Chapter V

IPR Protection in India with special reference to Biodiversity (BD) associated Traditional Knowledge (TK)

5. Introduction

As is well known, biodiversity Associated Traditional Knowledge is the foundation of the many innovations in the current pharmaceutical and other related industries but benefit-sharing arrangements are comparatively rare. As discussed earlier, there has been huge outcry from the indigenous people that the scientific community uses their knowledge to amass millions of dollars from the market without their consent and proper return. This process has been legitimised with the institutionalisation of IPR. So there is direct link between biodiversity associated knowledge and market as the scientific community heavily depends on the former for the new lead. But one of the major questions addressed in this chapter is as to whether the intellectual property regime would be 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 the 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 IPR and traditional knowledge, there is a case for the development of a sui generis regime specifically adapted to the nature and characteristics of indigenous knowledge. Such questions related to IPR protection have been examined in this chapter with its focus on India.

5.1 Global Biodiversity Scenario

Biodiversity is defined as ‘the variability among living organisms from all sources, including terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are a part; this includes diversity within species, between species, and of ecosystems’. Biodiversity plays an important economic, social, and cultural role in the lives of
indigenous and local communities. Preserving biodiversity in the face of a variety of well-documented encroachments is more than an aesthetic or strictly environmental concern. Agriculture, pharmaceuticals, forestry, fisheries, and tourism are all key areas that are heavily dependent upon biodiversity, attracting the attention of industry researchers and investors. Management of biological resources has a profound effect on biodiversity and the ecological services that sustain life. Habitat destruction as a result of competing human needs has resulted in the loss of numerous plant and animal species, some known and others unknown.¹

Biodiversity is mostly located in the global south. The region's countless varieties of plants and trees are viewed as a treasure trove of genetic material with innumerable potential applications. One of the easy ways to identify a useful compound 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. The "discovered" compound can then 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.

Most legal regimes award the mantle of "property," with its attendant rights, only to the tangible goods produced by indigenous cultures, paying no attention to the contexts in which those goods were produced and used. As a result, these legal regimes too often try to force indigenous resources into property definitions external to the cultures themselves. In this process, indigenous cultures wind up compartmentalised, with artifacts entitled to legal protection as "cultural property," but with the real wealth of indigenous peoples - their traditional knowledge about biodiversity, their folklore, designs and

traditions-left outside this mantle of protection. This compartmentalisation under the western Cartesian worldview in a way facilitates the transfer of wealth from indigenous cultures to multi-national corporations. (Bratspies 2006-2007: 320-322)

5.1.1 Plant Genetic Resources (PGRs) and Intellectual Property

PGRs consist of "seeds, plants, and plant parts useful in crop breeding, research, or conservation for their genetic attributes." (Fowler & Hodgkin 2004: 147-48) PGRs are divided into "raw" i.e., in their natural state and "worked" resources i.e., altered by deliberate human intervention, although the distinction can be difficult to discern in the context of agriculture. (Raustiala & Victor 2004: 279-286) Because breeding and research of plants may be conducted for the purposes of enhancing food and agricultural products, as well as developing industrial raw material, clothing, and medicine. Thus, PGRs "encompass an unidentified range of activities." (Rose 2003: 585-86)

States and private actors have important interests in having easy access to PGRs. States' principal concern with these IPR is the need for access to repositories of PGRs to ensure food security for their populations. (Fowler & Hodgkin 2004: 147-48) Therefore, it may be necessary to look abroad for plant resource stock that is resistant to new diseases or environmental problems. When doing this, researchers prefer to obtain samples from a national or international ex situ collection, because such accessions are usually accompanied by integral information. In fact, most food crops originally come from PGRs developed in developing countries. This is particularly the case in the developed world. (Moore & Halewood 2005: 2)

Private interests, like corporations, also want access to PGRs in order to improve existing plant varieties and develop commercial products, such as pharmaceuticals. Often, PGRs are analysed in a laboratory so that patentable compounds can be identified. Patents are one way to protect this type of innovation. However, these patents raise benefit sharing issues, because the raw material often comes from developing countries, while the resulting profit from the patent remains
with the developed world corporation that performed the research. Some
developing countries also have moral and cultural objections to patents on
living organisms. These states resent paying for products based on their
own PGRs, viewing this as theft and labeling it "bio-piracy," because
developed countries did not initially recognise IPRs in wild PGRs or
traditional knowledge bodies of know-how and skills that have been
developed by local communities over generations.

The international regime governing access to PGRs has changed
from an open commons to protected IPRs supported by national
sovereignty but is now showing some signs of shifting back towards a
commons once more. This is a process that has been shaped by the
dynamics of negotiations between developed and developing states and by
the particular plant resource advantages that states have been able to
obtain from forum shopping. In reality, there has been a continuing
tension between the desire for strong IPRs and a desire for open access to
PGRs with states from both hemispheres on either side. However, broadly
speaking, the developed countries are more enthusiastic about IP
protection and have been successful in gaining international acceptance of
this agenda. There are indications that the developing states are beginning
to organise and successfully put forward their own interests. (Kennedy
2006: 4-6)

5.2 The Development of Indigenous Peoples' Knowledge

Indigenous peoples are fully identified with their natural and
cultural environment. The knowledge that these societies hold about their
ecosystems, combined with their management experience constitute a
repertoire that would enable an empowered advancement in their
economic, political, cultural, and spiritual development. The universe of
knowledge held by indigenous peoples is a result of a diachronic,
intergenerational, communal and holistic collection of 'in-corporated'
information about their local environment. It consists of an intellectual
construction resulting from the accumulation of experiences over historic
time and across the social and natural space. Indigenous peoples and their
communities not only possess detailed information about species of
plants, animals, mushrooms and some microorganisms, but also they recognize many types of minerals, soils, water, snows, vegetations and landscapes.

The knowledge is holistic because it is intrinsically connected with the use and management of local ecosystems; it is consistent with their cosmovision. In terms of the practical management of natural resources, they apply a permanent and systematic observation procedures to long and short natural cycles occurring in different spatial scales: not only at local levels but also on more extensive geographical spaces. Everything must be monitored: from the birth-giving of animals or the sprouting of a plant, to the frequency of hail storms and their connection with animal or plant sicknesses. With regard to cosmovision, their set of beliefs and values determines their attitude towards nature which, considered a sacred mother, is subject to a variety of expressions of utmost respect. (Muñoz & Patrick 2006: 260-262)

5.2.1 Value of Traditional Knowledge in the Global Economy

Biodiversity associated traditional knowledge is considered as the cradle of inventions that provide leads in the discovery, development, and manufacture of pharmaceutical products. Ethno-botanical knowledge is a foundation for the pharmaceutical and other related industries but benefit-sharing arrangements are comparatively rare. There is large outcry from the indigenous people that the scientific community uses their knowledge to amass millions of dollars from the market without their consent and proper return. In the recent past, this process has been legitimised with the institutionalisation of IPR. (Overwalle 2005: 585)
### The Use of Traditional Knowledge by Industry Sectors

<table>
<thead>
<tr>
<th>Sector</th>
<th>Manner of Use</th>
<th>Source</th>
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<tbody>
<tr>
<td><strong>Pharmaceuticals</strong></td>
<td>TK is not considered a useful tool during the early stages of high-throughput screening, but once an active compound is identified, most companies use TK (when available) to guide subsequent research. A (very) few companies direct their research programs based on TK; some will use TK as the basis for setting up screens to select for competing (or better) compounds with similar bioactivity, that is, as a reference compound to select more active synthetic analogue compounds.</td>
<td>Literature, databases, inter-mediary brokers. A minority of companies commission field ethnobotanical collection. Ethnobotanical information is often attached to samples as an &quot;add-on,&quot; even if collections are primarily chemotaxonomic or ecology driven.</td>
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<tr>
<td><strong>Botanical medicine</strong></td>
<td>TK is used as the basis of identification of potential new product development; in safety and efficacy studies; and formulation. It is widely used in marketing commercial products, sometimes in developing wildcrafting or cultivation strategies for raw materials.</td>
<td>Literature, databases, trade-shows, Internet, and so forth. Middlemen brokers will follow up on leads in literature with local communities and research institutions. In rare cases the literature leads marketing companies to conduct field-based research on species of promise; this is directed, rather than bulk collecting, research.</td>
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<td><strong>Personal care and cosmetics</strong></td>
<td>TK is used as the basis of identification of potential new leads and to direct research on a species' commercial potential. It is used in safety and efficacy studies; is widely used in marketing commercial products; and is sometimes used in developing sourcing strategies for raw materials.</td>
<td>Literature, databases, trade shows, Internet, and so forth. Occasionally, middlemen brokers will follow up on leads from the literature with local communities. Companies conducting high-throughput screening will commission the collection of ethnobotanical samples with identified uses. Other companies have entered into direct, field-based partnerships with communities to use their TK in product development.</td>
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<td><strong>Crop protection</strong></td>
<td>A small proportion of companies use TK to guide the collection and screening of samples. As with pharmaceuticals, once activity is demonstrated, TK is sometimes used to decide on the direction of subsequent research.</td>
<td>Literature, databases.</td>
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<td><strong>Biotechnology</strong></td>
<td>Many biotechnology applications, such as brewing and bread-making, are based on TK dating back millennia, but contemporary biotechnology makes little use of TK.</td>
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<td><strong>Seeds</strong></td>
<td>Companies make little use of TK, but they do use germ plasm that has been pre bred by other organizations to which genes from traditional varieties may have made an important contribution.</td>
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<td><strong>Horticulture</strong></td>
<td>Many popular ornamental varieties and horticultural vegetable crops owe their existence to traditional domestication and selection over long periods of time. However, TK is rarely used in the selection and breeding of new horticultural varieties today.</td>
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Traditional peoples and communities are responsible for the discovery, development and preservation of a tremendous range of medicinal plants, health-giving herbal formulations, and agricultural and forest products that are traded internationally and generate considerable economic value. TK is also used as an input into modern industries such as pharmaceuticals, botanical medicines, cosmetics and toiletries, agriculture and biological pesticides. So TK has an important role in the global economy. For pharmaceuticals, the estimated market value of plant-based medicines sold in 1990 was $61 billion. Grifo and others demonstrated that the top 150 plant-derived prescription drugs are derived from the traditional medical use. Norman Farnsworth’s estimate that of the 119 plant-based compounds used in medicine worldwide, 74 per cent had derived from TK. But it is impossible to estimate accurate value of TK. Because TK is an essential component in the development of many products, and most TK derived products may not enter modern markets. Besides, TK’s cultural and spiritual value cannot be measured in monetary terms. (Dutfield 2002: 51)

Pharmaceutical research greatly benefit from sampling medicinal plant knowledge to avoid the process of screening all of them which is time-consuming and costly. Thus, TK can minimise search costs and drive researchers toward the most promising therapeutic paths. In this manner success of research to make products is much higher than conventional practise of sampling entire plants and passing those costs to consumers. (McManis 2004: 547) Western practices with the use of indigenous medical plant knowledge, the possibility of "developing at least one marketable pharmaceutical from 1,000 samples grows from 22 percent to 78 percent or three and half times." Similarly, when using traditional knowledge, the efficiency of screening plants for medicinal properties increases by more than 400 percent.

According to one of the estimates, the annual market value of pharmaceutical products derived from tropical rainforest plant-based medicinal knowledge of indigenous peoples exceeds $32 billion. Traditional healers have employed most of the compounds used in modern medicine
today for centuries. For example, twenty five percent of American prescription drugs contain active ingredients derived from indigenous knowledge of plants and seventy-five percent of these have been gathered from information provided by indigenous peoples. All over the world a number of pharmaceutical companies are dedicated to drug discovery based on indigenous or so-called "shamanic" knowledge. Such appropriation threatens the cultural integrity of indigenous knowledge, because the knowledge-protection and reward mechanism of the Western intellectual property regime is not designed to accommodate epistemic narratives other than Western science. There are several ways IPRs are mismatch for indigenous knowledge forms. (Chidi Oguamanam 2004: 140-141)

This has become an issue at many national and international foras due to its commercial potentiality. Scientific developments in the fields of biochemistry, molecular biology, cell biology, immunology, and information technology continue to transform the process of product discovery and development. Scientific community’s inhibition to acknowledge and share the monetary benefit with indigenous community is a rare practice in the society. So there is direct link between biodiversity associated knowledge and market as the scientific community heavily depended on former for the new lead. Studies of Kate and Laird show that there is huge global markets for products in the healthcare, agriculture, horticulture, and biotechnology sectors derived from genetic resources which is approximately estimated between US$500 billion and US$800 billion (Kerry ten Kate and Sarah A. Laird (1999).

