilizing their knowledge base. In this sense the traditional knowledge holder act, in a

[22]Dr. Darrell Posey, "Intellectual Property Rights-An Indigenous Affair", *Anthropology Today* (August 1990) as referred by Prof. N.S Gopalakrishnan in Diversity Related Intellectual Property Rights: GATT Final Act, The Convention on Biological Diversity and the Challenges, Academy Law Review, Vol. XVIII 1994, Page 263.

limited sense, as a 'co-inventor' of the new product sharing his knowledge though in a crude form viewed from the perspective of the modern science and patent system."[23] Analysing these, in no uncertain terms, it can be said that TRIPs does not protect already existing traditional or individual knowledge base. Unless existing knowledge gets recognition and effective protection by new TRIPS, the business houses will consider it as common property-free for all and by alteration by their modern technological advantages from others, will convert it into private property without any benefit being given to the holders of such knowledge. The holders of traditional knowledge will also have no right to prevent its exploitation or claim any benefit deriving out of it in the absence of legal rights. Lord Denning's famous saying that law is an ass has come true in case of TRIPs.

That was very clever decision to keep the existing knowledge into public domain and use it freely by the technologically advanced developed countries. It was a very innovative idea of exploitation- a clear example of intellectual dishonesty. With their technological advancement and state of the art, they can derive something innovative or so called new thing from the maximum use of the existing knowledge of all the technologically disadvantaged developing and under-developed countries, which the latter countries will not be able to do even if they have legal right to use the existing knowledge of whole world. Every country is not on equal standing on knowledge, technological know-how and state of the art and most importantly investment of money for research and development. Additionally, the most intelligent brains of those countries have been purchased by developed nations and they are working the research institutes and big corporations in developed countries. So this public domain concept is a farce and practices latent inequality in the entire TRIPs legal framework and discriminates against developing and under-developed bio-rich nations.

The concern in this regard is conspicuous inasmuch as the freedom of the developing countries to legislate independently for intellectual property protection is taken away by making it obligatory to follow international standards in this regard. In this context the provisions relating to Trade Related Intellectual Property Rights (TRIPS) in the GATT final Act in the recently concluded GATT negotiations assume importance. These provisions make it obligatory on the part of contracting parties to change their intellectual property laws in accordance with the GATT Final Act (now WTO). The TRIPs agreement in the GATT Final Act is a concerted and calculated effort of the holders of intellectual property to declare them as private rights. It is also an attempt to internationalize the intellectual property regime for the benefit of the owners of intellectual property who are global traders. The uniform norms they wanted to enforce on all the trading partners will enable them to keep weak nations

[23] Prof. N.S.Gopalakrishnan, "TRIPS and Protection of Traditional Knowledge of Genetic Resources: New Challenges to the Patent System", European Intellectual Property Review, January, 2005, Page 11.

always technology-dependent and stall the efforts of some of these nations to become self-reliant in many areas.[24]

It is mandatory on the part of contracting parties to GATT (now WTO) to provide patent protection to any invention, whether product or process, in all fields of technology. This is available only to inventions which are new, involve an inventive step, and are capable of industrial application. It is also clear that patents are available and the rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced. The impact of the provision is far-reaching. It takes away the right of sovereign states to decide the patentable subject matter within their territory according to their social, economic and industrial needs. It also takes away the rights of the state to discriminate the inventions on the ground that it is not locally produced for the benefit of the country. It also denies the right of the state to have different standards on novelty and utility depending upon their industrial growth. These provisions are very important especially in the field of new technologies like bio-technology.[25]
According to the provisions of the TRIPs agreement certain products of genetic material are completely exempted from the protection of intellectual property rights while some other products can be protected through a *sui generis* system. But the parties are bound to give patent protection to certain other products. Thus according to Article 27(3)(b) parties must give patent to 'micro-organisms' and 'non-biological and micro-biological processes' for the product of plants and animals. Similarly parties are bound to give patent or effective *sui generis* protection or any combination thereof for plant varieties. What is kept out of protection according to the provision is only 'animals' and 'biological process for the production of plants and animals'. Thus it is clear that only very limited products and processes produced from genetic materials are kept outside the domain of one or the other form of intellectual property protection.[26]

Excluding these, there is also false invention. The product or the process not only derives or draws upon but also consist of the traditional knowledge of the subject matter. In these cases patent is obtained by suppressing the 'prior art' or not disclosing the documents. There are thousands and thousands of patents have been obtained in various countries in this way.

TRIPs is not based on true democratic principles while honouring the sovereignty of the countries and protecting equal rights of them. This is the main reason for the negation of traditional knowledge protection. According to Vandana Shiva the TRIPs is based on the concept of bio-imperialism-the belief that only the knowledge and

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[24] Prof. N.S. Gopalakrishnan, "Diversity Related Intellectual Property Rights: GATT Final Act, the Convention on Biological Diversity and The Challenges", Academy Law Review, Vol. XVIII 1994 Page 270.
[25] Ibid, Page 271.
[26] Ibid, Page 271-272.

production of Western corporations need protection. If unchallenged and not amended, TRIPS will become an instrument of for displacing and dispensing with the knowledge, resources and rights of Third world peoples, especially those who depend on bio-diversity for their livelihoods and who are the original owners and innovators in the utilisation of bio-diversity.[27] The consequences of TRIPs substantially vindicated her concerns. In addition to that concerns, she says that TRIPs is based on a highly restricted concept of innovation. The first restriction is the shift from common rights to private rights. The second restriction of IPRs is that they are recognised only when knowledge and innovation generate profits, not when they meet social needs.[28] Profits and capital accumulation are the only ends of creativity; social good is no longer recognised. By denying the creativity of nature and other cultures even when that creativity is exploited for commercial gain, IPRs becomes another name of intellectual theft and bio-piracy. Simultaneously, people's assertion of their customary and collective rights to knowledge and resources is turned into 'piracy' and 'theft'.[29]

CONVENTION ON BIOLOGICAL DIVERSITY-CBD

An important event happened when United Nations Conference on Environment and Development (UNCED), which met in Rio de Jeneiro in 1992 under the auspices of UNEP. To encourage the protection of biological diversity by national governments, Convention on Biological Diversity (CBD), an international legal binding treaty, was adopted there, to promote the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of benefits arising out of the utilization of genetic resources. Provisions on the respect and recognition of TK are a key element of the CBD, and important work is under way within the CBD framework to implement these
provisions. It is one of the international laws which deal with the traditional knowledge of biological resources as part of bio-diversity protection of this world. CBD is a very sincere and serious global initiative of United Nations Organisation-UNO.

DEFINING BIODIVERSITY[30]

"Biological diversity" means the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the

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[27] Vandana Shiva, "Biopiracy: The Plunder of Nature and Knowledge", in 'Biodiversity and People's Knowledge', RFSTE, New Delhi, 1997, Page 81.
[28] See, Article 27.1, TRIPs, to be considered an IPR, invention has to be capable of industrial application.
[29] Vandana Shiva, "Biopiracy: The Plunder of Nature and Knowledge", in 'Knowledge, Creativity and IPRs', RFSTE, New Delhi, 1997, Page 10.

[30] Article 2, CBD.

ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems. In general, the medicinal plants of India or elsewhere are species of bio-diversity.

BIOLOGICAL RESOURCES[31]

'Biological resources' includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity. It includes within its ambit the bio-chemical ingredients or components of plants.

PREAMBLE OF CBD

Being conscious about the intrinsic value and specifically the ecological, genetic, social, economic, scientific, educational, cultural, recreational and aesthetic values of biodiversity and the importance of it for evolution and for maintaining life sustaining systems of the biosphere, CBD affirms that the conservation of biological diversity is a common concern of humankind and reaffirms sovereign rights of the states over their own biological resources where States are responsible for conserving their biological diversity and for using their biological resources in a sustainable manner because it is determined to conserve and sustainably use biological diversity for the benefit of present and future generations. This Convention is really concerned as biological diversity is being significantly reduced by certain human activities and things that it is vital to anticipate, prevent and attack the causes of significant reduction or loss of biological diversity and aware the general lack of information and knowledge regarding biological diversity and of the urgent need to develop scientific, technical and institutional capacities to provide the basic understanding upon which to plan and implement appropriate measures. Specifically about traditional knowledge CBD recognizes the close and traditional dependence of many indigenous and local communities embodying traditional lifestyles on biological resources, and the desirability of sharing equitably benefits arising from the use of traditional knowledge, innovations and practices relevant to the conservation of biological diversity and the sustainable use of its components. For the conservation and sustainable use of biodiversity, this convention gives stress on the importance and the need to promote, international, regional and global cooperation among States, intergovernmental organizations and NGOs. It expects that ultimately, the conservation and sustainable use of biological diversity will strengthen friendly relations among States and contribute to peace for humankind. So CBD desires to enhance and complement existing international arrangements for the conservation of biological diversity and sustainable use of its components.

