Chapter I

Introduction

Technology has been one of the important determinants in economic growth and social development. As a matter of fact, technological changes have always been accompanied by fundamental socio-economic and cultural changes. The industrial growth and material prosperity that characterise the industrially advanced western countries have been made possible by the successive waves of technological revolution. At the same time, it is also argued that technology remains central to the uneven development of societies. In fact, it is not an exaggeration to state that technology has been increasingly used as an instrument of domination and control. This has been found to be true of both in the pre and post war history of civilization.

The new IPR regime that has come into being seems to have vital linkages with the revolution in New Generic Technologies (NGT) Information and Communication Technology (ICT) and Biotechnology (BT) in particular. The New Generic Technologies, by virtue of being capital and research intensive together with its monopoly control by Transnational Corporations, seem to have ushered in a new era characterised by new forms of hegemony and control, with far reaching implications to developing countries. In that sense, the new IPR regime with its extended scope and reach, has not only introduced new dimensions to the development debate but seems to be shaping the nature and direction of contemporary international relations as well.

The New Generic Technologies, with its generic nature, are capable of redefining not only industrial growth and economic development, but fundamental social transformation as well. Of late, the world is increasingly characterised by the international exchange of information, technologies and creative goods and services. In this environment, the economic value of products, services and technologies is primarily a function of the creativity that goes into them and how they apply to market needs. A crucial
component of this process is that while the focus of competition shifts increasingly toward invention and innovation, the cost of many creative activities rises even as it is becoming much easier to copy them. In this context, the international protection of Intellectual Property Rights (IPR) forms a core component of the advancing global regulatory framework.

Biodiversity associated traditional knowledge has been one of the most contentious issues of concern in the contemporary dialogues on IPR. The root cause for the concerns emerges from the lack consensus on how to protect indigenous materials, as also due to the complexities involved in defining and classifying such materials within the framework of Intellectual Property Rights (IPR). Central to such a concern has been the level of protection sought/ contested on the rights rendered in recognition of the intellectual input/creativity underlying an invention or an artistic expression.

The debate over IPR acquired an all-pervasive connotation in the wake of the Trade Related Intellectual Property Rights (TRIPS) Agreement, with the World Trade Organisation (WTO) at its centre on the one side and the Convention of Biological Diversity (CBD) on the other side.

It all started with the emergence of new global regime that facilitated the patenting of life forms. This, in turn, has placed the local and indigenous communities in a vulnerable position as their knowledge, innovation and practices are often used as the foundation for the bioprospecting that lead to patentable invention. At the same time, IPRs tend to disregard these systems of knowledge, as they are freely available to all. The differences between the developed and developing countries in the WTO, on the question of life patenting remain unresolved. When goods and services are made possible by combining traditional knowledge with western science, the contributor of the western scientific thinking is entitled to patent protection and the contributor of traditional knowledge is entitled to nothing. At its worst, it is argued that, TRIPS legitimises the transfer of exclusive ownership and control of biological resources and traditional knowledge from indigenous innovators to western ones, with no recognition, reward or protection for the contributions of the indigenous innovators.
The advent of new generic technologies that augmented the institutionalisation of IPRs appears to erode the Biodiversity associated Traditional Knowledge not only in a pure economic and technological sense but the underlying socio-cultural matrix as well. Thus, a new phenomenon has been emerging where indigenous knowledge and biological resources have become patentable properties. This has stimulated the ongoing debate on the patenting of life and implications of its protection at local, regional, national, and international levels.

Several factors seem to have contextualised the debate. First, the ability to isolate and manipulate genes that has resulted in the growth and expansion of the biotechnology industry. Secondly, the growing market for biological or genetic resources - due to their demand in the biotechnology, pharmaceutical, cosmetics, agriculture and other industries - has led to a rise in bio-prospecting activities in developing countries. And finally, a provision in the TRIPS which requires member countries of the WTO to patent living organisms.