There are annual sales of between US$75 billion and US$150 billion of pharmaceuticals and between US$20 million and US$40 billion worth of botanical medicines derived from genetic resources each year. Farnsworth and others make a direct link by saying that approximately 120 pharmaceutical products derived from plants in 1985, 75 percent were discovered through the study of their traditional medical use. (Farnsworth et. al 1985: 965-981) From this viewpoint, TK solves a market failure problem by providing incentives to invest in potential paths of research. Indigenous creation of TK is not driven by the incentives of a market economy; local communities do not aim at obtaining exclusive rights to
exploit their innovations, as such knowledge is generally shared within the community. (Overwalle 2005: 585)

Misappropriation of TK and biological resources pose serious environmental risks due to unregulated and unmonitored taking of biodiversity. This process severely damages the Developing Countries’ economy. First, Developing Countries are deprived of the right to trade their biodiversity with foreign companies and make a profit. Similarly, when foreign companies succeed in patenting inventions based on TK in their own countries, these companies deprive indigenous communities’ right to export their knowledge to profit from it. Moreover, as Professor James Boyle has pointed out, TK often flows out of Developing Countries free of legal constraints and yet returns embedded in foreign patents. When this occurs, there is a strong risk that indigenous people lose any opportunity to retain and exploit their collective knowledge in their own country. (Arezzo 2007: 374)

Hocking looks at the often-cited connection between indigenous knowledge and environmental protection. There is no doubt that 40,000 years of resource use by original inhabitants in Australia did not bring about as much change in the landscape, biodiversity and the knowledge systems as the 200 years of European rule. There is a merit in recognising the dynamic interplay that exists between the contours of creativity within indigenous or traditional knowledge system and the influence of interaction with formalised science. It is not that the local knowledge becomes less local when it incorporates the elements of modernity. The modern also becomes local when it is contextualised in a local use system. For instance, when a farmer makes selection of an off type plant from an institutionally released plant variety, he develops a local adaptation by selecting that mutant. Thus, the road that connects local or indigenous knowledge with institutional science and knowledge systems is actually a two street. It is true that traffic form one side is much more than the other.

The ethical values that indigenous communities have evolved for sustainable resource use are an important building block of modern institutions. The modern systems have put sustainability at much greater risk than the traditional systems. But it is also true that with increase in
population, general health and education levels, the ability of traditional systems to sustain the economic and social aspirations may not be easy. In fact, the very effort to map local knowledge on institutional scientific parameters is to reduce the relative importance of both. The contention is that local knowledge provides the possibility of creative and innovative exploration of resource use opportunities by people who are extremely physical and economic resource constrained.

The sterile debate between the conception of science as being opposed or distinct from the formulations about the way world is in local knowledge, needs to be abandoned. Just as scientific systems accommodate use of local knowledge in refining the scientific principles, local knowledge systems can also use scientific principles for achieving the similar goals. There should be a synergy between the local and the global, formal and the informal and indigenous and the exogenous.2

Conservation of biodiversity and other natural resources over a long period of time has been possible because of the cultural, spiritual and other social institutions that have guided the relationship of local communities with the resources. It is not just the resources but also the knowledge about these resources which have been conserved through practice and innovations. It has been generally believed that the knowledge systems of local communities and indigenous peoples are holistic in nature. Centuries of association with an environment have produced a deep understanding of the inter-relationships among the different elements of a landscape or a habitat. Because fluctuations in the environment require adaptive responses, communities have developed a wide range of diversified survival strategies at intra and inter-household levels as well as at community level (Anil K Gupta 2000).

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5.2.2 North-South Division over the Protection of Biodiversity Associated Traditional Knowledge

The protection of biodiversity and TK presents another conflict of interest between technology-rich industrialised countries and the biodiversity-rich Developing Countries. Cooperation between these two groups could bring about significant innovation in products ranging from drugs to agricultural products to cosmetics. However, only rarely has such cooperation resulted in revenue for developing countries. In the best case scenario, the unequal bargaining power of the contracting parties tends to lead to biased licensing schemes whereby indigenous communities are rewarded only for the biological resources and are not compensated for the intellectual resources they provide. (McManis 1998: 270-75)

Furthermore, the indigenous communities are typically excluded from sharing in the results of the subsequent research. Often, no agreement between the countries takes place at all. (James Boyle 1996: 125) In some cases, bond between TK and genetic resources is clear, as indigenous communities have come to realise the specific applicability of the germplasm. In such a case, foreign companies simply isolate the molecules, embed them in a commercial product, and file for patent protection. (Vecchio 2007)

Notwithstanding the close link between the two, biodiversity and TK differ in that the former is material while the latter is abstract and intangible. Biodiversity, however, presents a very peculiar case. Biological resources, like all genetic resources, represent a set of codes, with each piece carrying specific information that deals with a certain function. Once the relation between a portion of the code and its function has been revealed, the genetic resource acquires value. Conversely, TK has value only in connection to that specific biological resource. When a germplasm is transferred, parties' unequal bargaining powers tend to lead to unfair licensing agreements in which companies compensate local communities only for the genetic resources through lump sums or royalties. (Ghidini 2005: 695) The value of TK goes unacknowledged. Although there could be contractual schemes envisioning "grant back" provisions or granting
foreign companies non-exclusive licenses for "research use" and (derivative) innovations based on TK, such arrangements are rare. (McManis 2004: 547)

5.2.3 Similarities between TK and Scientific Knowledge

Many times researchers have tried to portray traditional knowledge systems as totally different and opposed to the so called modern and western knowledge systems. Some aspects of traditional knowledge systems contain most of the elements that make a scientific proposition valid. At the same time, many scientific institutions use traditional cultural symbols and practices to generate an extra ounce of confidence or certainty (Anil K Gupta 2000). Indigenous knowledge is differentiated from formal Western knowledge as it is transmitted through oral traditions, dynamic and varies within and between societies as well as within and between generations, and finally it is both "a way of life" and a "worldview". (Maragia 2006: 203-204) The distinction between traditional and modern, or formal and informal may be thin. In the informal knowledge system, the method of knowing, feeling and doing follows a very different logic than in the formal system. The problem arises when one tends to ascribe local knowledge a consistency which is impossible among so many variations of locals. In other words, the expectation that universalistic features of institutional science would somehow become apparent in indigenous or local knowledge is only partly true.  

Local and indigenous knowledge systems, while generally holistic, have some reductionist elements too. In order to cope with the complexity of ecological change, some people in the community specialise by knowing more and more about less and less. Such specialised expertise requires focusing, targeting and steering strategies on specific themes or aspects of nature. So-called Western science is biased in favour of reductionist relationships, whereas local knowledge systems are biased in favor of systemic linkages and a holistic perspective on nature. Local and indigenous

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3 Ibid.
knowledge system is not static. They evolve, adapt and transform dynamically with time. New materials are incorporated, new processes are developed, and sometimes new uses or purposes are evolved for existing knowledge besides the acquisition of knowledge. Hence, there is a need for rewarding not only traditional knowledge but also contemporary innovations.

Transfer traditional knowledge from one generation to another in a cultural context that is quite different from the scientific knowledge. But one can not deny the scientific nature of traditional knowledge systems as traditional knowledge and traditional ways of knowing are different. But there is general perception that this knowledge never get updated and transferred to subsequent generation in a fossilised form. The production and reproduction of knowledge, innovation and practices are adapted to the distinctive cultural set up of the particular community which is quite different from place to place. Every generation contribute to improvise it further. The traditional ways of knowing may give a lead to many innovations which may even advance the frontiers of knowledge. This source of creativity need to get incentives for both, the knowledge produced in the long past and carried forward by subsequent generations through their own improvisations and the knowledge produced in recent past using traditional ways of knowing and blending it with other knowledge systems. Indigenous ingenuity based knowledge systems are sustainable in nature and have less inimical impact on the environment and biodiversity compared to the so-called scientific knowledge systems.4

Indigenous knowledge in pedagogic sense is a way of knowing of a community or a culture. This knowledge is considered indigenous despite being contemporary. Indigenous knowledge need not essentially be traditional in nature. Contemporary knowledge serving indigenous ends, or using indigenous materials or processed through indigenous rules or heuristics can also be part of indigenous knowledge systems provided it

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is interpreted through local cultural meanings. The cognitive anthropologists also used the word ‘ethno’ to characterise the knowledge of local communities such as ethno botany or ethno zoology. Much of the literature on indigenous knowledge paradoxically, fails to recognise indigenous efforts to reflect on local and global knowledge systems.

Gupta argues that knowledge is produced locally and sometimes indigenously without any interface with the community or outsiders developed autonomously. Merely because a particular innovation builds upon traditional reserve of knowledge produced within the community or outside does not invalidate or minimise the contribution of individual in the contemporary context. So there is a need for modifications and adaptations in the IPR laws to reward different kinds of contributions by individuals and communities in long past or recent times through improvement or innovations in local materials, knowledge systems, or external materials or knowledge systems or a combination of these (Anil K Gupta (2000)).

Many studies on knowledge systems have identified a need to distinguish among different types of knowledge and recognise the need for building bridges between local or indigenous knowledge vis-à-vis formal scientific knowledge. Both formal and informal sciences are capable of producing abstract as well as practical knowledge, although the latter tends to produce more of the practical kind. Rose Mary Coombe acknowledges, “that opposition between dominant and indigenous culture are often oversimplified, blurring the actual fluidity and permeability of knowledge and cultural boundaries. Just as dominant cultures appropriate knowledge from indigenous ones, indigenous knowledge itself contains knowledge shared between cultures, as well as information brought by colonists, settlers, and traders (Anil K Gupta (2000)).

The knowledge produced through sacred and profane aspects of our understanding does not always synergise. The secular mind suggests equanimity whereas the sacredness advises sanctity of certain actions even at personal costs or sacrifice. It is indigenous because the meanings as well as the categories of sense making are generated internally within a cultural
community. While the role of indigenous knowledge in solving local problems is recognised, the macro level problems are supposed to be solved by global pool of knowledge. The indigenous/local knowledge seems to lose its significance in solving global problems just because it evolves from a local context. Modern scientific systems will not generally accommodate location specific meanings or boundaries of the concept. Whereas the local knowledge systems often combine specific and general aspect of knowledge with great ease.

The learning between formal and informal can indeed be a two way street. The problem is that today the traffic from formal to informal is much heavier and often uncontrolled. Moddie recommends the notion of participatory epistemology for understanding indigenous knowledge. He argues that a proper evaluation of African and other indigenous knowledge systems must address the duality of ontological and epistemological dimensions of knowledge. Huntington agrees that the problem arising out of incoherence in studies on traditional knowledge arises more on account of assumed universality of meanings than on account of legitimately different ways of understanding and explaining.

5.2.4 Importance of Oral Tradition

It is very important to understand that different indigenous and local communities develop knowledge systems through a tradition of invention and also develop languages through which to articulate their knowledge systems. If a language dies, a knowledge system partly or completely dies with it. Hence, the conservation of language or oral tradition become a crucial factor for conserving taxonomies because each word, conceptually speaking in the context of a natural resource, is a category. Modern science will benefit a great deal and so will the ability of humans to understand their environment and cope with it, if the scientific basis for these categories is better understood.

The property right regime governing a resource influences not only the constellation of stakeholders but also the possibility of disadvantaged communities and individuals benefiting from a resource-centered benefit sharing mechanism. Benefit sharing need not be seen only among
international users of resources and knowledge but among by the domestic users. After all a tribal community or individual healer gets no respite from the fact that the exploiter is from within the community or country and not from abroad. In most developing countries, the greatest damage to the biodiversity and greatest exploitation of local communities has been caused by domestic interest groups in relative terms, exceptions apart.

5.3 Protecting TK through the IPR system

Article 23.4 of TRIPS provides for negotiations to be undertaken in the Council for TRIPS on the establishment of a multilateral system of notification and registration of geographical indications in the context of wines. There is no reason why such negotiations should be restricted only to wines and not include traditional knowledge as well as contemporary innovations of local communities and individuals. The application of IPR laws to traditional knowledge and innovations hinges on the conceptualisation of the traditional or indigenous knowledge itself. Brush (1993) includes all folk of popular knowledge preserved in local and traditional practices as indigenous knowledge. Agarwal, leading scholar, decries the tendency to view indigenous knowledge as a counterpoint to western or scientific knowledge.