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[31] Article 2, CBD.

OBJECTIVES OF CBD[32]

The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.

PRINCIPLE[33]

States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.

COOPERATION[34]

Each Contracting Party shall, as far as possible and as appropriate, cooperate with other Contracting Parties, directly or, where appropriate, through competent international organizations, in respect of areas beyond national jurisdiction and on other matters of mutual interest, for the conservation and sustainable use of biological diversity.

IN-SITU CONSERVATION[35]

Each Contracting Party shall, as far as possible and as appropriate: (a) Establish a system of protected areas or areas where special measures need to be taken to conserve biological diversity; (b) Develop, where necessary, guidelines for the selection, establishment and management of protected areas or areas where special measures need to be taken to conserve biological diversity; (c) Regulate or manage biological resources important for the conservation of biological diversity whether within or outside protected areas, with a view to ensuring their conservation and sustainable use; (d) Promote the protection of ecosystems, natural habitats and the maintenance of viable populations of species in natural surroundings; (e) Promote environmentally sound and sustainable development in areas adjacent to protected areas with a view to furthering protection of these areas; (f) Rehabilitate and restore degraded ecosystems and promote the recovery of threatened species, inter alia, through the development and implementation of plans or other management

[32]Objectives, Convention on Bio-logical Diversity, 1994, Article 1, CBD.
[33] Article 3, CBD.
[34] Article 5, CBD.
[35] Article 8, CBD.

strategies; (g) Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health; (h) Prevent the introduction of, control or eradicate those alien species which threaten ecosystems, habitats or species; (i) Endeavour to provide the conditions needed for compatibility between present uses and the conservation of biological diversity and the sustainable use of its components; (j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices; (k) Develop or maintain necessary legislation and/or other regulatory provisions for the protection of threatened species and populations; (l) Where a significant adverse effect on biological diversity has been determined pursuant to Article 7, regulate or manage the relevant processes and categories of activities; and (m) Cooperate in providing financial and other support for in-situ conservation outlined in subparagraphs (a) to (l) above, particularly to developing countries.

EX-SITU CONSERVATION[36]

Each Contracting Party shall, as far as possible and as appropriate, and predominantly for the purpose of complementing in-situ measures: (a) Adopt measures for the ex-situ conservation of components of biological diversity, preferably in the country of origin of such components; (b) Establish and maintain facilities for ex-situ conservation of and research on plants, animals and micro- organisms, preferably in the country of origin of genetic resources; (c) Adopt measures for the recovery and rehabilitation of threatened species and for their reintroduction into their natural habitats under appropriate conditions; (d) Regulate and manage collection of biological resources from natural habitats for ex-situ conservation purposes so as not to threaten ecosystems and in-situ populations of species, except where special temporary ex-situ measures are required under subparagraph (c) above; and (e) Cooperate in providing financial and other support for ex-situ conservation outlined in subparagraphs (a) to (d) above and in the establishment and maintenance of ex- situ conservation facilities in developing countries.

SUSTAINABLE USE OF COMPONENTS OF BILOGICAL DIVERSITY[37]

Each Contracting Party shall, as far as possible and as appropriate:

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[36] Article 9, CBD.
[37] Article 10, CBD.

(a) Integrate consideration of the conservation and sustainable use of biological resources into national decision-making; (b) Adopt measures relating to the use of biological resources to avoid or minimize adverse impacts on biological diversity; (c) Protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements; (d) Support local populations to develop and implement remedial action in degraded areas where biological diversity has been reduced; and
(e) Encourage cooperation between its governmental authorities and its private sector in developing methods for sustainable use of biological resources.

ACCESS TO GENETIC RESOURSES[38]

1. Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation. 2. Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention. 3. For the purpose of this Convention, the genetic resources being provided by a Contracting Party, as referred to in this Article and Articles 16 and 19, are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention. 4. Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article. 5. Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party. 6. Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties. 7. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.

PROTOCOL ON CBD-SOME REFLECTIONS[39]

There is a new development regarding CBD. A protocol is going to be implemented. The **Nagoya Protocol** on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilisation to the Convention on Biological

[38] Article 15, CBD.
[39] Available at http://www.wipo.int/wipolex/en/other_treaties/text.jsp?doe_id=152423&file_id=202956. Visited 6th July 2011 at 7.21 PM.

Diversity has come up. This Protocol shall be open to the State Parties and regional economic integration organizations to the Convention for ratification through signatures at the UNO from 2 February 2011 to 1 February 2012. This Protocol shall enter into force on the 19th day after the submission of the fiftieth instrument of ratification, acceptance, approval or accession by the States or regional economic integration organizations to the Convention. The date of enforceability of this Protocol on the above mentioned States or regional economic integration organizations those ratify, accept or approve this Protocol or accede, shall be decided accordingly either counting the date of its ratification etc or in general of the fiftieth ratification etc.

On certain twenty-six issues[40](some of them have been cited) there is or has to be an agreement of all the joining countries to follow the protocol- the system of rules and acceptable behaviour and thereby by committing all of them to the achievement of objectives of this formal agreement. These are essentially very important for the fulfilment of the objectives of this protocol where TK is an inalienable part of CBD. At the outset the protocol recalls that the fair and equitable sharing of benefits arising from the utilization of genetic resources is one of three core objectives of the Convention it recognises that this Protocol pursues the implementation of this objective within the Convention. It reaffirms the sovereign rights of States over their natural resources and according to the provisions of the Convention. It also acknowledges the potential role of access and benefit-sharing to contribute to the conservation and sustainable use of biological diversity, poverty eradication and environmental sustainability and thereby contributing to achieving the Millennium Development Goals. It further gives recognition of the importance of promoting equity and fairness in negotiation of mutually agreed terms between providers and users of genetic resources and innovative solution is required to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in trans-boundary situations or for which it is not possible to grant or obtain prior informed consent. This protocol recognises another the important subject i.e., providing legal certainty with respect to access to genetic resources and the fair and equitable sharing of benefits arising from their utilization and that international instruments related to access and benefit-sharing should be mutually supportive with a view to achieving the objectives of the Convention. By recalling the relevance of Article 8(j) of the Convention, it takes the note that the interrelationship between genetic resources and traditional knowledge, their inseparable nature for indigenous and local communities, the importance of the traditional knowledge for the conservation of biological diversity and the sustainable use of its components, and for the sustainable livelihoods of these communities. Another important thing is that it recognises the diversity of circumstances in which traditional knowledge associated with genetic resources is held or owned by indigenous and local communities and further recognises the unique circumstances where traditional knowledge associated with genetic resources is held

[40] See the first part of Nagoya Protocol.

in countries, which may be oral, documented or in other forms, reflecting a rich cultural heritage relevant for conservation and sustainable use of biological diversity.