Western concepts of exclusive ownership, alienability and monopoly rights are largely inconsistent with indigenous peoples' traditional forms of ownership which tend to focus on collective, intergenerational creations that often do not contain rights of alienability and which are produced from community-based economies. Thus, attention has recently turned to the sui generis laws of indigenous peoples as the source for developing legal regimes to protect indigenous works. It is widely argued that the Access and Benefit Sharing (ABS) approach based on legally binding contracts would allow for flexible solutions to bio-piracy. Action at the national level would be inadequate for achieving the stated objectives of CBD unless an international recognition is given to these national systems, through an enforceable instrument. Hence, the need for a internationally accepted solution to such bio-piracy.

Developing countries seek to amend the TRIPS framework as a vehicle to enforce the benefit-sharing requirements of CBD. There are many open and complex issues that need to be addressed in any IPR disclosure scheme, whether within TRIPS or within the CBD. There is an
implicit recognition that outsiders misappropriate resources and associated traditional knowledge, and therefore a benefit sharing mechanism would reverse the wrong. The issue of benefit sharing cannot be resolved unless these rights are assured, and unless the community is provided the legal means and incentives to conserve the resources for long-term sustainable benefit to themselves.

Of late, institutionalisation of IPRs through TRIPS has given new twist to the entire debate, especially on its implications to social development. Because developing countries consider technological advancement as a means of economic development, which in turn needs to stimulate social development. Several perspectives have emerged over the primacy of public domain over private and vice versa.

Invariably, a study on the nature and features of the emerging intellectual property regimes with its focus on the Access and Benefit Sharing in the realm of biodiversity associated traditional knowledge acquires considerable significance.

**Nature and Scope**

Historically and otherwise, property has been one of the fundamental institutions of the society. The concept and nature of the property evolved in course of time due to the philosophical, cultural, economic and socio-political aspects of the particular stage of the society. In the contemporary scenario, intellectual property as a personal property received great attention as the basis of economic development and competitive advantage depends greatly on the exclusive control and management of intangible objects such as information and knowledge. The unique feature of property rights is that there is an inherent dichotomy between private and public interests. When the power of the owner is stressed in the construct of property rights, property rights are deemed to become a commodity and on the other hand, the social aspect of ownership stresses the interests of society as a whole. What intellectual property has common with tangible or physical property is the political significance of exclusion from possession and enjoyment of real property that is virtually as palpable as the property itself.
Extension of natural rights arguments for the protection of physical property and intellectual property i.e., knowledge on a similar platform is said to be problematic on three grounds: Firstly, Intangible nature of knowledge can not excluded as physical property. Secondly, exclusion and monopoly right over physical property is absolute in nature, whereas intellectual property rights provide only limited monopoly for a specific duration. Finally, the value of intellectual property is not confined by international boundaries but each state is compelled to protect IP value within its jurisdiction and must consider imitation as theft.

It is widely argued that biodiversity associated traditional knowledge must remain in the public domain to enrich the private domain. It is also argued that the new IPR regime that promotes monopoly proprietary rights is likely to lead a steady transfer of the "ownership" of intellectual "products" from the developing world to the developed world.

Most southern countries do not have extensive internal technological and scientific capacity to enable them to transform indigenous knowledge into knowledge that could be protected under current intellectual property frameworks. Without the establishment of structures within current global intellectual property frameworks intended to help the development of such capacity, TRIPS has the potential to exacerbate existing disparities in technological and scientific capacity. Thus, TRIPS agreement also appears to ensure minimum standards of intellectual property protection upon developing countries and thus seems to have set the stage for enduring structural inequity.