5.3.1 Patents

Traditional knowledge would be broad enough to embrace traditional knowledge of plants and animals in medical treatment and as food. But can patent law actually provide promising solutions? According to Graham Dutfield (2002) the main objections are as follows:

(i) TK is collectively-held and generated while patent law treats inventiveness as an achievement of individuals; This is because patents require that an individual inventor be identifiable. Yet while TK is merely part of the public domain, a new and non-obvious modification to this knowledge achieved by an individual or identifiable group can be the subject of a patentable invention. In the late nineteenth century, large research-based corporations were already finding the heroic inventor paradigm to be rather
inconvenient. They much preferred to treat invention as a collective and routinised corporate endeavour in which individual flashes of genius were unnecessary. Through their lobbying efforts patent law and doctrine began to accommodate the collective notion of inventorship from as early as the 1880s, first in Germany and then elsewhere. This suggests that the collective nature of TK production and ownership need not be a bar to the acquisition of a patent. It certainly has not been for corporations.

(ii) Patent applicants must supply evidence of a single act of discovery. Patent specifications must nonetheless provide evidence of an inventive step or an act that would not be obvious to one skilled in the art. Applying the same criteria to TK would exclude much of it from patentability. This is not only because it is difficult to identify a specific act of creation in the area of TK, but also because such acts may have taken place in the distant past. Many anthropologists have demonstrated that TK in many societies is evolutionary, dynamic and adaptive.

(iii) Patent specifications must be written in a technical way that examiners can understand. It would be extremely difficult for indigenous group to describe their knowledge to a patent attorney in a way that would enable the latter to complete a patent specification on their behalf. While a useful characteristic of a plant or animal may be well-known to such an individual or group, the inability to describe the phenomenon in the language of chemistry or molecular biology would make it almost impossible to apply for a patent even if the fees could be afforded, which is unlikely. This is a situation that a company can take advantage of. Patent rules in most countries require a company to do more than describe the mode of action or the active compound to acquire a patent. Minimally, it would probably need to come up with a synthetic version of the compound or a purified extract. But in the absence of a contract or specific regulation, the company would have no requirement to compensate the communities concerned.
Applying for patents and enforcing them once they have been awarded is prohibitively expensive. The lack of economic self-sufficiency of many traditional communities, the unequal power relations between them and the corporate world, and the high cost of litigation, would make it very difficult for them to protect their IPRs through the patent system. The costs of preparing and prosecuting a patent application, and of periodically renewing the patent after it has been granted, are well beyond the financial means of most communities. Even though patent fees in some jurisdictions may be reduced for small and medium-sized enterprises, using the patent system is still likely to be prohibitively expensive.

Nevertheless, most traditional peoples and communities seem to be fundamentally opposed to patents. There are various reasons why traditional peoples and communities are sceptical that patent law can be utilised to further their interests. The main practical difficulty that deters them from filing patents is the expense of doing so, which includes payments to the patent attorney hired to complete the application, and the filing, prosecution and renewal fees. Legally enforcing the patent against infringers is likely to be even more expensive. Moreover, patents with overly broad claims encompassing non-original products or processes are sometimes mistakenly awarded. Due to poverty, few if any indigenous groups could mount legal challenges to patents on the grounds that their knowledge or, say, landraces, have been fraudulently or erroneously claimed.

Supporters of patents argue that ‘traditional knowledge’ can not be registered under patents. While patent law generally supports such a defence, ‘the state of the art’ is to some extent subjective, especially from a cross-cultural perspective. To give a recent example, *Phyllanthus amarus*, a medicinal plant used in India for treating various ailments including jaundice, was discovered in tests to show effectiveness against viral hepatitis-B and E. Subsequently, the Fox Chase Cancer Center was awarded a U.S. patent for a pharmaceutical preparation comprising an extract of the plant. While the invention was sufficiently new, useful and non-obvious to be patentable, Indian ayurvedic healers are unlikely to be as
impressed as the Patent and Trademark Office examiner who granted the patent. 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 rarely if ever taken into account when patent regulations are reformed. It can be argued that a democratic IP system should take into account a wider set of interests including those of TK holders. (Dutfield 2002: 54-60)

5.3.2 Copyright

At the international level, the idea of applying copyright law to protect intangible cultural expressions including those of traditional peoples and communities dates back to the 1960s. The term commonly applied to such manifestations of culture was not TK but folklore, or ‘expressions of folklore’. Copyright law has some fundamental limitations in the folklore context.

First, whereas copyright requires an identifiable author, the notion of authorship is a problematic concept in many traditional societies. It is sometimes argued that IPR, and copyright law especially, unduly emphasise the role of individuals in knowledge creation and consequently fail to reward those knowledgeable communities and collaborators that provided the intellectual raw material that formed the true basis for the copyrighted work or patented invention. In other words, creative expressions and collective innovations such as those of traditional communities are ineligible for protection yet may legally be treated as free inputs for industrial R&D and the copyright industries. According to this view copyright law is more likely to be used to undermine the interests of traditional peoples and communities than to promote them.

Second, copyright has a time limit: for folkloric expressions that are important elements of people’s cultural identity, it would be more appropriate to have permanent protection. But for many traditional peoples and groups certain expressions and works are central to their cultural identity and should therefore never be fully released into the public domain, at least not to the extent that others would be free to do whatever they like with them. This is not to say that copyright protection should therefore be
permanent for culturally significant expressions and works, but that copyright law should not be seen as the appropriate approach for each and every kind of cultural work.

Third, copyright normally requires works to be fixed. However, among some traditional groups, folkloric expressions are not fixed, but are passed on orally from generation to generation. This normally excludes such expressions from eligibility for copyright protection. Since communities often do not have the means of recording their cultural expressions, they cannot acquire copyright protection. However, this bar to protection can be removed with the will to do so. Several countries have incorporated protection of folkloric expressions into their national copyright laws. These include Tunisia (1967), Bolivia (1968), and Kenya (1975). But the most powerful actors in international IPR negotiations are still resistant to the idea of modifying international copyright rules to more effectively protect folklore.

Proposals to reform TRIPS to protect TK have paid little attention to copyright. Unfixed cultural expressions can to a limited extent also be protected under performers’ rights in cases where performances have been fixed without the authorisation of the original performers. TRIPS partially incorporate the 1961 Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organisations, allowing performers to prevent the recording and reproduction of their performance on a phonogram, and the broadcast and public communication of a live performance. But neither the Rome Convention nor TRIPS makes any reference to folklore.

However, the 1996 WIPO Performances and Phonograms Treaty defines ‘performers’ as ‘actors, singers, musicians, dancers, and other persons who act, sing, deliver, declaim, play in, interpret, or otherwise perform literary or artistic works or expressions of folklore’. Apart from these theoretical difficulties, there are practical obstacles, too. For example, the entity wishing to assert its copyright – or indeed to claim any other IPR – must have a legal personality. Such collective groups as rural communities
and smaller groups within communities rarely have the status of being juristic persons according to the national legal system. (Dutfield 2002: 54-60)

5.3.3 Trade Secrets

While the sharing of knowledge is common in many traditional societies, but healers and other specialist knowledge-holders as well as clans and lineage groups are unlikely to share knowledge with anybody. Conceivably, a considerable amount of TK could be protected under trade secrecy law.

An experimental project based in Ecuador and supported by the InterAmerican Development Bank is currently trying to protect TK as trade secrets. The project, ‘transforming traditional knowledge into trade secrets’, aims to enable traditional peoples and communities to benefit from bioprospecting through effective trade secret protection of their knowledge. An NGO called Ecociencia is documenting the botanical knowledge of the participating indigenous groups, and registering it in closed-access databases. If an entry is not in the public domain, the community or communities with the knowledge have a trade secret. The trade secret can then be disclosed to companies with benefit sharing guaranteed by a standardised contract. These benefits would then be distributed among the trade secret-holding communities and the Ecuadorian government. So far the database contains 8,000 entries provided by six participating indigenous groups. 60 per cent of the uses appear so far not to have been disclosed through publications. Already, three companies have expressed interest in accessing the database. Trade secrecy to be deployed as a means to protect TK and to realise its commercial potential for the benefit of the knowledge holders and their communities. (Dutfield 2002: 54-60)

5.3.4 Geographical Indications

The GI Act was required by TRIPS originally as a means to protect French makers of wines and champagnes, and gives trademark-like protection to distinctive goods or services whose quality and reputation derive from the geographical area in which they are produced. In a country
such as India, which has a vast cultural heritage and a store of traditional knowledge dating back to the Vedas, the GI Act is seen as a potentially important source of recognition and income for India's rural poor. There is also hope that GI protection will allow cultural diversity to thrive and artisans to remain in their villages, resisting the pull of city industry. Tradition is cultivated, not discovered. Developing marketable uses for Third World cultural products is "ultimately perhaps the most effective way to protect their traditions.

There is significant economic value here, although just how much is unclear. The United Nations estimates that developing countries lose about $5 billion in royalties annually from unauthorised use of traditional knowledge. But the turn to intellectual property for the poor is not simply another instance of a misguided "if value, then right" mentality. Dismissing these claims on such grounds obscures the ways in which poor people's intellectual property claims present a broader understanding of the purposes and effects of intellectual property law, beyond traditional renderings of intellectual property as incentives alone. Poor people's turn to property is surely about economics, but is about social and cultural values as well. These claims recognise that the relationship between intellectual property and development goes beyond GDP. People, rich and poor alike, want recognition of their creativity and contributions to science and culture. This capacity for innovation, work, and cultural sharing is part of what makes us human.

While the patent provisions of TRIPS have posed clear challenges for developing countries, which typically lack manufacturing capacity or capital for R&D intensive breakthroughs, GIs, in contrast, are hailed as the poor people's intellectual property rights, recognising the knowledge of weavers, farmers, and craftspeople rather than just the high technology contributions of MNCs. The structure of GIs also makes them particularly well-suited to poor people's knowledge. First, GIs recognise collective intellectual property rights; under the Indian GI Act, multiple associations of artisans may be recognised as the authorised producers or users of a GI. GI applications are also relatively cheap, at least for a group of artisans
working together. Under the Indian GI Act, it costs a modest five thousand rupees to apply (little more than $100).

India's effort to step up Geographical Indication protection for its traditional knowledge is commendable in the recent past. There is a rising tide of applications for intellectual property rights filed with a national registry established pursuant to the Geographical Indication of Goods (Registration and Protection) Act of 1999. Indian farmers and artisans from across the country were getting in line to register their wares, from Darjeeling tea to Alfonso mangoes, Kolhapuri chappals, Mysore silk and sandalwood, and the uniquely woven sarees from the village of Pochampally in the shadow of high-tech Hyderabad. Not even the makers of the famous laddus in Tirupati, who prepare these sweets for worshippers to offer to God at this popular Hindu pilgrimage site, have been immune to the frenzy.

But while GIs certainly hold promise for the poor, they have their own limits. The Indian GI Act protects goods whose quality or reputation are shown to be "due exclusively or essentially to the geographical, environment, with its inherent natural and human factors." GI applications require "proof of origin" and "historical records" of continuous use of the goods. Registrants obtain the exclusive right to use the GI, and licensing of GIs is prohibited. Such requirements and restrictions take a narrow view of traditional knowledge, linking culture to land. The rule against alienability poses special concerns. While this approach may enable people to remain within their communities (and preserve the physical environment as well), what if they move? What rights do traditional weavers from Mysore have if they move to North India—or the U.K.? Of course, there are good reasons to prevent the alienation of the GI from the particular geographical community. It prevents the scenario where a large foreign corporation hires a member of that community away and then begins to produce "authentic" work elsewhere, using that GI—and decimating the livelihoods of the traditional community left behind. At the same time, such a restriction could stifle opportunities for some individuals, as they remain within a traditional community by economic necessity, not choice. People move, intermarry, and change jobs. Culture flows with them. The GI Act does not
recognise this dynamic nature of culture, ossifying authentic production in today's localities.

Elizabeth Povinelli notes that cultural rights often lead to the ironic production of authenticity or indigeneity, which conforms to traditional structures from the past, rather than celebrating cultures as diachronic peoples who are dynamic and heterogeneous. GIs also pose economic concerns. While GIs protect Darjeeling tea, for example, they also prohibit the Indian manufacture of Scotch whiskey, driving up the cost of Scotch in India. It is possible that the poor may reap greater economic rewards in a system with fewer production constraints. Yet, it is clear that GIs do potentially offer a range of benefits, from recognising the innovation of collectives to preserving geographic diversity and stimulating some redistribution of wealth. (Sunder 2006: 298-303)

India has proposed that in order to harmonise the CBD and TRIPS, geographical indications (GI) should be expanded to protect more forms of TK. They clearly envisaged that a strong GI system would have hindered the well known neem patent in the USA. In practice, however, it is unclear how this would have been the case. TRIPS article 22 outlines that geographical indications: "...identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin." TRIPS article 23 outlines additional protection for wines and spirits. This method offers a way that rights could be maintained for an unlimited amount of time. It does not confer a monopoly right on a few individuals. Geographical indications "...reward producers that are situated in a certain region and that follow production practices associated with that region and its culture and customs. They are designed to reward goodwill and reputation created or built up by a group of producers over many years, and in some cases over centuries."