Article 1 sets the objectives of Nagoya Protocol. These are: the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components. On its scope Article 3 of the protocol says apart from general genetic resources that this protocol shall also apply to traditional knowledge associated with genetic resources within and to the benefits arising from the utilization of such knowledge. Article 4 is on the relationship with other international agreements and instruments. Among other things it says that the provisions of this Protocol shall not affect the rights and obligations of any Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity and the Protocol shall be implemented in a mutually supportive manner with other international instruments relevant to this Protocol. Article 5 deals with fair and equitable benefit-sharing. It says that the benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources, that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention, which will be upon mutually agreed terms etc. Article 6 is about the method of access to genetic resources in general. Article 7 is especially for the access to traditional knowledge associated with genetic resources It is: In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that traditional knowledge associated with genetic resources that is held by indigenous and local communities is accessed with the prior and informed consent or approval and involvement of these indigenous and local communities and on the mutually agreed terms. Another important issue Article 10 touches upon. It is the global multilateral benefit-sharing mechanism which states that the Parties shall consider the need for and modalities of a global multilateral benefit-sharing mechanism to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in trans-boundary situations or for which it is not possible to grant or obtain prior informed consent. While talking about another aspect of TK associated with genetic resources, Article 12 says apart from other matters that on implementing their obligations under this Protocol, Parties shall in accordance with domestic law take into consideration indigenous and local communities' customary laws, community protocols and procedures, as applicable, with respect to traditional knowledge associated with genetic resources and as far as possible, not restrict the customary use and exchange of genetic resources and associated traditional knowledge within and amongst indigenous and local communities. Article 15 mandates that the compliance with the domestic legislation or regularity requirements

on access and benefit-sharing in general. Article 16 directs the compliance with domestic legislation or regulatory requirements on access and benefit-sharing for traditional knowledge associated with genetic resources. Mainly it says that each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures, as appropriate, to provide that traditional knowledge associated with genetic resources utilized within their jurisdiction has been accessed in accordance with prior informed consent or approval and involvement of indigenous and local communities and that mutually agreed terms have been established, as required by domestic access and benefit-sharing legislation or regulatory requirements of the other Party where such indigenous and local communities are located. Article 17 makes provision for the monitoring of the utilisation of genetic resources. Article 21 emphasises the awareness-raising by advising that each Party shall take various types of measures to raise awareness of the importance of genetic resources and traditional knowledge associated with genetic resources, and related access and benefit-sharing issues. There is a provision suggesting the monetary and non-monetary benefits. These are:1. Monetary benefits may include, but not be limited to: (a) Access fees/fee per sample collected or otherwise acquired; (b) Up-front payments; (c) Milestone payments; (d) Payment of royalties; (e) Licence fees in case of commercialization; (f) Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity; (g) Salaries and preferential terms where mutually agreed; (h) Research funding; (i) Joint ventures; (j) Joint ownership of relevant intellectual property rights. 2. Non-monetary benefits may include, but not be limited to: (a) Sharing of research and development results; (b) Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the Party providing genetic resources; (c) Participation in product development; (d) Collaboration, cooperation and contribution in education and training; (e) Admittance to *ex situ* facilities of genetic resources and to databases; (f) Transfer to the provider of the genetic resources of knowledge and technology under fair and most favourable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity; (g)Strengthening capacities for technology transfer; (h) Institutional capacity-building; (i)Human and material resources to strengthen the capacities for the administration and enforcement of access regulations; (j) Training related to genetic resources with the full participation of countries providing genetic resources, and where possible, in such countries; (k) Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies; (l) Contributions to the local economy; (m) Research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in the Party providing genetic resources; (n)Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities; (o) Food and livelihood security benefits; (p) Social recognition; (q)Joint ownership of relevant intellectual property rights.

ANALYSIS OF CONVENTION ON BIOLOGICAL DIVERSITY

It has to be kept in mind that aim of CBD is biological diversity protection, where traditional knowledge associated with medicinal plants is part of it. CBD for the first time explicitly recognises the importance of traditional knowledge and the rights of the holders of such knowledge. It has accommodated the various longstanding demands of the bio-diversity rich countries to protect the plants and biological resources from biopiracy. The Convention on Biological Diversity (CBD) is a landmark in the environment and development field, as it takes for the first time a comprehensive rather than a sectoral approach for the protection of Earth's biodiversity. The concept of 'protection' in CBD is multifaceted and rather comprehensive in its approach. Simultaneously, this convention has all the potentialities to protect medicinal plants and related traditional knowledge within its framework which can be exploited to the maximum possible advantage. Biodiversity convention has also proved to be one of the liveliest forums for the issues concerning traditional knowledge partly because it is a near universal treaty and partly because it is much more open than other forums. "CBD has three main objectives, (i) conserving biological diversity, (ii) using biological diversity in a sustainable fashion and (iii) sharing the benefits of biological diversity fairly and equitably."[41] India became a party to this international treaty in 1994.

CBD is a major international convention of UNO that for the first time that settles a longstanding ownership disputes over the biological diversities. It fundamentally conceptualises to whom biological diversity belongs. CBD recognises community knowledge; rights of indigenous cultures to preserve and protect their knowledge and resources assign the ownership of biodiversity of indigenous communities albeit through the State. It means that it also recognises that Nation States have sovereign rights over their biological resources, and that the access and use of those resources should be determined by appropriate national legislations. With this legal recognition of sovereign rights over the biological resources, now the States have acquired recognition of the legal rights over huge numbers of biological resources which are not the biological resources of the indigenous communities. These are the properties of the society in general in a country. With this recognition, Indian medicinal plants and its traditional knowledge protection get an encouraging and a very positive assertion. *Historically, biological resources were part of the 'global commons' based on the premise that they were the common heritage of mankind. The moral position taken by the United Nations FAO buttressed this position stating that, 'The major plants of the world are not owned by any one people but are rather quite literally a part of our human heritage of the past' This means, in other words, that plant genetic resources were free goods which entails only the cost of collection. Free availability mandated unrestricted exchange of plant germ-plasms among plant breeders and other scientists. The norm of free exchange had been sufficient to maintain the*

[41] Environment Audit Report, Report No. 17 of 2010-2011.

relatively free international flow of plant genetic material stored in the gene banks across the world. The notion of state sovereignty over biological resources changed this. CBD might have had in mind the historical asymmetry in the flow of germ-plasms, which was largely uni-directional from the South to the North, in vesting states with an opportunity to regulate access to plant resources and to deny that access if they considered to it to be inimical to their national interests. State ownership of biological resources re-conceptualised these resources, and the knowledge embedded within them, as something that belonged to an entity (in the case of nation states) or to people (in the case of indigenous people or private owners). The vary language of ownership, property and hence compensation that the CBD introduced in relation to biological resources was essential to the emergence of both the notion of intellectual property rights in biological resources as well as to the emergence of the debate on the rights that indigenous people pressed-rights to, what now considered, 'their resources' and ' their knowledge'.[42]

The convention suggests two types of conservation of biological diversity. The former is in-situ conservation. It means the preservation in the original and natural place and environment of those particular plants instead of being moved to another place. According to Article 8 (j), this includes respect, preservation and maintenance of knowledge, innovations and practices of indigenous and local communities, embodying traditional lifestyles relevant for the conservation and sustainable use of those medicinal plants, meeting the demands of the present generations without compromising the demands of the future generations and promote their wider application with the approval and involvement of the holders of such knowledge and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices. This is a very significant approach as CBD provides for the conservation of biodiversity with its sustainable utilization. Another type of conservation is ex-situ conservation. It means that the preservation in a place outside of the natural habitat, by creating such atmosphere which are congenial for those medicinal plants. The resolutions of CBD is to a great extent comprehensive; because according to CBD, the conservation includes preservation, sustainable use of the resources, commercialisation and benefit sharing with the owners if is used commercially etc.

One of the important recommendations which in a way settled the disputes about the ownership issue of the biological resources is Article 15 (a). This Article recognises the sovereign rights of States over their natural resources. The authority to determine access to genetic resources rests with the national governments subject to national legislation. It also recognizes the role of traditional knowledge of local and indigenous communities in the conservation, development and utilization of biological and genetic resources. Though it is a welcome step, the Article does not

[42] Rajshree Chandra, "Knowledge as Property", in 'Indigenous Knowledge Rights', Oxford University Press, New Delhi, 2010, P 287.

give ownership over biological resources and related traditional knowledge to the indigenous community. The States should not take control of the resources which are exclusively the traditional knowledge of some indigenous communities but only that are available out of the indigenous domain. There is mandate to the states to determine the terms of access to these resources. CBD is appreciable as it is in favour of the prior informed consent of the holders of the traditional knowledge to be taken by those who want to commercialise it.

One major weakness of CBD is that it leaves the protection of the traditional knowledge, innovations and practices in the absolute discretion of State parties. Some State parties to the CBD may in fact invoke Article 8 (j) not to undertake any measures that protect traditional knowledge as it is "subject to national legislation" and that national legislation might not live up to the expectations of the knowledge holders community and the very basic object of CBD would be frustrated.