Development encompasses not only economic but also cultural, social, and political dimensions of national well-being. A rethinking and reconsideration of these new concepts in development economics could ameliorate intellectual property's one-sided emphasis on pure wealth- or utility-maximisation. In regards to indigenous peoples in particular, scholars raise the question of what is the appropriate balance between their respective contributions and their rightful share in the vastly increased output of goods and services which have been made possible by the combination of traditional knowledge with modern science.
IP laws appear to presume that the act of innovation is largely individual, rather than social, and that innovators are motivated by financial gain whereas custodians of local knowledge believe that knowledge is socially created through interaction among humans, animals, nature and the spirit world, that individuals are obliged to put their knowledge to use for the good of the community, and that holders of such knowledge have a responsibility to ensure its proper use. The desire of indigenous peoples to contribute to an alternative vision of IPR needs to be viewed in the context of the wave of indigenous renaissance in the global constitutive process. Indigenous peoples have linked their quest for self-determination to the protection of their knowledge, thus making knowledge the new frontier of the indigenous question in international law.

In this regard, CBD is being viewed as the one capable of setting the stage for a global framework for the protection of indigenous knowledge on the basis of indigenous conceptions and as a global plan of action on how to conserve biological diversity. It is widely argued that the tribal law which provides vital cultural context must serve as the foundation because it is suited to indigenous groups' particular cultures and normative framework. Tribal law is inimitably capable of capturing and accommodating the unique features of the tribal community. Thus, attention has recently turned to the sui generis laws of indigenous peoples as the source for developing legal regimes to protect indigenous works.

While the question of the relationship between intellectual property and genetic resources associated with traditional knowledge has been internationally discussed since the adoption of the CBD in the early 90s, the debate on this issue received a significant boost to its political profile starting with the review of article 27.3b of the TRIPS Agreement and the events leading to and at the WTO Seattle Ministerial Conference in 1999. Around the same time, the issue gained prominence in WIPO in the context of the Substantive Patent Law Treaty (SPLT) diplomatic conference which resulted into the eventual creation of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC).

Since then, the issue has been discussed in many fora and there are a number
of important processes underway to deal with this question ranging from the WTO discussion on TRIPS and CBD and issues around disclosure, prior informed consent (PIC) as well as the question of ABS.

Developing countries demanded the insertion of a provision in the TRIPS agreement “that mandates patent applicants for inventions that use biological resources and traditional knowledge, to disclose the source of origin of such resource and knowledge, as well as to provide evidence that they have obtained the necessary prior informed consent (PIC), and complied with national laws on benefit sharing.” On the other, the US appears to maintain that the traditional knowledge should be removed from the agenda of the TRIPS Council. Besides, US and Japan opposed the checklist arguing that there is no conflict between the CBD and the TRIPS Agreement and hence no need to amend the TRIPS Agreement.

TRIPS changed all that by establishing a universal and uniform standard for intellectual property law. India, for example, did not permit patenting of pharmaceuticals or living organisms. TRIPS, by contrast, it is widely criticised, imposed a one-size-fits-all approach that created mandatory minimum standards regardless of the state's domestic situation. The most controversial portion of the TRIPS agreement, at least from the indigenous rights perspective, has been Article 27.3 that requires states to include plants and animals within the inventions eligible for patenting or develop a sui generis plan for protecting these inventions.

The Indian Patents Act, 1970, was amended twice, first in June 2002 and later in April 2005 to comply with TRIPS obligations. Bio-piracy, appropriation and monopolisation of a traditional knowledge and biological resources, including the smuggling of diverse forms of plants and animals, have been a major concern to India. The controversy stems from the multinational companies accumulating huge benefits while remain reluctant to share any of the profits with the countries providing the resources. As a result of several cases dealing with the purported infringement of TK, the First Inter-Ministerial Committee on Protection of Rights of Holders of Indigenous Knowledge was convened in New Delhi. This meeting seems to have given an impetus to the Biological Diversity Act 2002 which seeks to
regularise access to genetic materials on the one hand, while protecting TK on the other. The Bio-diversity Act intended to address the problem of foreign companies patenting India’s Traditional Medicine.