Perhaps best known for the protection of regional foods, such as wine or cheese, GI have been proposed as a method for protecting TK. It is uncertain how effective this would be in practice. Most GI are French,
where special attention is paid to products that are distinctive due to a combination of cultural and territorial factors. Regional associations have established standards for particular products. National laws' enforcement upholds the integrity of the geographical indication.

A more relevant example, used to protect indigenous products, is American Indian arts and crafts. Particularly in the case of Southwestern tribes, non-native producers were using inauthentic methods and materials to make products put forth as genuine. The state of New Mexico passed the Indian Arts and Crafts Protection Law that gives retailers the duty of determining if a product was made by a Native American by hand. Somewhat controversially, there is no test to determine whether an item was made using traditional methods. Only after examination by a retailer can it then can bear a distinctive label stating it is an authentic, hand made Indian product. As is clear with the latter point, it would be quite difficult for a non-specialist to determine if the product was made using traditional methods. However, the law acts as a barrier to imitation.

GI have a limited role for protecting Traditional Medicine, if it is clear that certain medicines originate from a particular region. In order to make geographical indications an efficient and accurate form of protection there needs to be a high level of appreciation, both in the public and in the examining authorities. In the case of French food products, one could find such expertise widely. There is still a debate regarding the correct method of manufacture for American Indian arts and crafts. A very small group of specialists have knowledge of this area, and in order to make a definitive statement there would have to be a specially constituted committee. While buyers of art may be satisfied with certification by a retailer, the situation with drugs is more complicated. There needs to be a high level of organisation to make protection feasible.

While at first sight protection using GI appears to be simple, it may be - in practice - very complicated. Committees to establish standards must be formed, and national laws must be made to enforce these standards. The system may be applicable to well established TM systems, such as in China, but may have limited coverage in other TM systems.
In addition, a patent protects an idea, not the products themselves. Patented TM could be made under license by a concern unconnected with the inventor. Even a group with limited production facilities could benefit from an invention if it held a patent. GI best suit a more extensive operation. (Eiland 2007: 73-73)

### Advantages and disadvantages of various IPRs for local communities

<table>
<thead>
<tr>
<th>IPR Type</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patent</td>
<td>• Can safeguard knowledge legally • Available in most countries</td>
<td>• Limited term of protection • Applications expensive and require legal advice • Protect knowledge of individual inventors, not collective knowledge of communities • Difficult and expensive to defend</td>
</tr>
<tr>
<td>Utility models</td>
<td>• Can safeguard knowledge legally • More traditional knowledge may be protected than under patent • Compared with patents, less-expensive application procedure and shorter and less-stringent examination</td>
<td>• Available only in a few countries • No international agreements to facilitate application in different countries • Shorter period of protection than patents</td>
</tr>
<tr>
<td>Breeders’ rights</td>
<td>• Less expensive than patents • Communities may have very large numbers of folk varieties (landraces)</td>
<td>• Folk varieties do not usually meet eligibility criteria</td>
</tr>
<tr>
<td>Copyright</td>
<td>* Easy to obtain (no registration requirement) • Long period of protection</td>
<td>• Protects expression of ideas, but not knowledge itself • Protection period not indefinite • Subject matter must be in a physical form</td>
</tr>
<tr>
<td>Trademarks</td>
<td>• Can protect collective knowledge • Inexpensive compared to patents • Indefinite protection period, although may have to be renewed periodically • May attract more customers to products of indigenous traders and trading organisations</td>
<td>• Does not protect knowledge per se</td>
</tr>
<tr>
<td>Trade secrets</td>
<td>• Can protect traditional knowledge with commercial application • Can protect more knowledge than the other IPR types • Can be traded for economic benefits by contract • Inexpensive to protect</td>
<td>• Does not protect knowledge from reverse engineering and independent discovery</td>
</tr>
<tr>
<td>Geographical indications</td>
<td>• Can protect collective knowledge • Inexpensive • Indefinite protection period • May attract more customers to products of indigenous traders and trading organisations</td>
<td>• Does not protect knowledge per se</td>
</tr>
<tr>
<td>Neighbouring rights (such as performers’ right?)</td>
<td>• Can protect folkloric performances</td>
<td>• Protection is limited in time • Protection only covers certain types of unauthorised use</td>
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</table>

5.4 Alternatives to Intellectual Property Rights

The difficulty of applying intellectual property right laws to local knowledge, innovations and practices arise from the consideration of the local knowledge as essentially cultural and community construction. Posey and Dutfield maintain that, “IPR laws are generally inappropriate and inadequate for defending the rights and resources of local communities. IPR protection is purely economic, whereas the interests of the peoples are only partly economic and linked to self-determination. Furthermore, cultural incompatibilities exist in that traditional knowledge is generally shared and, even when it is not, the holders of restricted knowledge probably still do not have the right to commercialise it for personal gain”. They advocate the concept of Traditional Resource Right (TRR) which recognises, “the inextricable link between cultural and biological diversity and sees no contradiction between the human rights of indigenous and local communities, including the right to development and environmental conservation”.

The Community Intellectual Property Rights (CIPR) were articulated by Crucible Group to enable local communities to assert their “rights to seed” such that no outside company or institution could use their knowledge or resources without their permission – a proposition which is in line with Article 8J and some aspects of FAO’s Farmers Right Concept. The Crucible Group also suggested a need for national legislation, an international database for tracing germplasm possibly through CGIAR system and appointing a `public defender’ to mediate or act as ombudsman. The Third World Network suggested a model Community Intellectual Right aimed at preventing the privitisation and usurpation of the rights and knowledge of the communities to be called as, “Community Intellectual Rights” (CIR). A `registry of invention’ was also suggested with which the community biodiversity register could be linked. This knowledge would lie in public domain. Subsequently, Ghate, Gadgil and Rao have modified the concept to include only public domain knowledge in the community registers and mentioning the name of local experts (but not their knowledge or innovations) in the register. This was in response to the suggestion by
Stephen Gudeman argues that IPR are another form of market forces which would further erode an already endangered commons. He does not believe that technical essence of a local knowledge can be abstracted from the context of its use and tested in laboratory to develop something of common use. He argues that if scientists could not validate a particular knowledge, they might consider it faulty. He observes, “The scientists draw a distinction between res cogitans (thinking being without spatial extension) and res extensa (material things as extended substance)–between the mental and the material, intellect and emotion, knowledge and context. (Gudeman 1998) Undoubtedly, what Stephen has argued has an element of truth. Large number of scientists have treated local knowledge in such a manner. At the same time, the fact that 74 percent of the plant derived human medicines are used for the same purpose for which local communities discovered their use proves that scientists have not hesitated in drawing upon the useful, valid, and abstractable local knowledge when it was appropriate. Obviously the evidence only shows how much great the potential is of using local knowledge even out of its strict socio-cultural context.

Coombs agrees with the proposal of Gupta that “every patent office in a Western country should insist that the patent applicant declare that the knowledge and resources used in a patent have been obtained lawfully and rightfully”. The lawful acquisition will imply that the prior informed consent and approval and involvement of local communities and creative individuals have been ensured, assuming that the donor country has laws requiring such consent and approval. Blakeney (1999) reviews various mechanisms for the protection of indigenous knowledge and seems to endorse the suggestion of Gollin to make it obligatory for any user of biodiversity to pay fees to the personal group that discovered or traditionally used a particular specie through access legislation. Lesser
(1998) suggested that a registry of traditional uses of genetic material be maintained in sufficient detail to permit their identification.

Swanson looks at the property right issues in the same context and observes, “existing IPR system creates incentives to invest in R&D at the end of the industry (the plant breeding sector), but is not generating investments in the earlier parts of the industry (the genetic resource providers)”. This happens, Swanson suggests, because (a) farmers in developing countries do not have property rights on their genetic resources and have no direct incentive to invest in diversity and (b) plant breeding industry located primarily in the developed world did not feel it necessary to justify their own independent investments in conservation of in-situ diversity in developing countries because of lack of control or rights over this diversity in developing countries. This formulation has obvious limitations because lack of property rights need not be the major barrier to investment in conservation of in-situ diversity. After all there is enough literature to show that common property right institutions can generate very efficient and viable outcome given three sets of appropriate rules that is dealing with (a) boundaries, (b) resource allocation and when conflict arise in implementation of both kinds of rules, then (c) rules for conflict resolution. The point still remains that seed industry need to learn ways of dealing with local institutions having customary rights rather than well defined property rights. It is true 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. For the sake of argument, one can even suggest that the users of biodiversity need to deal with current diffused status of property rights in developing countries with much greater responsibility and reciprocity rather than using this ambiguity as an excuse for not fulfilling ethical and institutional responsibilities towards conservators of diversity (given the provisions of CBD). Leisinger (1999) considers urgent evolution of binding national and international regulation as necessary for fair compensation to the gene-rich developing countries.

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5.4.1 Institutional Frameworks

WIPO has given serious consideration to the possible protection of indigenous knowledge through various forms of intellectual property rights (IPRs), including copyright, patents, plant varieties, industrial designs, and trademarks. As a practical matter, however, it may be difficult to protect traditional knowledge through IPRs due to "certain accepted notions of intellectual property relating to ownership, originality, duration, fixation, inventiveness and uniqueness," among others. (Kuruk 1999: 769-793) According to WIPO, "traditional knowledge" comprises: tradition-based literary, artistic or scientific works; performances; inventions; scientific discoveries; designs; marks, names and symbols; undisclosed information; and, all other tradition-based innovations and creations resulting from intellectual activity in the industrial, scientific, literary or artistic fields.\(^6\)

In the above definition, tradition-based refers to knowledge systems, creations, innovations and cultural expressions which: have generally been transmitted from generation to generation; are generally regarded as pertaining to a particular people or its territory; and, are constantly evolving in response to a changing environment.\(^7\) Characteristically, traditional knowledge is thus knowledge that: is traditional only to the extent that its creation and use are part of the cultural traditions of a community; "traditional," therefore, does not necessarily mean that the knowledge is ancient or static; is representative of the cultural values of a people and thus is generally held collectively; is not limited to any specific field of technology or the arts; is "owned" by a community and its use is often restricted to certain members of that community. (Gervais 2005: 141-142)

By contrast, intellectual property protection, in the form of copyrights, trademarks, designs & patents usually applies to: "An identifiable author, inventor or other originator (who will be individually rewarded); An identifiable work, invention or other object; and Defined restricted acts." Traditional knowledge does not fit well within these three

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\(^7\) Ibid.
characteristics of intellectual property rights. There are rarely well-identified authors or inventors of creations, inventions and knowledge passed on and improved from one generation to the next. The knowledge is sometimes amorphous and hard to circumscribe for the purposes of a patent application or to identify as one or more copyrighted works. Finally, the types of acts that indigenous communities want to prevent are not necessarily those that propertisation provides. For instance, benefit-sharing obligations, which can be based on ethical standards, or national or international legal norms, or a combination thereof, resemble more a liability-type regime, or perhaps a compulsory license, than a full intellectual property right, in large part because they do not include a right to exclude or prohibit. (Gervais 2005: 142-143) For example, it has been argued that IPRs are unsuitable for indigenous knowledge because they focus on individual rather than group rights, they offer protection for fixed periods of time unlike the indeterminate periods applicable to indigenous knowledge, and the requirement of a writing for protected works virtually excludes much of the indigenous knowledge that is transmitted orally through generations in traditional societies. Additionally, IPRs are expensive to obtain and the costs of enforcement high. Long and costly administrative and judicial procedures would render the IPR option unattractive for many indigenous people. (Kuruk 1999: 794-798) 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. Unlike intellectual property law, traditional knowledge is designed not to confer economic benefits to individual creators but is intended for common exploitation. "Consequently, it does not make sense to try to fit it within the rigidities of national intellectual property law." (Mugabe1998) The establishment of a sui generis regime, however, poses a number of complex conceptual and practical issues, including the definition of
subject matter of protection, goals for protection, requirements of protection, extent of rights to be conferred, the title holders (individuals or communities), modes of acquisition, and duration and enforcement measures. Presently, no internationally binding sui generis regime exists, although a number of related regional and national instruments have been developed within the past decade in part to assist national governments in complying with their obligations under the Convention of Biological Diversity (CBD). (Correa 2001: 27)

Specifically, Article 8, Section j, of the CBD calls on Contracting States to "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." In addition to "promoting their wider application . . . of such knowledge, innovations, and practices" with "the approval and involvement of the holders thereof," the CBD also encourages the equitable sharing of the benefits arising from the utilisation of such knowledge, innovations, and practices. (Kuruk 2007: 74)

Essentially, these provisions of the CBD reflect a compromise between the need by parties from the North for access to biological resources of the South versus the demands of the South to restrict such access. The balance struck was to facilitate access to biological resources while ensuring the transfer of some benefits to providers of such resources. The hope, in part, was that such returns would in turn provide the incentive for the preservation of environmentally sound practices. To the extent that mutual arrangements were envisaged as the principal mechanisms for effecting these exchanges, however, the CBD and the sui generis regional and national instruments, which implement its provisions, reflect contract-based solutions.