Though there are reasons for criticism for its shortcomings, yet it can be said that it has very near to perfection theoretically. More or less it has everything to fight against biopiracy. The success of CBD depends on the agreement of all major countries of the world and its full implementation. But its actual success of CBD in protecting the traditional knowledge of the society or indigenous community as part of biological diversity protection would be judged by various ways. Firstly, whether it could lead to revocation of all the international and national patents which were granted on non-original inventions over which there were traditional knowledge about medicine or not. Secondly, after the full implementation of CBD, whether the granting of patents for non-original inventions over traditional knowledge of the medicinal value of the plants has been stopped totally or not. There is one more way to judge success of CBD, by assessing whether the developed countries which are the signatories of CBD i.e. USA or Germany (where there are incidents of biopiracy) are amending or altering their national laws to proscribe biopiracy or granting of patents where prior art is of written or oral description, according to CBD. Till date this has not been done. This raises the concern for the actual protection of traditional knowledge in those countries. The question has become pertinent due to the reason that though CBD allows the countries to enact laws to regulate access to genetic resources including medicinal plants within their geographical areas, but actually it has failed to stop the expropriation of medicinal plants and related traditional knowledge by countries, companies and research institutions from the North. Ironically, the most controversial cases of biopiracy occurred after CBD came into force in1992. So, unless it is newly enacted or present law is modified in these countries, there is no hope.

Moreover, CBD as an international law to protect biological diversity which implies the protection of traditional knowledge of the medicinal plants is coming in the way of TRIPs. The purpose of the two instruments which have such profound impact on traditional knowledge is very different. TRIPs is an instrument for trade and profit

and CBD for conservation and sustainability. Both exclude each other. This shakes the very basis of United Nations Organisation. The success of CBD would largely depend on its ability to exclude TRIPs provisions or reshaping TRIPs. Though the time is short but to overcome this weakness, it can take correctional measures to the wronged nations and societies while recognising equality of nations and respecting each nation's sovereignty. 'Might' cannot be the right in post modern civilisation in 21st century. This is one of the difficulties of international law when there is no unanimity of voice of the international community and exertion of pressure by the strong countries is a factor. This is one reason for the steady and smooth development of international law on a particular subject. Another reason is the conflict between fairness and unfairness, reasonableness or unreasonableness of a one set of international law and multi sets of international laws. This is against the basic tenets of democracy and principle of equality of Nation States. CBD itself is some steps forward in this direction to have a fair and reasonable international law, but due to these problems, it is not fulfilling its objectives and has become a mute spectator of international biopiracy.

CBD advices the cooperation among the countries for the conservation of bio-diversity, but in reality for traditional knowledge related bio-diversity, there is no effective cooperation as such. Some developed countries like U.S.A. have not ratified it. Let it be accepted by those countries which commercialise traditional knowledge unfairly and unethically. Let it be seen how much it can do for the protection of TK or be another example of failure. Time has not come to say anything encouraging. It is in a very nascent stage in the making of an internationally binding law. In India's legal context, though India has a Biodiversity Act to protect biodiversity especially traditional knowledge of genetic resources of the plants, enacted some years before, in furtherance of CBD, nothing substantial and positive outcome for the medicinal plants associated with TK is visible.

OBSERVATION OF PROF. N.S.GOPALAKRISHNAN ON CBD

The major concern of the Rio Summit was protection of the rights of people who are custodians of the bio-diversity on the one hand and the constant demand of technology-rich developed countries backed by big transnational corporations for access to the genetic material for research and commercial exploitation for profit.....Though there is no mention of protection of rights of the technology holders in the preamble, the objectives of the Convention attempt to make a balance between rights of owners of genetic material and that of the technology holders who could exploit the resources. It is clear from the objectives that while recognizing the

right over resources, there is an emphasis on the importance of protecting rights of the user of resources.[43]

The above provision in the convention is a clear understanding that contracting parties have the right to recognize and protect existing traditional knowledge system. This is beneficial to the gene rich south inasmuch as it enables the State to protect the rights of people over their existing knowledge system. These provisions also enable the State to empower the holders of traditional knowledge system with diversity-related intellectual property rights to bargain with the exploitation of their knowledge. Unless the state through legislation recognize and protect these traditional knowledge systems, the exploiters will consider this as common property and by alteration they will convert this into private property without any benefit being given to the holders of traditional knowledge systems. The holders of traditional knowledge will also have no right to prevent its exploitation or claim any benefit deriving out of it in the absence of legal rights.[44]

The significant outcome of the Convention is the recognition of the sovereign right of states over their natural resources including genetic materials. It is also quite pertinent to note that the right of the state to provide access to genetic resources rests with the national government and is subject to national legislation. While exercising the power under the Article, the state must recognize the ownership right of people over the bio-diversity which is the product of use of traditional knowledge systems. This is significant because access to genetic resources shall be based on prior informed consent of the provider of such resource on mutually agreed terms and the parties have to recognize the trade-related intellectual property rights on the new products and technologies. Thus it is clear that if the contracting parties in possession of genetic resources are not careful to protect the interest of the holders of these resources, there is every possibility of the technology rich nations exploiting the resources without returns. The consequence is the obligation to recognize the intellectual property rights in the new products developed out of the genetic materials. The government can also include safeguards regarding the ways through which one could find out whether the access to bio-diversity was based on 'prior informed consent'. A significant role can be played by government in this regard by incorporating appropriate terms and conditions into the agreement on transfer of genetic materials.[45]

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[43] Prof. N.S. Gopalakrishnan, "Diversity Related Intellectual Property Rights: GATT Final Act, the Convention on Biological Diversity and The Challenges", Academy Law Review, Vol. XVIII, 1994 Page 263.
[44] Ibid, Page 267-268.
[45] Ibid, 268-269.

WORLD INTELLECTUAL PROPERTY ORGANISATION (WIPO)

The World Intellectual Property Organization (WIPO) is a specialized agency of the United Nations[46]. It was the outcome of an agreement between UNO and WIPO. WIPO was formally created by the Convention Establishing the World Intellectual Property Organization, which entered into force on April 26, 1970. It was established with the objectives to promote the protection of intellectual property throughout the world through cooperation among States and, where appropriate, in collaboration with any other international organization and to ensure administrative cooperation among the Unions.[47] The Agreement marked a transition for WIPO from the mandate it inherited in 1967 from BIRPI[48]. WIPO expanded its role and further demonstrated the importance of intellectual property rights in the management of globalized trade in **1996** by entering into a cooperation agreement with the World Trade Organization (WTO). World Intellectual Property Organization of today-a dynamic entity with 184 member States, and with a mission and a mandate that are constantly growing. WIPO expanded its role and further demonstrated the importance of intellectual property rights in the management of globalized trade in 1996 by entering into a cooperation agreement with the World Trade Organization (WTO). WIPO administers 24 treaties (three of those jointly with other international organizations) and carries out a rich and varied program of work, through its member States. "The United Nations recognizes the World Intellectual Property Organization as a specialized agency and as being responsible for taking appropriate action in accordance with its basic instrument, treaties and agreements administered by it and inter *alia,* for promoting creative intellectual activity and for facilitating the transfer of technology related to industrial property to the developing countries in order to accelerate economic, social and cultural development, subject to the competence and responsibilities of the United Nations and its organs, particularly the UNCTD, the UNDP and the UNIDO as well as of the UNESCO and of other agencies within the United Nations system".[49]

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[46]Agreement between the United Nations and the World Intellectual Property Organization, in consideration of the provisions in Article 57 of the Charter of the United Nations and of Article 13, paragraph (1), of the Convention Establishing the World Intellectual Property Organization, the United Nations and the World Intellectual Property Organization. Available at http://www.wipo.int/treaties/en/agreement/index.html. Visited on 14the May, 2011 at 10.02 AM.

[47]Article 3, Convention Establishing the World intellectual Property Organization (Signed at Stockholm on July 14, 1967 and as amended on September 28, 1979). Available at http://www.wipo.int/treaties/en/convention/trtdocs_wo029.html. Visited on 14th May, 2011 at 10.18 AM.