One of the easy ways to identify a useful compound of biodiversity is to review the work of local communities that have long studied and experimented to uncover the medicinal, agricultural and scientific properties of these resources. Then the discovered compound can be patented by the researchers, enabling them to exploit the biological resource for a profit and to exclude others from freely accessing and exploiting their proprietary resource. The local communities that developed the know-how, by contrast, owns nothing and receives nothing as the legal system places their technology and knowledge in the public domain.

Traditional knowledge about ecosystems, specifically regarding medicinal plants and animals, has become the "green gold" of transnational corporations. Ethnobotanical knowledge is a foundation for the pharmaceutical and other related industries but benefit-sharing arrangements are found to be comparatively rare. In the recent past, this process has been legitimised with the institutionalisation of IPR. Hence, it could be argued that direct link between biodiversity associated knowledge and market as the scientific community heavily depended on former for the new lead.

At the same time, it appears to be reasonable in recognising the dynamic interplay that exists between the contours of creativity within traditional knowledge system and the influence of interaction with formalised science. The modern systems have put sustainability at much greater risk than the traditional systems. But it could be argued that with increase in the population, general health and education levels, the ability of traditional systems to sustain the economic and social aspirations may not be easy.

But can patent law actually provide promising solutions? While patent law has been contoured in ways that tend to be highly supportive of corporate interests, the demands of traditional peoples and communities are rare, if ever taken into account when patent regulations are reformed. The difficulty of applying intellectual property laws to local knowledge,
innovations and practices arise from the consideration of the local knowledge as essentially cultural and community construction. IPR protection is purely economic, whereas the interests of the peoples are only partly economic and linked to self-determination. It is widely argued that recognition of community rights in the national legislation will be a prior condition for legitimising the contractual mode of agreements and possible investments by seed and other biotech industries in the in-situ conservation.

Given this perceived incompatibility between IPRs and traditional knowledge, the case has been made for the development of a sui generis regime specifically adapted to the nature and characteristics of indigenous knowledge. The argument for adopting a separate instrument for traditional knowledge is based on the recognition that traditional knowledge is created, owned, and utilised differently. Customary law, as the system of rules and customs that governs conduct and rights in such groups are cited to be relevant to any analysis of rights and obligations under traditional knowledge provided for under the sui generis models. The link just noted between traditional knowledge and customary law suggests the relevance of customary law as the primary regulatory mechanism over uses of traditional knowledge.

As a corollary to this fundamental right of ownership, custodianship, or other relevant right in traditional knowledge by indigenous groups, there is also an acceptance in the model laws of the principle that the scope of such rights would be determined with reference to customary practices and not qualified by rules laid down by States. Of prime importance is whether customary law is recognised as a viable component of the national legal system; no legal basis will otherwise exist for the enforcement of customary law rules. An equally important consideration is how the relevant institutions ascertain and apply customary law rules.

The dynamic seems to be a tug of war between two alternative property visions: state ownership of biological resources, as articulated in Article 8j of the Convention on Biological Diversity (CBD), and private ownership of these resources under the WTO's TRIPS agreement. There is, however, a third aspect to this struggle over traditional knowledge and
biological resources as indigenous leaders conceive of these resources as an aspect of self-determination, as a recognition of their fundamental rights to property and culture.

The traditional knowledge base of indigenous and local communities in India is perhaps the richest in the Third World and hence appears to have the potential to capture the world drug and pharmaceutical markets, provided the country strives to bring in substantial improvement and value addition to the existing traditional knowledge base through appropriate scientific and technological intervention and policy support. Using some form of IPRs or sui generis systems for protection of TK based on prior informed consent and benefit sharing are likely to supplement the efforts available for the prevention of bio-piracy. It is argued that a uniform international system for protection of biological resources and associated TK would not cater to the requirements of individual country. Rather, the need is for a system, which recognises such diversity preserved through national legal systems. Action at the national level would be inadequate for achieving the stated objectives of CBD unless an international recognition is given to these national systems, through an enforceable instrument. Hence, an internationally accepted solution to such bio-piracy was considered necessary.