5.4.2 Regional Frameworks

One of the earliest comprehensive regional sui generis instruments on traditional knowledge is the African Model Law for the Protection of the Rights of Local Communities, Farmers, Breeders and Regulation of Access to Biological Resources (African Model Law) adopted by Council of
Ministers of the Organisation of African Unity (OAU) in June 1998. The African Model Law reaffirms the sovereignty of the State and people over their biological resources and provides for the establishment of a National Competent Authority to administer the instrument's provisions. Article 16 of the African Model Law recognises the rights of communities over their innovations, practices, knowledge, and technologies acquired through generations. It also recognises their right to collectively benefit from the utilisation of such resources. These community rights are to be protected in accordance with "norms, practices and customary law found in, and recognised by, the concerned local and indigenous communities, whether such law is written or not."  

To be granted access to biological resources and knowledge or technologies of local communities in any part of the country, one must apply for the prior informed consent and written permit of the National Competent Authority. The applicant must also include such details as the identity of the applicant, type and reasons for resources requested, risks in the use of the resources, benefits to the local communities, and proposed benefit-sharing arrangements. To ensure transparency, the African Model Law requires publication of the application in a public registry or newspaper. The consent of the concerned local community must also be obtained and access carried out; without local and State consent, the access is invalid. The National Competent Authority is required to verify with local communities that their consent was in fact sought and granted. Under the African Model Law, the local communities may "withdraw consent or place restrictions on activities relating to access where such activities are likely to be detrimental to their socio-economic life, or their natural or cultural heritage."  

Significantly, Article 23 of the African Model Law recognises Community Intellectual Rights, which are defined to include those rights

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9 Ibid.
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held by traditional professional groups, especially traditional intellectual property practitioners. Non-registration of any community innovations, practices, knowledge, or technologies will not disqualify protection as community intellectual rights. Neither will publication of information about biological resources or local use or presence of the resources in a genebank "preclude the local community from exercising its community intellectual rights in relation to those resources." The communities are guaranteed a right to at least fifty percent of the access permit fees to be shared equitably with "the full participation and approval of the concerned local communities."

Like the African Region, the Pacific Region has developed a sui generis framework entitled Model Law for the Protection of Traditional Knowledge and Expressions of Culture (Pacific Model Law). The Pacific Model Law recognises as traditional owners and as holders of traditional cultural rights individuals, clans, or groups in whom the custody or protection of the traditional knowledge or expressions of culture is entrusted in accordance with customary law and practices. Such traditional cultural rights are inalienable, perpetual in duration, and valid whether or not the underlying traditional knowledge or expressions of culture are in material form. The rights are considered to be supplementary to, and therefore, not to affect any rights that may subsist under intellectual property law. In addition to traditional cultural rights, the owners also enjoy moral rights in traditional knowledge. (Kuruk 2007: 76-77)

Under the Pacific Model Law, certain uses of traditional knowledge and expressions of culture are subject to the prior and informed consent of the traditional owners. To obtain such consent, an application must first be addressed to the Cultural Authority required to be created under the Pacific Model Law. Upon receipt of the application, the Cultural Authority is authorised to publish it in the national newspapers and to endeavor to identify and notify the relevant owners of the traditional knowledge that is the subject-matter of the application.

Rights-holders, if interested in the proposal, could at this stage enter into negotiations with the applicants over the terms of access to, or
use of traditional knowledge. Although any agreement reached between the applicant and the traditional group is subject to review by the Cultural Authority, the traditional owners may accept, reject, or modify any comments made by the Cultural Authority after its review. If traditional knowledge is to be used for a commercial purpose, the agreement must contain a benefit-sharing arrangement providing for equitable monetary or non-monetary compensation to the traditional owners. (Kuruk 2007: 77-78)

The Pacific Model Law makes it a criminal offense, punishable by a fine or jail term, to use traditional knowledge in a non-customary manner (whether or not of a commercial nature) and in relation to which the required prior and informed consent has not been obtained. In addition, civil suits can be brought by the traditional owners in relation to such non-customary use of traditional knowledge for remedies including injunctive relief, damages, seizures, and accounting for profits. The term "customary use" is employed in this context to mean "the use of traditional knowledge or expressions of culture in accordance with the customary laws and practices of traditional owners." Significantly, while the Pacific Model Law envisages a resort to the national court systems to resolve disputes concerning traditional knowledge, it states quite categorically that it does not preclude the use of customary law and practice as a dispute resolution mechanism. (Kuruk 2007: 78)

In September 2000, the Andean Community adopted Decision 486 on a Common Intellectual Property Regime, which sought to create a sui generis system for traditional knowledge. Under Decision 486, the Andean Community member states undertook to safeguard and respect "their biological and genetic heritage, together with the traditional knowledge of their indigenous, African American, or local communities." The Decision also recognises "the right and the authority of indigenous, African American, and local communities in respect of their collective knowledge."10

The Decision requires any application for a process or product patent obtained from or developed on the basis of the traditional knowledge of the indigenous, African American, or local communities to contain a benefit-sharing arrangement providing for equitable monetary or non-monetary compensation to the traditional owners. (Kuruk 2007: 78)

knowledge of indigenous, African American, or local communities in the member states to include written proof from a member country of authorisation to use such knowledge. It also provides for the invalidation of patents based on such knowledge but in respect of which proper evidence of authorisation was not provided at the time of the application. Furthermore, unless an "application is filed by the community itself or with its express consent," the Decision bars from registration as trademarks, signs that "consist of the name of indigenous, African American, or local communities, or of such denominations, words, letters, characters, or signs as are used to distinguish their products, services, or methods of processing, or that constitute an expression of their culture or practice."\(^{11}\)

5.4.3 National Frameworks

In addition to the regional frameworks discussed above, some national measures are equally noteworthy. For example, a legislation on the intellectual property rights of indigenous communities of Panama subjects "the rights of use and commercialisation of the art, crafts and other cultural expressions based on the tradition of the indigenous community, to . . . the regulation of each indigenous community approved and registered in the DIGERPI or in the National Copyright Office of the Ministry of Education." For purposes of the law, indigenous collective rights means "indigenous intellectual and cultural property rights law relating to art, music, literature, biological, medical and ecological knowledge and other subject matter and manifestations that have no known author or owner and no date of origin and constitute the heritage of an entire indigenous people."\(^{12}\)

On its part, Ecuador's Law on Intellectual Property of 1998 provides that protection given to industrial property should ensure the protection of the country's biological and genetic heritage. The 1998 Law also conditions the grant of product or process patents that relate to such heritage on the

\(^{11}\) Ibid.

legal acquisition of elements of the heritage from the relevant traditional owners.\textsuperscript{13}

In 1997, the Philippine Congress passed the Indigenous Peoples Rights Act to "recognise and promote all the rights of Indigenous Cultural Communities/Indigenous Peoples (ICCs/IPs)," including "the rights of ICCs/IPs to preserve and develop their cultures, traditions and institutions." The Act recognises rights of indigenous peoples to ancestral domains, self-governance and empowerment, social justice and human rights, and cultural property. With respect to cultural property, the Act affirms the right of ICCs/IPs to the full ownership and control and protection of their cultural and intellectual rights.\textsuperscript{14}

Under the Philippine Act, access to biological and genetic resources and to indigenous knowledge related to the conservation, utilisation, and enhancement of these resources is permitted within ancestral lands and domains of the ICCs/IPs "only with a free and prior informed consent of such communities, obtained in accordance with customary laws of the concerned community." As used in the Act, the term "free and prior informed consent" means "the consensus of all members of the ICCs/IPs to be determined in accordance with their respective customary laws and practices, free from any external manipulation, interference coercion, and obtained after fully disclosing the intent and scope of the activity, in a language and process understandable to the community."

The Philippine Act guarantees ICCs/IPs the right to practice and revitalise their own cultural traditions and customs and obligates the State to "develop the past, present and future manifestations of their cultures as well as the right to the restitution of cultural, intellectual religious, and spiritual property taken without their free and prior informed consent or in violation of their laws, traditions and customs." The Act also recognises the right of ICCs/IPs "to practice and teach their spiritual and religious traditions, customs

and ceremonies; the right to maintain, protect and have access to their religious and cultural sites; the right to use and control of ceremonial objects; and, the right to the repatriation of human remains." (Kuruk 2007: 80)

5.5 Traditional Cultural Expression and Self Determination

Michael Blakeney (2006) considers the protection of traditional knowledge assumes the necessity for this protection and also assumes that the primary beneficiaries of this protection will be Indigenous peoples and community groups. However, the state as guardian of its people’s cultural heritage, also has an interest in the preservation of the traditional knowledge which exists within it. A corollary to the assumption of the necessity to protect traditional knowledge, is the assertion of the right of Indigenous peoples and traditional communities “to determine the appropriateness of the use being made of their culture”. Thus Erica-Irene Daes (1993) states that “each indigenous community must retain permanent control over all elements of its own heritage. It may share the right to enjoy and use certain elements of its heritage under its own laws and procedures, but always reserves a perpetual right to determine how shared knowledge is used”. For Fourmile (1989) Indigenous peoples in Australia regard the protection of traditional knowledge as an issue of self-determination.

So far, 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. Most of the world's remaining biodiversity exists within indigenous lands and territories. Rather than as an aspect of state sovereignty over territory, or the fruits of private invention, indigenous leaders conceive of these resources as an aspect of self-determination, as a recognition of their fundamental rights to property and culture. Indigenous groups are thus trying to expand the discourse over biological resources so that it includes their interests and their hopes for wresting back control over their territories, resources and heritage.
This effort is critical because while the tug of war may currently be between TRIPS and CBD over whether to assign ownership of these resources to individuals or states, both of these regimes potentially conflict with indigenous claims and aspirations to group ownership of these same biological materials. To date, their success has been muted. Indigenous peoples find themselves in direct conflict not only with states but also with multinational corporations—all vying for control over traditional knowledge, land and resources. As has happened throughout history, aboriginal peoples are too often finding themselves on the losing end of this struggle over ownership and access to resources. (Bratspies 2006-2007: 318-319)

5.5.1 The Relevance of Customary Law

Common to the sui generis instruments just surveyed is the requirement to ascertain and enforce traditional knowledge in accordance with the practices of indigenous groups. Customary law, as the system of rules and customs that governs conduct and rights in such groups, would therefore be relevant to any analysis of rights and obligations under traditional knowledge provided for under the sui generis models.

The scope of customary law rules can be traced to the structure of indigenous societies. In Australia, for example, Aboriginal customary rules have evolved based on social relations with the family as the basic social unit. Kinship relations in Aboriginal societies involve rights and obligations with respect to such matters as "marriage and private arrangements, food gathering, distribution and sharing of the other goods, certain trading relationship and educational roles." Aboriginal customary law also recognises procedures for the conduct and resolution of disputes, and "responsibilities for land and for objects and ideas associated with land." (Obilade1979: 83)

In general, customary laws are not uniform across ethnic groups in indigenous societies. Differences in the customary laws of indigenous groups can be traced to such factors as language, proximity, origin, history, social structure, and economy. Generally, the customary law rules among ethnic groups speaking a common language tend to be similar, but the rather significant differences that can sometimes exist make it misleading to
talk of a uniform customary law rule applicable to all members of the language group. (Allott & Cotran 1971: 32)

An important characteristic of customary law is its dynamism. Customary law is not static, and its rules change from time to time to reflect evolving social and economic conditions. As noted in one judicial decision, "one of the most striking features of native custom is its flexibility; it appears to have been always subject to motives of expediency, and it shows unquestionable adaptability to altered circumstances without entirely losing its character." Like any system of unwritten law, customary law has a capacity to adapt itself to new and altered facts and circumstances as well as to changes in the economic, political, and social environment. (Cotran & Rubin 1970)

Similar elements are found in the definitions of folklore, traditional knowledge, and indigenous knowledge, suggesting a link with customary law. In relation to folklore, it has been noted that "descriptions of the amorphous term folklore tend to emphasise its diverse nature, as consisting of, for example, the traditional customs, tales, sayings, or art forms preserved among a people," applicable "not only to ideas, or words, but also to physical objects." Other characteristics of folklore include "its oral nature, group features, and mode of transmission through generations of people." (Kuruk 1999: 776-77)

With respect to the use of the term indigenous knowledge as alternative terminology, one can distinguish between a broad and narrow meaning, with the former for all practical purposes being equated with traditional knowledge. (Simpson 1997: 22-23) Therefore, like customary law, all these definitions focus on rights of particular ethnic groups and practices that are constantly evolving and not static. In this sense customary law on the one hand, and traditional knowledge and indigenous knowledge on the other, are interrelated. Accordingly, one cannot seek to understand traditional knowledge without reference to customary law which is the system within the scope of rights in such knowledge is determined.