[48] United International Bureaux for the Protection of Intellectual Property, which had been established in 1893 to administer the Berne Convention for the Protection of Literary and Artistic Works and the Paris Convention for the Protection of Industrial Property.

[49] Ibid, Article 1.

PREAMBLE[50]

Desiring to contribute to better understanding and co-operation among States for their mutual benefit on the basis of respect for their sovereignty and equality; Desiring, in order to encourage creative activity, to promote the protection of intellectual property throughout the world; Desiring to modernize and render more efficient the administration of the Unions established in the fields of the protection of industrial property and the protection of literary and artistic works, while fully respecting the independence of each of the Unions.

FUNCTIONS[51]

In order to attain the objectives described in Article 3, the Organization, through its appropriate organs, and subject to the competence of each of the Unions: (i) shall promote the development of measures designed to facilitate the efficient protection of intellectual property throughout the world and to harmonize national legislation in this field; (iii) may agree to assume, or participate in, the administration of any other international agreement designed to promote the protection of intellectual property; (iv) shall encourage the conclusion of international agreements designed to promote the protection of intellectual property; (v) shall offer its cooperation to States requesting legal–technical assistance in the field of intellectual property; (vi) shall assemble and disseminate information concerning the protection of intellectual property, carry out and promote studies in this field, and publish the results of such studies;

REVISED AND EXPANDED STRATEGIC GOALS

The revised and expanded Strategic Goals will provide the framework for WIPO's six year Medium Term Strategic Plan (2010 - 2015). These are:

- Balanced Evolution of the International Normative Framework for IP.
- Provision of Premier Global IP Services.
- Facilitating the Use of IP for Development.
- Coordination and Development of Global IP Infrastructure.
- World Reference Source for IP Information and Analysis.
- International Cooperation on Building Respect for IP.
- Addressing IP in Relation to Global Policy Issues.
- A Responsive Communications Interface between WIPO, its Member States and All Stakeholders.

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[50] Article 3, Convention Establishing the World intellectual Property Organization (Signed at Stockholm on July 14, 1967 and as amended on September 28, 1979). Available at http://www.wipo.int/treaties/en/convention/trtdocs_wo029.html. Visited on 14th May , 2011 at 10.18 AM.

[51] Article 4, Ibid.

- An Efficient Administrative and Financial Support Structure to Enable WIPO to Deliver its Programs.

THE PROTECTION OF TRADITIONAL KNOWLEDGE: POLICY OBJECTIVES[52]

In late 2000, the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore was established. The Committee has made substantial progress in addressing both policy and practical linkages between the IP system and the concerns of practitioners and custodians of traditional knowledge. Various studies have formed the basis for ongoing international policy debate and assisted in the development of practical tools. Drawing on this diverse experience, the Committee is moving towards an international understanding of the shared objectives and principles that should guide the protection of TK.[53]

REVISED PROVISIONS FOR THE PROTECTION OF TRADITIONAL KNOWLEDGE
POLICY OBJECTIVES AND CORE PRINCIPLES

I. POLICY OBJECTIVES
(i) Recognize the holistic nature of traditional knowledge, including its social, spiritual, economic, intellectual, educational and cultural importance.
(ii) Promote respect for traditional knowledge systems; for the dignity, cultural integrity and
intellectual and spiritual values of the traditional knowledge holders who conserve and maintain those systems.
(iii) Meet the actual needs of holders of traditional knowledge.
(iv) Promote conservation and preservation of traditional knowledge.
(v) Empower holders of traditional knowledge and acknowledge the distinctive nature of traditional knowledge systems.
(vi) Support traditional knowledge systems.
(vii) Contribute to safeguarding traditional knowledge.
(viii) Repress unfair and inequitable uses of traditional knowledge.
(ix) Operate consistently with relevant international agreements and processes
(x) Promote innovation and creativity.
(xi) Ensure prior informed consent and exchanges based on mutually agreed terms.
(xii) Promote the fair and equitable sharing of benefits arising from the use of traditional knowledge.

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[52]Recommendations of Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Seventeenth Session, Geneva, December 6 to 10, 2010.
[53] Available at http:// www.wipo.int/tk/en/tk/index.html. Visited on 15th June 2011 at 6.30 PM.

(xiii) Promote community development and legitimate trading activities.
(xiv) Preclude the grant of improper intellectual property rights to unauthorized parties.
(xv) Enhance transparency and mutual confidence in relations between traditional knowledge
holders on the one hand, and academic, commercial, educational, governmental and other users of traditional knowledge on the other, including by promoting adherence to ethical codes of conduct and the principles of free and prior informed consent.
(xvi) Complement protection of traditional cultural expressions.

CORE PRINCIPLES

II. GENERAL GUIDING PRINCIPLES
(a) Responsiveness to the needs and expectations of traditional knowledge holders.
(b) Recognition of rights.
(c) Effectiveness and accessibility of protection.
(d) Flexibility and comprehensiveness.
(e) Equity and benefit-sharing.
(f) Consistency with existing legal systems governing access to associated genetic resources.
(g) Respect for and cooperation with other international and regional instruments and processes.
(h) Respect for customary use and transmission of traditional knowledge.
(i) Recognition of the specific characteristics of traditional knowledge.
(j) Providing assistance to address the needs of traditional knowledge holders.

III. SUBSTANTIVE PRINCIPLES

1. Protection Against Misappropriation
2. Legal Form of Protection
3. General Scope of Subject Matter
4. Eligibility for Protection
5. Beneficiaries of Protection
6. Fair and Equitable Benefit-sharing and Recognition of Knowledge Holders
7. Principle of Prior Informed Consent
8. Exceptions and Limitations
9. Duration of Protection
10. Transitional Measures
11. Formalities
12. Consistency with the General Legal Framework
13. Administration and Enforcement of Protection
14. International and Regional Protection

POLICY OBJECTIVES

The protection of traditional knowledge should aim to:

Recognize value

recognize the holistic nature of traditional knowledge and its intrinsic value, including its social, spiritual, economic, intellectual, scientific, ecological, technological, commercial, educational and cultural value, and acknowledge that traditional knowledge systems are frameworks of ongoing innovation and distinctive intellectual and creative life that are fundamentally important for indigenous and local communities and have equal scientific value as other knowledge systems;

Promote respect

(ii) promote respect for traditional knowledge systems; for the dignity, cultural integrity and intellectual and spiritual values of the traditional knowledge holders who conserve, develop and maintain those systems; for the contribution which traditional knowledge has made in sustaining the livelihoods and identities of traditional knowledge holders; and for the contribution which traditional knowledge holders have made to the conservation of the environment conservation and sustainable use of biodiversity, to food security and sustainable agriculture, and to the progress of science and technology;

Meet the actual rights and needs of holders of traditional knowledge

(iii) be guided by the aspirations and expectations expressed directly by traditional knowledge holders, respect their rights as holders and custodians of traditional knowledge, contribute to their welfare and economic, cultural and social benefit and reward and recognize the value of the contribution made by them to their communities and to the progress of science and socially beneficial technology;

Promote conservation and preservation of traditional knowledge

(iv) promote and support the conservation and preservation of traditional knowledge by respecting, preserving, protecting and maintaining traditional knowledge systems and providing incentives to the custodians of those knowledge systems to maintain and safeguard their knowledge systems;

Empower holders of traditional knowledge and acknowledge the distinctive nature of traditional knowledge systems

(v) be undertaken in a manner that empowers traditional knowledge holders to protect their knowledge by fully acknowledging the distinctive nature of traditional knowledge systems and the need to tailor solutions that meet the distinctive nature of such systems, bearing in mind that such solutions should be balanced and equitable, should ensure that conventional intellectual property regimes operate in a manner supportive of the protection of traditional knowledge against misuse and misappropriation, and should effectively empower associated traditional knowledge holders to exercise due rights and authority over their own knowledge;

Support traditional knowledge systems

(vi) respect and facilitate the continuing customary use, development, exchange and transmission of traditional knowledge by and between traditional knowledge holders; and support and augment customary custodianship of knowledge and associated

genetic resources, and promote the continued development of traditional knowledge systems;