The Indian experience in this regard suggests that despite the constitutional protections of tribal autonomy, confrontations between the Indian State and the tribal communities have marked the loss of cultural autonomy that has resulted in the degeneration of traditional legal systems, infringing on the fundamental right to culture guaranteed by the Indian Constitution. The formal structures of justice administration in India seem to have failed to adequately protect the tribal communities' right of equal access. Although indigenous right is enshrined in the common law principles, and recognised through jurisprudence in India, and at times even converted into a statute for a more predictable rights regime, it is not necessarily recognised outside the jurisdiction of India.

The UN Convention on Biological Diversity maintain that genetic resources and associated traditional knowledge can no longer be treated as
a free good and that there is scope for framing regulations to control access to such resources in the interest of the national and local communities. However, CBD appears to be ambiguous and it does not clarify who has the rights on the resources in the first place: the country, the community concerned, the individual or some association on behalf of the individuals. The ‘rights’ issue, therefore, is perhaps left for resolution at the national level.

Developing countries seem to be pushing for rapid adoption of a legally binding regime that will require users of genetic resources to ensure fair and equitable benefit-sharing. Developing countries seek to amend the TRIPS patent framework as a vehicle to enforce the benefit-sharing requirements of CBD. Some developed countries argue that TRIPS and CBD are not incompatible, and oppose those proposals for mandatory disclosure. However, Paragraph 19 of Doha Development Agenda did acknowledge the need of CBD and TRIPS relationship to be looked into. However, most of the developed countries rejected ABS on the pretext that ABS is not a viable option and issues should be addressed at the national level rather than placing it on the multilateral regime implying the underlying politics.

In general, the discussions within the CBD seem to be taking place against the backdrop of those IPR debates. Naturally, therefore, almost all the basic questions appear to remain the subject of debate: the legal nature of the regime, its scope, its modalities, and consequences for noncompliance. International certificates of origin have been discussed as a potential mechanism to trace genetic resource flows and identify whether PIC requirements for their use have been satisfied. There are many open and complex issues that would need to be addressed in any IPR disclosure scheme, whether within TRIPS or within the CBD.

The basic question that needs attention is as to whether the regime will impose excessive and unworkable burdens or increase legal uncertainties associated with the development of these resources. The main opportunity is said to be that a well-designed ABS regime could minimise existing obstacles to genetic research in a way that would maximise the
sustainable use of these resources, while at the same time ensuring their
cconservation and the equitable sharing of benefits associated with their
development. A well-designed ABS regime is being advanced as one that
could resolve current obstacles at the national level to bioprospecting.

There is an implicit recognition that outsiders misappropriate
resources and associated traditional knowledge, and therefore a benefit
sharing mechanism would reverse the wrong. It is this realisation that has
perhaps made countries, like India to install regimes that provide for State
intervention in determining access as well benefit-sharing arrangements. In
this regard, there appears to be substantial merit in examining the
experience of Kani tribe of Kerala.

The scenario being what it is, efforts have been made in this study
to examine the political construct of intellectual property rights, its genesis
and growth as well as nature and features. It has also been attempted in the
wider context of the historical and contemporary perspectives on proprietary
rights. The focus of the study is on the question of Access and Benefit
Sharing as well as Prior Informed Consent pertaining to Biodiversity
Associated Traditional Knowledge in the backdrop of TRIPS and CBD. Such
issues have been examined specific in the context of a developing country
like India and the experience of Kani tribes in Kerala particular.

Specifically, this study has examined, among other things:

- perspectives on proprietary rights, IPR and its protection;
- genesis and growth of the global IPR regime;
- implications of new IPR regime to developing countries;
- issues and concerns related to Access and Benefit Sharing in the
  background of CBD and TRIPS agreement;
- challenges and opportunities involved in the protection of
  Biodiversity Associated Traditional Knowledge in India;
- experience of the Kani tribe in Kerala vis-a-vis the ABS
We began this study with certain important research questions which are placed below as hypothesis;

- Institutionalisation of intellectual property rights through TRIPS appears to safeguard the interests of the multinational companies and their parent countries compared to developing countries.