5.5.2 Customary Law Principles

The link just noted between traditional knowledge and customary law confirms the relevance of customary law as the primary regulatory
mechanism over uses of traditional knowledge. This link also suggests that solutions to traditional knowledge issues drawn from customary law are likely to be more successful than the western oriented top-down approaches reflected in current international instruments on traditional knowledge. (Riley 2005: 90)

First is the recognition that indigenous groups own or have rights of custodianship over indigenous resources. Accordingly, the African Model Law provides for the rights of communities over their innovations, practices, knowledge, and technology acquired over generations. The Pacific Model Law emphasises the rights of individuals, clans, and groups as owners and holders of cultural rights. Such formal recognition is significant because it confirms the primacy of rights of indigenous groups to traditional knowledge and relegates to a secondary right any claim the State may purport to assert in relation to traditional knowledge. It also clarifies the rather tenuous basis of claims in some international instruments that purport to provide for State "sovereign" rights in traditional knowledge.15

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. The African Model Law incorporates this principle by noting that community rights are to be "protected under the norms, practices and customary law found in, and recognised by, the concerned local and indigenous communities."16

Given the objective under the sui generis models to mitigate the problems posed by the application of intellectual property criteria to traditional knowledge, the model laws permit deviations from established IP criteria where necessary to effectively protect traditional knowledge.

16 Ibid, art-17.
For example, the African Model Law tackles the bias evident for "individuals" under intellectual property law by emphasising instead the "collective" nature of indigenous rights in traditional knowledge. To remedy the problem caused by the IP requirement that protected matter be recorded or reduced to some form of writing, the sui generis models dispense with such a requirement altogether. Thus, traditional knowledge would be protected under the African and Pacific Model Laws whether or not it is in writing or material form. (Ekpere 2000: 11)

Another difference between IP and customary law taken up in model laws is the duration of rights. Unlike the limited period of protection for IP rights, customary law rights in traditional knowledge are held for an indefinite period. Accordingly, the Pacific Model Law provides that such rights "continue in force in perpetuity." (Kuruk 1999: 798) While there is a general disposition under customary law to allow free use of traditional knowledge under notions of reciprocity, the right to such use is not automatic. Access to traditional knowledge could be denied on account of the sacred secret nature of an item or simply out of a desire of the indigenous group not to commercialise it. The right to refuse access as an important means of protecting traditional knowledge is also incorporated into the sui generis models. The African Model Law not only recognises this right, but like the Pacific Model Law, provides elaborate rules on prior informed consent to ensure that indigenous groups have sufficient information on proposed uses of traditional knowledge to make a decision on whether or not to grant access. Even where approval has been granted, such consent can be withdrawn for reasons including the failure to comply with the conditions of the grant or unauthorised uses of traditional knowledge. (Janke 1998: 21)

Significantly, the sharing ethic, which is part of the concept of reciprocity, imposes an obligation on the individual who benefits from the exploitation of communal property or rights to pass on some of the benefits from the exploitation, either in the same form or in kind to other members who may require such assistance. Because this sharing ethic has been threatened by exploiters who have taken undue advantage of
indigenous groups by not rewarding them appropriately for uses of traditional knowledge, it is imperative that a protective scheme based on customary law incorporate some form of benefit-sharing arrangement. (Correa 2001: 5-6)

The scheme should require that a portion of the benefit obtained from access to traditional knowledge be assigned to indigenous groups to be applied in accordance with traditional practices. Also, such benefits need not be in monetary terms only; they could include in-kind arrangements such as the construction of schools, hospitals, or roads to benefit traditional communities. Accordingly, the Pacific Model Law provides for equitable monetary or non-monetary compensation, while the African Model Law guarantees indigenous groups at least fifty percent of the benefits gained from the utilisation of indigenous resources.17

Regarding the enforcement of these rights and obligations, the expectation under the African Model Law is for the enforcement of rights and obligations in accordance with traditional practices. The Pacific Model Law contemplates use of national courts but does not preclude a resort to customary dispute resolution mechanisms. Unfortunately, both model laws do not elaborate on the enforcement mechanisms under customary law. For an understanding of the effectiveness of customary law in protecting traditional knowledge, relevant issues surrounding such mechanisms must be clarified. (Kuruk 2007: 87) 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.

5.6 The Indian Experience

5.6.1 Biodiversity under Constitutional Framework

The world look at India with wonder as there are little parallels elsewhere that can boast of such rich biodiversity in terms of mountain ranges, forests, grasslands, water bodies, rivers, marine wealth and deserts. Imagine the beauty of the rain forest in the Silent Valley of Kerala and the dense untouched forests in Arunachal Pradesh. Or the vast Chilka lake in Orissa that pans out for nearly 1,14,000 hectares that supports numerous forms of marine life apart from catering to thousands of livelihoods. The extent of micro-organisms has not even been assessed. India may have only 2.4 per cent of the world's area, but it has over eight per cent of the world's biodiversity (Ramesh Menon 2006).

India’s biodiversity encompass a wide spectrum of habitats from tropical rainforests to alpine vegetation and from temperate forests to coastal wetlands. India figured with two hotspots - the Western Ghats and the Eastern Himalayas - in an identification of 18 biodiversity hotspots carried out in the eighties. In addition, India has 26 recognised endemic centres that are home to nearly a third of all the flowering plants identified and described to date. India contributes significantly to this latitudinal biodiversity trend.

The endemism of Indian biodiversity is high. About 33% of the country's recorded flora are endemic to the country and are concentrated mainly in the North-East, Western Ghats, North-West Himalaya and the Andaman and Nicobar islands. Of the 49,219 plant species, 5150 are endemic and distributed into 141 genera under 47 families corresponding to about 30% of the world's recorded flora, which means 30% of the world's recorded flora are endemic to India. Of these endemic species, 3,500 are found in the Himalayas and adjoining regions and 1600 in the Western Ghats alone. About 62% of the known amphibian species are endemic with the majority occurring in the Western Ghats. Nearly 50% of the lizards of India are endemic with a high degree of endemcity in the Western Ghats. India is a centre of crop diversity - the homeland of 167
cultivated species and 320 wild relatives of crop plants. India's record in agro-biodiversity is equally impressive. There are 167 crop species and wild relatives. India is considered to be the centre of origin of 30,000-50,000 varieties of rice, pigeon-pea, mango, turmeric, ginger, sugarcane, gooseberries etc and ranks seventh in terms of contribution to world agriculture.¹⁸

The economic significance of Indian biodiversity can be gauged by the fact that the domestic trade in medicinal herbs and its extracts is to the tune of Rs. 3 billion and is increasing. The medicinal herbs are extracted by the local people and reach the industry, through middle men, to be utilised for production of value added natural products (Anil K Gupta 2000).

India has not done well to conserve its rich biodiversity, which is considered most diverse in the world. The National Bio-Diversity Action Plan says 41 per cent of India's forest cover is at different levels of degradation and the country is making limited use of its vast gene pool in agriculture and livestock, thereby creating a risk of food security. The Environment ministry released a comprehensive document detailing the major areas of concern for India's biodiversity and the proposed action plan to check further degradation and conserving biodiversity (Chetan Chauhan 2007). Biodiversity must be protected not only for purely ecological reasons but because it sustains livelihoods. Biodiversity in agriculture helps millions eke out a living. It helps people get food, jobs, nutrition, bio-pesticides, traditional medicine, housing material, fodder and fuel. That is not all. It helps stabilise the climate, improve rainfall and enrich the soil and water table. Life cannot go on without biodiversity.

India has already lost more than forty per cent of its forests, mangroves and a large part of its wetlands. Adding to the problem are destructive trade practices, poor remuneration for indigenous food grain and cereals, demographic changes due to development and poor planning that sidestepped the importance of biodiversity. There were also

¹⁸ “Biodiversity,” at http://static.teriin.org/biodiv/biodiv.htm#case
unsustainable methods being adopted that ignored traditional management practices. It would be a rewarding idea to document traditional knowledge before it is lost and use it to save resources that are being eroded. One evocative example is of how our forefathers protected biodiversity by declaring some areas as sacred groves. As they were sacred, it was worshipped and left alone. Hundreds of years ago, they had the vision of how important species of plants and animals would be destroyed if they did not devise some ingenious way. So, they declared habitat rich areas as sacred groves. As it had a spiritual value, it got cared for and protected (Ramesh Menon 2007).

5.6.1 Biodiversity under Constitutional Framework

The Constitution of India is the fountain of law in the country. The Eleventh Schedule appended to the text of the Constitution, lists over a score of subjects on which the local village body may take decisions on, these include agriculture, land reforms, soil conservation, water management and maintenance of community assets. The 1996 Panchayat Act extends this vision of self-government to tribal areas in India. The law has the potential to empower local village communities to make decisions on their biological resources, and to be “consulted” on decisions regarding developments on their lands. Beyond the 1996 Panchayat Act, additional measures are required to provide villages with more substantive input in the decision-making process. Mere consultation is not tantamount to meaningful participation.

Apart from the legal changes in India, local communities have taken other actions to assert their sovereign rights over local biological resources. One such endeavour is that of the Jaiv Panchayat - The Living Democracy Movement, wherein villagers have even issued letters in protest to multinational corporations such as Monsanto, RiceTec and W.R. Grace for attempting to pirate their local biodiversity-related knowledge and claiming ownership rights to this knowledge through patents. Also, across many parts of tribal India, there have been movements towards “tribal self-rule,” and many villages have simply taken back de facto control over forests and water bodies that had once
been usurped by the state or by non-tribals. Then there are the widespread movements against destructive development projects such as major dams, industries, and infrastructure, and against over-exploitation of the seas in the name of export-oriented fisheries development. As far as domestic legislation on biodiversity is concerned, the 1972 Wildlife (Protection) Act is the most noteworthy. This law essentially deals with wild flora and fauna, also providing for national parks and sanctuaries as protected areas.

Though several amendments have been made to the legislation since its inception, it still does not deal with the entire range of genetic and biological resources. After the Constitutional Amendment in 1976 making the administration of forest law a concurrent subject, the 1980 Forest Conservation Act was enacted. This law intended objective is to check deforestation and impose restrictions on dereservation of reserved forests or use of forestland for non-forest purposes.

Following the Stockholm Conference, in 1986 Indian enacted general legislation entitled the Environment Protection Act. The Act empowers the Central government to take all such measures as it deems necessary for protecting and improving the quality of the environment and preventing, controlling and abating environmental pollution. It is under this rule-making power that in 1989 the Government issued the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells, which to date comprises India’s biosafety law. These Rules must be updated pursuant to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, signed by India on 23 January 2001. There is an urgent need to bring the Rules up to date with the international scientific knowledge, information and experience on biotechnology.\(^\text{19}\)


N. N. Prasad, joint secretary, Department of Industrial Policy and Promotion said: "The Intellectual Property Rights (IPR) issues regarding traditional knowledge, genetic resources and folklore cannot be dealt with a singular kind of thinking. Developed countries need to build a sense of
confidence among developing countries who would like to see these aspects included in the Substantive Patent Law Treaty."

"India is willing to share with its digital knowledge library on 170,000 traditional medicines with the USPTO and its European counterpart on the condition that it should not be put in the public domain," Prasad said. But the US is insisting that such a database be made public because as per its laws patents, if any such prior knowledge is in public domain, it can be cited against the patent applicant to ensure that patents are given only for completely new inventions.

First secretary for Intellectual Property at the US Embassy in New Delhi, Dominic Keating said, "Washington believes that including new disclosure requirements in IPR laws may be detrimental to innovation. In addition, it would not be an effective means to ensure prior informed consent, access to genetic resources and equitable benefit sharing (Economy Bureau 2008)."