Contribute to safeguarding traditional knowledge

(vii) while recognizing the value of a vibrant public domain, contribute to the preservation and safeguarding of traditional knowledge and the appropriate balance of customary and other means for their development, preservation and transmission, and promote the conservation, maintenance, application and wider use of traditional knowledge, in accordance with relevant customary practices, norms, laws and understandings of traditional knowledge holders, for the primary and direct benefit of traditional knowledge holders in particular, and for the benefit of humanity in general on the basis of prior informed consent and the mutually agreed terms with the holders of that knowledge;

Repress unfair and inequitable uses or misappropriation and misuse

(viii) repress the misappropriation of traditional knowledge and other unfair commercial and non-commercial activities, recognizing the need to adapt approaches for the repression of misappropriation of traditional knowledge to national and local needs;

Respect for and cooperation with relevant international agreements and processes

(ix) take account of, and operate consistently with, other international and regional instruments and processes, in particular regimes that regulate access to and benefit-sharing from genetic resources which are associated with that traditional knowledge;

Promote innovation and creativity

(x) encourage, reward and protect tradition-based creativity and innovation and enhance the internal transmission of traditional knowledge within indigenous and traditional or local communities, including, subject to the consent of the traditional knowledge holders, by integrating such knowledge into educational initiatives among the communities, for the benefit of the holders and custodians of traditional knowledge;

Ensure prior informed consent and exchanges based on mutually agreed terms

(xi) ensure the use of traditional knowledge with prior informed consent and exchanges based on mutually agreed terms, in coordination with existing international and national regimes governing access to genetic resources;

Promote equitable benefit-sharing

(xii) promote the fair and equitable sharing and distribution of monetary and non-monetary benefits arising from the use of traditional knowledge, in consistency with other applicable international regimes, the principle of prior informed consent and including through [fair and equitable compensation in special cases where the individual holder is not identifiable or the knowledge has been disclosed;

Promote community development and legitimate trading activities

(xiii) if so desired by the holders of traditional knowledge, promote the use of traditional knowledge for community-based development, recognizing the rights of traditional and local communities over their knowledge; and promote the development of, and the expansion of marketing opportunities for, authentic products of traditional

knowledge and associated community industries, where traditional knowledge holders seek such development and opportunities consistent with their right to freely pursue economic development;

Preclude the grant of improper IP rights to unauthorized parties

(xiv) curtail the grant or exercise of improper intellectual property rights over traditional knowledge and associated genetic resources, by requiring the creation of digital libraries of publicly known traditional knowledge and associated genetic resources in particular, as a condition for the granting of patent rights, that patent applicants for inventions involving traditional knowledge and associated genetic resources disclose the source and country of origin of those resources, as well as evidence of prior informed consent and benefit-sharing conditions have been complied with in the country of origin;

Enhance transparency and mutual confidence

(xv) enhance certainty, transparency, mutual respect and understanding in relations between traditional knowledge holders on the one hand, and academic, commercial, educational, governmental and other users of traditional knowledge on the other, including by promoting adherence to ethical codes of conduct and the principles of free and prior informed consent;

Complement protection of traditional cultural expressions

(xvi) operate consistently with protection of traditional cultural expressions and expressions of folklore, respecting that for many traditional communities their knowledge and cultural expressions form an indivisible part of their holistic identity.

ANALYSIS OF WORLD INTELLECTUAL PROPERTY ORGANIZATION

WIPO's revised and expanded strategic goals are part of a comprehensive process of strategic realignment taking place within the organization. These new goals will enable WIPO to fulfil its mandate more effectively in response to a rapidly evolving external environment and to the urgent challenges for intellectual property in the 21st Century. Actually the main forum where traditional knowledge protection and preservation find importance is WIPO.

Following the adoption of TRIPs agreement, WIPO has sought to maintain its leading position with regard to the development of intellectual property rights regimes. WIPO has therefore attempted to move in the past decade towards areas which were not yet the subject of major intellectual property rights debates at the time of the negotiations for the TRIPS agreement. The protection of traditional knowledge through intellectual property rights gained sufficient importance by the end of 1990s for WIPO to pick it up. It has since attempted to establish itself as a pivotal player in the various attempts to redefine and develop traditional knowledge protection. This has been done through the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (ICIPGRTKF). The role of WIPO, as a specialised agency of UNO, is really positive and encouraging. The sincere and serious commitments of WIPO for the protection of traditional knowledge (which

includes traditional knowledge of medicinal plants) are reflected in its revised provisions for the protection of traditional knowledge-policy objectives and core principles which were just accepted in December 2010. It recognizes the holistic nature of traditional knowledge and its social, economic, cultural importance. It promotes respect for traditional knowledge systems and promotes the conservation and preservation of traditional knowledge. CBD acknowledges the distinctive nature of traditional knowledge systems. It seeks to repress unfair and inequitable uses of traditional knowledge. In case of use of traditional knowledge it wants to ensure prior informed consent and exchanges based on mutually agreed terms and promote the fair and equitable sharing of benefits arising from the use of traditional knowledge etc. So now there is a new initiative of WTO especially to the protection of traditional knowledge with the revised provisions for the protection of traditional knowledge-policy objectives and core principles.

The main problem with WIPO is that these goals, policy objectives and core principles really are model in nature are not binding and enforceable. Countries are free to follow it or not to follow it as there is no such sanction against any country. It is in its nascent stage and needs time to make its presence felt in the international arena as the mandate of UNO.

There is lack of acceptability and adaptability in the developed countries. Even if international society has huge expectations from WIPO, it fails miserably to live up to the expectations because of its weakness. Most of the strong economic countries in the world are not really interested in committing themselves according to WIPO recommendations. This lack of interest is reflected in their national legislations. If WIPO resolutions were to be followed by all countries in the world, it would be really successful in protecting medicinal plants and related traditional knowledge by stopping all types of bio-piracy. This is one of the reasons that the developed countries are reluctant to sign it and are delaying the process. These countries do not want to stop the present advantage of exploiting the gene-rich countries traditional knowledge to further their economic development.

WIPO also conflicts with TRIPs on the issue of TK. While TRIPS does not accept traditional knowledge protection but WIPO is serious about this and its concern is genuine. The attitude of WTO through TRIPS is somewhat negative and un-accommodative in nature. WTO is not in a position to budge from its original position owing to the pressure from the protection of the rights of developed countries. On the one hand is WTO and on the other is WIPO and CBD. At present there is no accepted doctrine of international law, through which this conflict can be sorted out. The jurists of international law should explore with some doctrines like doctrines of 'pith and substance' or 'occupied field' or 'reasonable classification' or 'doctrine of eclipse' of Indian Constitutional Law, to ensure harmonious balance between the two sets of international laws to bring parity and rationality, justness, fairness and reasonableness in the system.

There is no answer nor there is any doctrine before the international law jurists to solve this problem i.e. when two sets of international laws are conflicting, which one would prevail upon whom. What should be the criteria to judge the validity and legality of international law. The question is very vital due two the reason that WIPO is the specialised body of United Nations Organisations but TRIPs is not. WIPO is old initiative but TRIPs is new development. The international law jurists must develop some doctrines to meet this kind of serious dispute. After all might is not right. There has to be logic and some rationality. As USA does not want it for its own interest, that cannot be the justification for the international forum not to listen to the voice of the developing countries. The issue of conflict between WIPO and TRIPs and total rejection of traditional knowledge related intellectual property rights advocated by WIPO by TRIPs is more serious because WIPO is the specialised agency of UNO and has the mandate of UNO as such. It is the absolute denial of UNO itself by a trade agreement. How is it possible? This situation has been continuing. There has to be a final settlement of the issue as early as possible to make WIPO resolutions a success. The success of WIPO again would depend upon its success to start and complete the process of revocation of all the wrong and bio-pirated patents from each and every country all over the world and to compensate reasonably and fairly to the wronged parties either countries or societies. At the same time there has to be adequate punishments to those guilty parties-either persons or companies for blatant violation of laws according to the old or amended laws with retrospective effect and disregard of morality. Also it must take initiative to refund the huge profit earned by the bio-pirated patent holders to the holders of the traditional knowledge.