- The new IPR regime appears to have widened the nature, scope and patentability of biodiversity associated traditional knowledge with immense challenges to developing countries.

- The commodification of knowledge through TRIPS seems to alienate the Biodiversity associated Traditional knowledge from indigenous communities not only in a pure economic and technological sense but from the underlying socio-cultural matrix as well.

- The provisions in the TRIPS Agreement appear to offset the potential benefits of the provisions related to ABS and PIC in the CBD.

- The issues and concerns in the protection of Biodiversity associated Traditional knowledge could be minimised through appropriate legislative, administrative and judicial initiatives.

- The absence of such initiatives seems to have deprived the Kani tribe of their legitimate right to access and protection of traditional and community knowledge and resources.

**Organisation of the Study**

From an analytical viewpoint, this study has been divided into five core chapters, besides the introductory chapter (I) and the concluding chapter (VII). The second chapter (II) delves into the perspectives on the political construct of the intellectual property from a social development perspective to understand how biodiversity associated traditional knowledge has been hierarchically placed into the lowest realm of the society vis-à-vis public domain to facilitate transfer of rich heritage of such information and knowledge into intellectual property regimes.
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Third chapter (III) traces the genesis and growth of the new IPR regime, its nature and features. Herein, we have made an attempt to compare and contrast the TRIPS Agreement vis-à-vis WIPO, UPOV, CBD, FAO and UNCTAD.

In the fourth chapter (IV), we have made a comprehensive review and analysis of the provisions related to the protection of Biodiversity Associated Traditional Knowledge. Herein in the wider context tries to sensitise illegal transfer of rich traditional knowledge that exist in the public domain of developing countries by delving into the experience of India and the nature of the international legal system that facilitates such transfer from south to north.

The thrust of discussion in the fifth chapter (V) is on the question as to whether the intellectual property regime has been able to protect the interests and rights of the custodians of biodiversity associated traditional knowledge? Why TK can not be protected under IPR framework as scientific knowledge? If not, what are alternatives available to protect this intergenerational knowledge which is valuable to biotechnology? IPR protection is purely economic, whereas the interests of the peoples are only partly economic and linked to self-determination. Given this perceived incompatibility between IPRs and traditional knowledge, the case has been made for the development of a sui generis regime specifically adapted to the nature and characteristics of indigenous knowledge. Customary law, as the system of rules and customs that governs indigenous knowledge therefore would be relevant to any analysis of rights and obligations under traditional knowledge provided for under the sui generis models.

Finally, the experience of the Kani Tribe in kerala on matters related to Prior Informed Consent and Access and Benefit sharing has been examined in chapter six (VI). Here, we have attempted to examine the experience of India and Kani tribe of Kerala in particular in the backdrop of the TRIPS and CBD. A comprehensive summary of the discussion and major findings have been placed in the final chapter.
**Introduction**

**Scope of the study**

Scope of the study has been limited to the Indian experience. Specifically, the political construct of the TRIPS regime has been examined in terms of the correlation of intellectual property rights vis-à-vis biodiversity associated traditional knowledge. Further, Indian experience has been examined at the micro level of Kerala, a region rich in biodiversity, well known for its traditional knowledge and resources related to the world renowned Kani Model of Benefit Sharing.

**Source material, Survey of literature and Methodology**

This study is based on primary sources and field data collected from institutions, agencies and individuals associated with patents and other forms of intellectual property rights. The data also include studies and reports published by international institutions such as WIPO, WTO, TIFAC, Government of India and Kerala. The Kerala experience was examined through field surveys and interviews.

The study employed interdisciplinary analytical mode of investigation, drawing insights from cultural, legal, social, political and economic milieu.