5.6.2 Bio-piracy in India

5.6.2.1 The Indigenous in India

The term "indigenous" describes tribes or semi-tribal populations in independent countries who lived in the country prior to colonisation or conquest by immigrants from outside the country or geographical region in question. These populations became increasingly marginalised after the conquest, which gradually led these people to develop particular social, economic, and cultural lifestyles distinct from those of the national mainstream. Adivasis, as the indigenous are understood in India, were not the original settlers of the regions in which they are found now. It is also difficult to make the claim that they were the only original inhabitants of India prior to the arrival of Aryans and that they have never migrated. Furthermore, not all of these communities have been marginalised or subjugated by the mainstream population, and the immigrant colonial populations that initially dominated some of these groups are no longer present. Hence there exists significant academic debate in India regarding the usage of the term "indigenous" and corresponding non-recognition of
the same under domestic law. As a result, despite the cultural and intellectual property rights of indigenous peoples finding recognition in international human rights instruments and in specific declarations of indigenous people, the application of these instruments in the Indian context is problematic. (Xaxa 1999: 3590-91)

"Indigenous knowledge" is interchangeably referred as "traditional knowledge," "local knowledge," "traditional ecological knowledge," "folklore," "traditional bio-cultural contribution," and "traditional bio-cultural knowledge." Broadly speaking, indigenous knowledge is knowledge developed by local people through direct interactions between human beings and nature. It is knowledge that the locals use in their everyday lives as they strive to sustain their livelihoods. (Maragia 2006: 203-204)

TK is created and shared by the members of local communities. It is the fruit of an intergenerational process, whereby generations pass on their cultural heritage which continuously grows. There is no need to commercially trade TK within the indigenous communities, there is no fear of such knowledge being stolen, and thus local people have not been compelled to codify it in a written form (WIPO 2003).
## Bio-piracy of India’s Traditional Knowledge

1. Basmati Rice: patented by RiceTec, Texas, USA in 1997 as aromatic rice. Recently on challenge by APEDA, withdraw four claims of its uniqueness. The use of the term ‘Basmati’ by RiceTec was also challenged on the inappropriate trademark usage (Texmati) and violation of Geographical Indication. However, the International Centre for Technology Assessment (ICTA, Washington, DC) and Research Foundation for Science, Technology and Ecology (RFSTE, New Delhi) have filed a suit to restrict the use of the term Basmati (and Jasmine of Thailand) to rice varieties grown in India and Thailand, respectively.

2. Turmeric: Patent granted to University of Mississippi Medical Centre (for wound healing) in the US, was revoked on challenge by CSIR.


4. Karela, Jamun and Brinjal: Patent granted to Cromak Research Inc., US on edible herbal compositions comprising the mixtures of the above to reduce sugar levels.


6. Aswagandha: patent granted to Relive International Inc. as a supplement for healthy joints. US patent office also granted a dozen patents on Aswagandha-centred findings.

7. Herbal Products: amla, vasabhr, saptrangi, bel etc Natreon Inc was granted patents for 13 claims of Amla by US patent Office, application also filed with European Patent Office.


    It may be granted that the Indian Patent granted to Agaracetus of the US on tissue culture of cotton cells was revoked in public interest in view of mounting criticism from the farmer community in India on its impact on the farming of major crop in India.

5.6.2.2 Tumeric

<table>
<thead>
<tr>
<th>Patent Number</th>
<th>Description of Invention</th>
<th>Year Issued</th>
</tr>
</thead>
<tbody>
<tr>
<td>5,401,504</td>
<td>Use of turmeric in wound healing</td>
<td>1995</td>
</tr>
<tr>
<td>5,494,668</td>
<td>Method of treating musculoskeletal disease and a novel composition therefore</td>
<td>1996</td>
</tr>
<tr>
<td>5,897,865</td>
<td>Turmeric for treating skin disorders</td>
<td>1999</td>
</tr>
<tr>
<td>6,048,533</td>
<td>Turmeric for treating health ailments</td>
<td>2000</td>
</tr>
<tr>
<td>6,200,570</td>
<td>Herbal formulation useful as therapeutic and cosmetic applications for the treatment of general skin disorders</td>
<td>2001</td>
</tr>
<tr>
<td>6,224,871</td>
<td>Dietary supplement for nutritionally promoting healthy joint function</td>
<td>2001</td>
</tr>
<tr>
<td>6,264,995</td>
<td>Herbal composition for reducing inflammation and methods of using same</td>
<td>2001</td>
</tr>
</tbody>
</table>


In 1995, the US patent office granted a patent (5,401,504) for tumeric (curcuma longa) for the 'invention' of wound healing. The applicants were a team of two scientists (expatriate Indians) from the University of Mississippi. The plant was well known in India for both culinary use and as a traditional medicine. The Council of Scientific and Industrial Research in India challenged the patent. It was invalidated for lack of novelty by the USPTO, who cited prior art in Indian TK. This is the earliest example of a successful challenge to a patent based on TK. (Eiland 2007: 62)
5.6.2.3 Neem

The people of India have made use of the medicinal properties (azadirachta indica) of the neem tree for more than 2000 years. More than 135 compounds have been isolated from the Neem tree since 1942, when nimbin from neem oil was first isolated. (Moyer-Henry 2008, p.3) The term azadirachta indica is known in Sanskrit as sarva-róga nívarini or "curer of all ailments" because the tree and its seed-oil have been used to produce chemicals with pesticidal, agricultural, medicinal, contraceptive, cosmetic, and dental applications. A few decades ago, the neem tree attracted the interest of foreign biotechnology and pharmaceutical companies, interested in its manifold practical applications. (Arewa 2006: 155-170) In the early 1970s, biologists and ethnobotanists moved to India to investigate the neem tree's attributes, observing and studying how local people utilised the tree. Thus, the fruits of the scientists' work-based on local heritage, i.e., the indigenous species and the community's traditional knowledge--led to the patenting of a wide variety of products. (Marden 1999: 279) Indeed, not only have Western companies come to understand the value of resources that indigenous communities have studied and cherished over centuries, but they have come to comprehend the value of the communities' traditional knowledge. (Jay McGown 2006)
### Chronology of Commercialisation of Neem Biopesticide

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1985</td>
<td>Robert Larson receives patent for stable neem extract.</td>
</tr>
<tr>
<td>1989</td>
<td>W.R. Grace buys Larson’s patents, trademarks, and registrations.</td>
</tr>
<tr>
<td>1991</td>
<td>Grace awards license to sell neem-based products to Ringer Corp., which will focus on home/gardening market.</td>
</tr>
<tr>
<td>1992</td>
<td>Agridyne goes public after receiving EPA registrations for Azatech and Azatin</td>
</tr>
<tr>
<td>1992</td>
<td>Ringer begins selling Neemix and Bioneem to gardeners through mail-order channels</td>
</tr>
<tr>
<td>1993</td>
<td>Grace announces joint venture with P.I. Mar go Pvt. Ltd. (Kamataka, India) to build first commercial facility for producing neem biopesticides. Margo Blocontrols is the subsidiary dealing with neem and other biopesticides. Demonstrations begin against Grace in India.</td>
</tr>
<tr>
<td>1993</td>
<td>Agridyne announces joint venture with Tata Oil Mills (Bombay). It receives a patent on a neem-extract purification procedure (5,229,007) and EPA registration for Align (agricultural market).</td>
</tr>
<tr>
<td>1993</td>
<td>Hindustan Lever Ltd. (a subsidiary of Unilever PLC) purchases Tata Oil Mills from the Tata Group. (Hindustan Lever holds a 1991 Indian patent on neem extraction.)</td>
</tr>
<tr>
<td>1994</td>
<td>Agridyne receives its second U.S. patent for neem extraction (5,352,697) and licenses its neem patents to Rohm &amp; Haas. (Rohm &amp; Haas presently holds four Indian patents on neem products or processes.) Agridyne announces agreement with Fa mam Companies to market animal husbandry biopesticides.</td>
</tr>
<tr>
<td>1994</td>
<td>Grace and Agridyne engage in a legal quarrel over patent infringement.</td>
</tr>
<tr>
<td>1995</td>
<td>Grace and Agridyne settle patent dispute. Grace licenses patents 5,001,146 and 5,124,349 to Agridyne.</td>
</tr>
<tr>
<td>1995</td>
<td>Blosys buys out Agridyne.</td>
</tr>
<tr>
<td>1996</td>
<td>Grace sells biopesticides division to Thermo Ecotek, which folds it into its new subsidiary, Thermo Trilogy.</td>
</tr>
<tr>
<td>1997</td>
<td>Blosys declares bankruptcy and sells assets to Thermo Trilogy.</td>
</tr>
<tr>
<td>1998</td>
<td>Ringer changes its name to Verdant Brands, which sells products under a variety of brand names.</td>
</tr>
<tr>
<td>2000</td>
<td>Verdant Brands sells its retail products division to Wood stream: it continues to market commercial products through the Consep subsidiary.</td>
</tr>
<tr>
<td>2000</td>
<td>Thermo Electron announces that Thermo Trilogy is a “non-core” business and seeks buyer.</td>
</tr>
<tr>
<td>2001</td>
<td>Mitsui purchases Thermo Trilogy and creates a subsidiary, Certls, to produce and sell pesticides.</td>
</tr>
<tr>
<td>2001</td>
<td>Verdant auctions off Consep’s assets and ceases operations.</td>
</tr>
<tr>
<td>2001</td>
<td>Grace files for Chapter 11 bankruptcy protection because of asbestos-related claims.</td>
</tr>
</tbody>
</table>

Indian texts dating back two millennia states that neem could be used as an insect repellent, medicine, and cosmetic. W.R. Grace & Co. - Conn. filed patent applications covering a hydrophobic extract of the neem tree, an oil, for use as an insecticide and fungicide. The chemical called Azadirachtin was identified as the active substance. A process to stabilise this chemical in water was patented, as was the stabilised form of the chemical. The foreign patents therefore drew a rapid response from India. (Marden 1999: 279)

5.6.2.4 The Neem Patent at the EPO

The European Patent Office (EPO) did not uphold the granting of the patent; it rejected it for lack of inventive step. Article 52(1) of the Munich Convention states that patents are granted on the basis of novelty, inventive step, and suitability of industrial application. Novelty is determined in relation to the state of the art, which according to Article 54(2) of the Munich convention means "...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." Unlike the case for the US system, where there is a clear division between information originating inside and outside the state, there is no such distinction here. The EPO can consider prior art that could be embodied orally or in practice, and not simply according to printed sources. These provisions clearly protect TK, the bulk of which is not written. In the neem case, however, the EPO did not consider TK rights per se. (Eiland 2007: 64)

5.6.2.5 Geographic Disparity in US Patent Law

The patent on the chemicals derived from neem was upheld in the US. Indian TK did not serve as prior art. While some authors have suggested that it is unconstitutional for the US to retain geographic disparity in its patent laws, (Bagley 2002: 679) other authors note that by not allowing foreign material to serve as prior art, there is an incentive to commercialise products in the USA. This could lead to compensation for the keepers of TK through contract law. Under this view, the US does not allow patents to encompass what is in the public domain, but instead encourages the development of products that may otherwise remain undeveloped.
In the case of neem, this would lead to the products derived from the plant being available to European customers only in the US but at 'monopolistic' pricing levels. Those in favor of geographic disparity would suggest: It is reasonable to assume that, absent a geographic distinction (i.e. absent patent rights), a pharmaceutical firm would not invest millions of dollars in commercialisation efforts, thus depriving all consumers. Moreover, exploiting the patent in the rich United States market could lead to significant profits that would form part of a benefit sharing arrangement. (Nard, 2003: 910) The fear is that Grace's patent in the US will deny Indian access to the US market. This may in turn allow Grace to control the cash-crop market of neem in India, as well as potentially bidding the price of neem seed beyond the reach of competitors. (Kadidal 1997: 401)

There are arguments both for and against the retention of geographical disparity in US patent law. However, it is clear that the framers of the law were concerned with the development of innovation in the US. In 1836 they did not envisage that the disparity could allow a US company to effectively control the world wide market in a product, such as could be said for neem. While such a monopoly could effectively develop a product, there is a great risk that such a position in the market could be abused.