Moreover, while the CBD covers only traditional knowledge related to biodiversity, the WIPO proposal is much more wider in scope, but the CBD is more expansive in that it does not only prevent misappropriation but also seeks the positive strengthening of the traditional knowledge systems. In view of the overlap between CBD and WIPO efforts, the two need to cooperate and to address the overlap in their negotiations to prevent conflict between the various proposals and contradictory forms of protection. Any international ABS regime needs to build bridges between national, regional and international ABS law and policy and the customary law and practices of indigenous people and local communities and that requires an intricate web of alliances, legal obligations, enforcement mechanisms and new working practices and relationships.[54] So, it is expected that CBD and WIPO as both seek to strengthen the traditional knowledge system and related IPR should avoid conflict and overlap. CBD should not come in the way of WIPO and WIPO also must not come in the way of CBD. Otherwise there would be great confusion and again it might be exploited by the medicinal companies.

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[54] Brendan Tobin, "The Role of Customary Law and Practice of Traditional Knowledge Related to Biodiversity, Traditional Knowledge, Traditional Cultural Expressions and Intellectual Property Law in the Asia-Pacific Region", Edited by Christoph Antons, Wolters Kluwer, Netherlands, 2009.

Though WIPO has entered into an agreement with WTO and it is agreed upon that in the matters of industrial property, Paris Convention 1883 is to be followed. It was hoped that something positive might happen and there would be acknowledgment, recognition and protection of traditional knowledge by TRIPs. Article 1 of the Convention of the agreement between WIPO and TRIPs says that the protection of industrial property has as its object patents, utility models, industrial designs, trademarks, service marks, trade names, indications of source or appellations of origin, and the repression of unfair competition.[55] It also says that industrial property shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive industries and to all manufactured or natural products[56] and the patents shall include the various kinds of industrial patents recognized by the laws of the countries of the Union, such as patents of importation, patents of improvement, patents and certificates of addition, etc.[57] But from these three clauses it is clear that there is no such protection to the traditional knowledge of the medicinal plants explicitly from the agreed standpoints. The patent, its definition, its criteria or its exceptions do not show anything that these are not applicable to traditional knowledge of the medicinal plants of any country. The world has not moved any step forward to address traditional knowledge protection. It is standing where it was earlier. But there is something implied which can be explored to give a legal protection, which was not attempted so far. When the agreement says that industrial property shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive industries and to all manufactured or natural products and the patents shall include the various kinds of industrial patents recognized by the laws of the countries of the Union, traditional knowledge of medicinal plants as a unique and different type of intellectual property could have been included into that. But it was not pursued, explained, interpreted and finally forcing WTO to agree on it. Paris convention should be followed in letter and spirit. Paris convention is the basis of patent and some other intellectual property protection and WTO agrees to follow it. But actually WTO through TRIPs is not adopting its spirit and WIPO has surrendered to the WTO and TRIPs.

WIPO negotiators refine texts on traditional knowledge, genetic resources and traditional cultural expressions[58]

Progress in negotiations among WIPO member States in the WIPO's Intergovernmental Committee meeting on May 9-13, 2011, has resulted for the first

[55] Article 1, Clause 2, Establishment of the Union; Scope of Industrial Property.
[56] Article 1, Clause 3, Establishment of the Union; Scope of Industrial Property.
[57] Article 1, Clause 4, Establishment of the Union; Scope of Industrial Property.
[58] Available at http://wwwml.wipo.int/tk/en/news/2011/news_0011.ht. Visited on 17th May 2011 at 6.35 PM.

time in a single negotiating text on each of the items about its mandate-traditional knowledge and genetic resources.

IGC followed two Intersessional Working Groups (IWGs) that had addressed traditional knowledge and genetic resources, respectively. On traditional knowledge, the IWGs had developed a text of articles on the protection of traditional knowledge. It accepted this text as the basis for negotiations, and, after a discussion on it, broke into an informal, open-ended drafting group to reduce the number of options, especially where differences were largely a matter of drafting. The streamlined text developed by the drafting group was noted by the IGC and transmitted to the next IGC meeting on July 18-22, 2011. The text addresses questions such as a definition of traditional knowledge, beneficiaries of protection and the scope of rights to be granted in traditional knowledge and how they would be managed and enforced. The IWG on genetic resources also had developed a draft text on objectives and principles on the relationship between intellectual property and genetic resources. The IGC accepted it also as a basis for its ongoing work and an open-ended informal drafting group was established to refine and streamline the text, especially to reduce the number of options where these were largely a matter of drafting. These modified objectives and principles were accepted by IGC and transmitted to the next IGC meeting. These are: conditions for access to and use of genetic resources, the prevention of erroneous patents, information systems to enable patent offices to make proper decisions in granting patents, the relationship between intellectual property and other relevant international agreements and processes, and the role of the intellectual property system in relation to genetic resources.

Let it be seen what it could do for the protection of traditional knowledge and biological resources and how much time it does take. It is also to be seen how it could compensate or take correctional measures for the earlier wrongs and the delay of the process. To conclude the analysis of WIPO, it can be said that for traditional knowledge protection by the patent law, it has proved itself to be ineffective when it fails to make WTO through TRIPs, non-committal to follow the spirit of Paris Convention 1883. Secondly, traditional knowledge protection by the special recommendations is yet to be finalised, adopted and implemented.

EUROPEAN PATENT CONVENTION-EPC

The European Patent Convention (EPC) is a multilateral treaty instituting the European Patent Organisation and providing an autonomous legal system according to which European patents are granted under the European Patent Convention. However, after grant a European patent is not a unitary right, but a group of essentially independent nationally-enforceable, nationally-revocable patents—subject to central revocation. It has established a single, unified patent examination system for 31 European countries. This Convention was signed in Munich in 1973 and came into force on 1 June 1978. The EPC is separate from the European Union (EU), and its

membership is also different; The Convention is, as of October 2010, in force in 38 countries. The applicant now files his application at the European Patent Office at Munich or Hague, instead of at the 31 national patent offices. After grant however, he receives 31 national patents or less, if he chooses to limit the number of countries. Enforcement of his patent rights also is a purely national matter. The European Patent Office is responsible for granting patents under the European Patent Convention. It is a system of law, common to the Contracting States (currently 31 contracting States), for the grant of patents for invention. The patents granted by virtue of this Convention shall be called European patents. The European patent shall, in each of the Contracting States for which it is granted, have the effect of and be subject to the same conditions as a national patent granted by that State, unless otherwise provided in this Convention. A diplomatic conference was held in November 2000 in Munich to revise the Convention. The revised text, informally called the EPC 2000, entered into force on 13 December 2007.

Bio-piracy of Indian traditional knowledge of medicinal plants also occurred when European Patent Office granted patents to the individuals and many companies of different countries including of European countries. There are many numbers of patents on traditional knowledge associated medicines derived from the bio-chemical ingredients of the medicinal plants of India and other bio-rich countries by European Patent Office.

PREAMBLE

The Contracting States:
DESIRING to strengthen co-operation between the States of Europe in respect of the protection of inventions; DESIRING that such protection may be obtained in those States by a single procedure for the grant of patents and by the establishment of certain standard rules governing patents so granted,DESIRING, for this purpose, to conclude a Convention which establishes a European Patent Organisation and which constitutes a special agreement within the meaning of Article 19 of the Convention for the Protection of Industrial Property, signed in Paris on 20 March 1883 and last revised on 14 July 1967, and a regional patent treaty within the meaning of Article 45, paragraph 1, of the Patent Cooperation Treaty of 19 June 1970.

PATENTABLE INVENTIONS [59]

(1) European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step. (2) The following in particular shall not be regarded as inventions within the meaning of paragraph 1 (a) discoveries, scientific theories and mathematical methods; (b) aesthetic creations; (c) schemes, rules and methods for performing mental acts,

[59] Article 52, EPC.

playing games or doing business, and programs for computers; (d) presentations of information. (3) The provisions of paragraph 2 shall exclude patentability of the subject-matter or activities referred to in that provision only to the extent to which a European patent application or European patent relates to such subject-matter or activities as such. (4) Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

EXCEPTIONS TO PATENTABILITY [60]

European patents shall not be granted in respect of: (a) inventions the publication or exploitation of which would be contrary to "ordre public" or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States; (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.

NOVELTY [61]

(1) An invention shall be considered to be new if it does not form part of the state of the art. (2) The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application. (3) Additionally, the content of European patent applications as filed, of which the dates of filing are prior to the date referred to in paragraph 2 and which were published under Article 93 on or after that date, shall be considered as comprised in the state of the art. (4) Paragraph 3 shall be applied only in so far as a Contracting State designated in respect of the later application, was also designated in respect of the earlier application as published. (5) The provisions of paragraphs 1 to 4 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 52, paragraph 4, provided that its use for any method referred to in that paragraph is not comprised in the state of the art.

NON PREJUDICAL DISCLOSURES [62]

(1) For the application of Article 54 a disclosure of the invention shall not be taken into consideration if it occurred no earlier than six months preceding the filing of the European patent application and if it was due to, or in consequence of: (a) an evident

[60] Article 53, EPC.
[61] Article 54, EPC.
[62] Article 55, EPC.

abuse in relation to the applicant or his legal predecessor, or (b) the fact that the applicant or his legal predecessor has displayed the invention at an official, or officially recognised, international exhibition falling within the terms of the Convention on international exhibitions signed at Paris on 22 November 1928 and last revised on 30 November 1972. (2) In the case of paragraph 1(b), paragraph 1 shall apply only if the applicant states, when filing the European patent application that the invention has been so displayed and files a supporting certificate within the period and under the conditions laid down in the Implementing Regulations.

INVENTIVE STEP[63]

An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art. If the state of the art also includes documents within the meaning of Article 54, paragraph 3, these documents are not to be considered in deciding whether there has been an inventive step.

INDUSTRIAL APPLICATION [64]

An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.

GROUNDS FOR OPPOSITION [65]

Opposition may only be filed on the grounds that: (a) the subject-matter of the European patent is not patentable within the terms of Articles 52 to 57; (b) the European patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art; (c) the subject-matter of the European patent extends beyond the content of the application as filed, or, if the patent was granted on a divisional application or on a new application filed in accordance with Article 61, beyond the content of the earlier application as filed.

EXAMINATION OF THE OPPOSITION[66]

(1) If the opposition is admissible, the Opposition Division shall examine whether the grounds for opposition laid down in Article 100 prejudice the maintenance of the European patent.
(2) In the examination of the opposition, which shall be conducted in accordance with the provisions of the Implementing Regulations, the Opposition Division shall invite

[63] Article 56, EPC.
[64] Article 57, EPC.
[65] Article 100, EPC.
[66] Article 101, EPC.

the parties, as often as necessary, to file observations, within a period to be fixed by the Opposition Division, on communications from another party or issued by itself.

REVOCATION OF THE MAINTENANCE OF THE EUROPEAN PATENT[67]

(1) If the Opposition Division is of the opinion that the grounds for opposition mentioned in Article 100 prejudice the maintenance of the European patent, it shall revoke the patent. (2) If the Opposition Division is of the opinion that the grounds for opposition mentioned in Article 100 do not prejudice the maintenance of the patent unamended, it shall reject the opposition. (3) If the Opposition Division is of the opinion that, taking into consideration the amendments made by the proprietor of the patent during the opposition proceedings, the patent and the invention to which it relates meet the requirements of this Convention, it shall decide to maintain the patent as amended, provided that: (a) it is established, in accordance with the provisions of the Implementing Regulations, that the proprietor of the patent approves the text in which the Opposition Division intends to maintain the patent; (b) the fee for the printing of a new specification of the European patent is paid within the time limit prescribed in the Implementing Regulations. (4) If the fee for the printing of a new specification is not paid in due time, the patent shall be revoked. (5) Provision may be made in the Implementing Regulations for the proprietor of the patent to file a translation of any amended claims in the two official languages of the European Patent Office other than the language of the proceedings. If the translation has not been filed in due time, the patent shall be revoked.

ANALYSIS OF EUROPEAN PATENT CONVENTION

Evidence of foreign public knowledge or use is admissible in EPO patent proceedings and infringement procedure. The wide geographically neutral definition of prior art, enabled evidence of foreign public use in India to be used to revoke Grace's EPO patent on neem. Though it can be difficult for non-patented, non-published foreign or domestic prior art, to meet the strict standards of proof and credibility required by the EPO, the inclusive and non-discriminatory definition is clearly workable and in use in EPO decisions. This is one of the remarkable international achievements in the fight against biopiracy all over the world when EPC takes the resolution for their common patent law in the meaning of 'invention' that 'the state of the art' i.e. 'prior art' shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way. Though EPC was amended to make it at par with TRIPs agreement, it did not change or alter the definition of 'prior art" from its legal framework. This 'prior art' has become a potential tool for traditional knowledge protection in the EPC countries. Though, likely to Indian legal framework, traditional knowledge of plants about its medicinal value, is not specifically excluded from the patentability, but, the same thing can be achieved by

[67] Article 102, EPC.

the above criteria of 'state of the art' or 'prior art'. This is exactly just the long desired demand, to be included in TRIPs and subsequently in the national legal frameworks of most of the developed countries. This is exactly the demand over which the bio-diversity and traditional knowledge enriched developing countries including India and other world forums have been fighting sine long. Now the demand is fulfilled, even though not all over the world, but at least, in an important continent of this world. As a result, now it has become absolutely impossible to obtain patent on an invention of a plant's medicinal property over which there is a traditional knowledge either documented knowledge or non-documented oral knowledge of the society or indigenous community in any country of this world. Even if, patent is granted on false, wrong or misrepresentation of facts or by its suppression, it also can also be revoked subsequently. In spite of this protection, the hard reality is that EPO granted so many patents for the medicines from the plants and the processes to prepare them over which there is traditional knowledge-either documented or oral description is really shocking to the Indians. It means that EPO is not following its own set of laws and rules, while granting patents. There might be several reasons for this failure. It might be intentional. EPO itself acting in tandem with the so called non-original inventors and the biopirators have been doing this. EPC itself is involved in the biopiracy. EPC might do it due to the reason that there is no effective mechanism to search for the 'prior existing knowledge' or 'prior art' and get any desired information. It might also be due to the reason that in EPC does not have any law to punish the biopirators, once it is proved that in the patent there was lack of novelty and non-obviousness and subsequently the patent is revoked. This is one of the major weaknesses of the EPC. Neither there is any law to ask the biopirators to give sufficient amount of money as reasonable compensation to the country of origin or to the indigenous community nor there is any such rule to ask the biopirators to refund the earned-profit back to the holders of the traditional knowledge. These are the actual reasons for EPC's failure. As there is no provision in EPC to ensure the refund of money to the original traditional knowledge holders either to the countries of the origin or the indigenous societies after the patent revocation nor there is any provision of punishment or penalty for those who obtained patent by not disclosing the documents or facts, it means that a wrongful patentee can earn huge profit by commercially using the patent for the years before the lengthy process of revocation is complete without any punishment or refund of money or extra compensation to the holders of such knowledge. It means that EPC is encouraging biopiracy indirectly. It can be said that the EPC patent law is incomplete and weak in nature. It is really surprising to find that though there is a paradigm shift in its approach radically different from TRIPs and TK protection of medicinal plants gets a very powerful support though not throughout the world but at least in an important sub-continent of this world by EPC and though it raised a ray of hope in the minds of the people who have been fighting against biopiracy, due to these reasons it has also failed. The issue has become more important due to the fact that EPO granted thousand numbers of patents to individuals and companies for the medicines which have to use active ingredients of bio-chemical properties of the plants of India and some other countries.

As a result India and other countries have suffered huge economic loss and patentees or the authorised persons and the companies have earned huge profit along with the country itself.

Ultimately, from the TK protection perspective, the success of EPC would depend on the application of its law with retrospective effect leading to the revocation of all the granted patents on the herbal medicines associated with traditional knowledge either written or oral description of the society or indigenous community. The sincerity and effectiveness of EPO have to be judged functionally and it should be result-oriented. Moreover, there would not be any grant of these kinds of patents in future by European Patent Office. Unless it is done in a positive manner, it would remain a lip service to the protection of traditional knowledge of medicinal plants.

CONCLUSION

After analysing the relevant international laws in the field related with traditional knowledge protection, it can be reasonably inferred by saying 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. 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.