5.6.2.6 Neem Patent in New Zealand

The New Zealand Patent Office had also issued an equivalent patent to the EPO. The main difference is that the standard of novelty is determined according to prior publication in New Zealand. Unless the TK has been published in that country, there can be no countering the claim for lack of novelty. The neem patent in New Zealand was not revoked. This has raised a number of problems in New Zealand where a large indigenous community with extensive oral traditions exists.20

In 2000, the government of New Zealand began a review of the Patents Act of 1953. In March 2002, the document Boundaries to

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Patentability was released. Information from submissions was incorporated into the Patents Act Review on 28 July 2003. On 20 December 2004 a Draft Patents Bill was released for public consultation and submissions closed on 11 March 1995. A main goal of the proposed act is to tighten the procedures for granting patents, particularly by more rigorously determining what could be considered a valid invention. The previous 'presumption of patentability' has been removed and has been replaced with a 'balance of probabilities test'.

The Draft for Consultation Patents Bill Part 1:3:c specifically addresses: "Maori concerns relating to the granting of patents for inventions derived from indigenous plants and animals or from Maori traditional knowledge..." and 1:3:e specifically notes that the patent regime of NZ should take into account international developments. This sets the stage for the most significant departure from current practice in New Zealand. According to patent law, an invention is "novel if it does not form part of the prior art base." The prior art base is determined: ...in relation to an invention so far as claimed in a claim, means all matter (whether a product, a process, information about a product or process, or anything else) which has at any time before the priority date of that claim been made available to the public (whether in New Zealand or elsewhere) by written or oral description, by use, or in any other way.

This introduced an absolute standard of novelty, not one just based on what is published in New Zealand. The revised legislation would clearly include the TK from India as part of the prior art. Unlike European legislation, TK is clearly in mind under the proposed legislation in New Zealand. The bill is still being debated to minimise the risk of unintended consequences.

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22 Ibid.
23 Ibid.
5.6.3 Major Legal Initiatives

5.6.3.1 The Protection of Plant Varieties and Farmers Rights Act of 2001

After independence, the government of India adopted a model of confining plant breeding to the public sector to address national food security issues. The model succeeded when at the end of the 1970s, India graduated from being an importer to achieving self-sufficiency in food. (Gopalakrishnan 2002: 157-158)

India's move toward promoting agricultural trade was partly prompted by the entry of foreign seed corporations into the Indian market in the early 1980s, which gave rise to demands for IP protection. Thus, the Protection of Plant Varieties and Farmers' Rights Act (PPVFA) is generally perceived as an outcome of the pressures from India's membership in the WTO, as well as entry of foreign corporations into the market. India, however, chose a sui generis structure to protect plant varieties with a view to balancing the interests of all players in the national agricultural trade. (Ragavan & O'Shields 2007: 114)

India, with a view to fulfill its TRIPS obligations, passed the Protection of Plant Varieties and Farmers Rights Act of 2001 (PPVFA). The Parliament passed the Protection of Plant Varieties and Farmers' Rights Act in 2001. Criteria for the registration of new plant varieties include novelty, distinctiveness, uniformity, and stability. Applications must be made to the Registrar-General of Plant Varieties; applications that comply with the requirements of the Act are advertised. Opposition to the registration must be made within three months of advertisement; the applicant has two months to respond. If there is no opposition, or if the opposition is rejected, the variety is registered in the Plant Varieties Registry and an official certificate given to the applicant. For registration of essentially derived varieties, the Registrar must forward the application and supporting documents to the Protection of Plant Varieties and Farmers' Rights Authority for examination. If the Authority is satisfied that the essentially derived variety has been derived from the initial variety, it directs the Registrar to register the new variety.
Chapter V

The term of protection is nine years for trees and vines and six years for other crops, renewable for a further nine years (for extant varieties of trees and vines, or a total of 15 years for annual crops from the date of notification under the Seeds Act 1966). However, under Chapter VI of the Act, a farmer is entitled to save, use, sow, resow, exchange, share or sell his farm produce, including seed (except branded seed), of a variety protected by the Act.

The Act represents a sui generis attempt to balance the rights of farmers and breeders, considering the huge farming population in the country. The term sui generis refers to systems engineered to meet the unique needs of a particular country or nation. The TRIPS agreement blesses such a form of protection for plant varieties by deviating from the norm of harmonising IP rights. Thus, Article 27.3 of TRIPS embodies flexibility to protect plant varieties via "patents or by an effective sui generis system or by any combination thereof." (Bodeker 2003: 790)

In enacting the PPVFA, India, like other developing nations, took advantage of the Article 27.3 flexibilities by embracing a sui generis regime. India's PPVFA was noticed by the rest of the world for two reasons. First, it highlighted the complexity of farming in the developing world, which requires balancing the interests of the variety of actors involved in agricultural trade. Second, flaws notwithstanding, the PPVFA presented an alternative model to UPOV for poorer nations. Presumably, the PPVFA was passed because India hoped to benefit by introducing PBRs. With a view to compliment the PPVFA, the Ministry of Agriculture introduced a Seeds Bill in 2004 to encourage seed trade to promote the seed industry, boost exports, and protect seed quality. While TRIPS does not require governments to regulate seed trade, the passing of the PPVFA perhaps necessitated a review of the existing framework governing seed trade (The Seeds Bill 2004).

The central tenet of the PPVFA is to address India's national concerns about protecting the rights of traditional farming communities, while at the same time promoting plant breeding by vesting IP protection. Thus, the PPVFA lumps plant varieties into three protectable categories: (a) New
Varieties, (b) Extant varieties, which refer to existing varieties discovered for the first time, and (c) Farmers' Varieties, based on community property concepts.24

The distinction of PPVFA lies in the registration regime, which enables protection for new varieties while at the same time recognizing the role of local farmers. For instance, every application for registration must include a denomination of the variety and describe (1) the geographical origin of the material, and (2) all information regarding the contribution of the farmer, community, or organisation in the development of the variety. Further, the application must state that all genetic or parental material used to develop the variety has been lawfully acquired. Moreover, section 40 requires the breeder to disclose information "regarding the use of genetic material conserved by any tribal or rural families in the breeding or development of such new variety." The information in the application is meant to facilitate benefit sharing, a system discussed below, introduced to protect farmers rights. Unlike UPOV, the PPVFA bears a set of public interest exceptions to registration of a new variety. A new variety, for instance, becomes unregisterable if it is likely to deceive the public, hurt the religious sentiments of any class or section of Indians, or cause confusion regarding the variety's identity, or is not different from every denomination which designates a variety of the same botanical species or of a closely related species registered under the Act.

The extant variety typology itself was introduced to protect traditional knowledge and indigenous rights. The extant variety register serves as a compilation of matters known and existing in the public domain. In essence, an extant variety encompasses a farmer's variety, or a variety about which there is common knowledge, or a variety in the public domain, as well as any variety included under section 5 of the Seeds Act. (Ragavan & O'Shields 2007: 115-116) An extant variety may be registered by a breeder, farmer, a community of farmers, a university, or a public sector. Although a breeder can register an extant variety, he is not entitled to

exclusive rights over the variety. Section 28 of the Act provides that the
Government, as the owner of the extant varieties, enjoys the rights to
determine their production, sale, marketability, distribution, importation or
exportation. The objective is to protect biodiversity by empowering the
government to negotiate with entities that require biodiversity materials for
creating biotechnology innovations.  (Ragavan & O'Shields 2007: 115-116)

A "farmers' variety" is one "which has been traditionally cultivated
and evolved by the farmers in their fields, or is a wild relative or land race
of a variety about which the farmers posses the common knowledge." The
manner of stylising protection of farmers' variety reflects a keen sense of
consideration for community and traditional rights by including provisions
for benefit sharing, community compensation, immunity from prosecution
for innocent infringement, and the creation of a Gene Fund to collect
breeders' annual fees. However, while a farmer can be a breeder qualifying
to register a new variety, a community of farmers that creates a new
variety, for instance, will not qualify for registration of the breeders'
variety. The breeders' variety is based on the western notion of IP rights.
The important aspect of a farmers' variety is not to appease farmers, but to
create community property rights in contrast to the breeders' variety.
(Ragavan & O'Shields 2007: 117-118)

The Act also provides for benefit sharing. Once the certificate of
registration is issued, the Authority publishes the contents of the certificate
and invites claims of benefit sharing in the registered variety; claims are
accepted only from Indian citizens or institutions established in India. The
breeder may submit an opposition to the claim. Moreover, any person or
group of persons may, on behalf of any village or local community in India,
file a claim attributable to their contribution to any new variety (Section 41).

Compulsory licences may be granted after three years from the date
of issue of the certificate of registration. A request may be made to the
Authority on the grounds that the reasonable requirements of the public for
seed or other propagating material of the variety have not been satisfied or
that it is not available to the public at a reasonable price. The term of a
licence will be determined by the Authority, who must ensure reasonable
compensation to the breeder (Section 51). The compulsory licence can also be revoked or modified by the Authority at any time. No compulsory licence has been granted so far.

Appeals against decisions by the Authority or the Registrar can be made to the Plant Varieties Protection Appellate Tribunal. The Tribunal, which has not yet started functioning must, to the extent possible, reaches a decision on an appeal within one year.

Infringement is defined as: the sale, export, import or production of a protected variety without the permission of its breeder or within the scope of a registered licence without the permission of the registered licensee or agent; or the use, sale, export, import or production of any other variety that is given an identical or deceptively similar denomination of a variety registered under the Act so as to cause confusion. The penalty for applying a false denomination is imprisonment for between three months and two years and/or a fine of Rs 50,000 to Rs 500,000. The penalty for selling varieties to which a false denomination is applied is imprisonment of between six months and two years and/or a fine of Rs 50,000 to Rs 500,000. The penalty for falsely representing a variety as registered is imprisonment of between six months and three years and/or a fine of Rs 100,000 to Rs 500,000. Repeat offences are liable to imprisonment of between one and three years and/or a fine of Rs 200,000 to Rs 2 million. No case of seizure or infringement has been reported.

5.6.3.2 Indian Bio-Diversity Act 2002

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. The Committee's focused primarily on protection and explored possibilities for future legislation. This meeting gave impetus to the Biological Diversity Act 2002, which specifically addresses TK. Broadly, it seeks to regularise access to genetic materials on the one hand, while protecting TK on the other. It provides for more centralised decision-making. Chapter 3 of the act gives exclusive rights to the Central government in the form of the National Biodiversity Authority (NBA) to be located in Chennai, although
regional offices can be established with permission of the Central Government. Thus, local offices can address community needs. (Srividhya Ragavan 2001: 272)

Chapter 2 (6:1) of the Bio-diversity Act establishes that no person shall apply for an IP right by whatever name in or outside of India for any invention: "based on any research or information on a biological resource obtained in India" without prior approval of the NBA. If a person applies for a patent, permission of the NBA may be obtained after the patent's acceptance but before the sealing of the patent by the patent authority. The Act clearly covers TK with the inclusion of the phrase 'information on a biological resource.' Chapter II (2) of the Bio-diversity Act establishes that while approval may be granted, the NBA may: "...impose benefit sharing fee or royalty or both or impose conditions including the sharing of financial benefits." This provision clearly follows the benefit sharing provisions of 8(j) of the CBD.

The new act has also drawn criticism in that even an Indian citizen or company registered in India will have to obtain permission in order to utilise biological resources according to Chapter II (7). Chapter II (7) states this will not apply to local communities as well as those practicing TM. Nevertheless, the fear is that this may in fact prevent basic research by non-local groups (such as universities) in India. The controlling body apparently holds that while domestic companies will have to register with authorities, no up front payment will be involved. Benefit sharing will be negotiated on a case by case basis. (Jyothi Datta 2002)

Chapter 5 (4) of the Bio-diversity Act states that the NBA shall give public notice of every approval for use of biological resources. This public scrutiny serves as a safety valve to allow other right holders to come forward. This is in keeping with India's proposal to revise the TRIPS agreement. (Kruger 2001:169) The Bio-diversity Act clearly signals India's intention of asserting rights to both biological resources and TK. It specifically addresses the problem of foreign companies patenting Indian TM.

The overall effect of the act remains to be determined. If the law is too restrictive it could hamper research with burdensome administrative
procedures. At best, however, it could protect national sovereignty in biological resources, including TK. While it is designed to protect the needs of local communities, the structure of the NBA suggests it will be more of a government organ. This being said, in an increasingly international environment it may require considerable resources to challenge the validity of US patents, as the neem controversy demonstrates. (Eiland 2007: 63)

5.7 Summary

Protection of biodiversity associated resources has been the central theme of sustainable development. Agriculture, pharmaceuticals, forestry, fisheries, and tourism are all key areas that are heavily dependent upon biodiversity, attracting the attention of industry researchers and investors. Management of biological resources has a profound effect on biodiversity and the ecological services that sustain life. Application of biotechnology for production purposes has had revolutionary effect on the use and transformation of biodiversity associated resources.

A cursory examination of the stock of biodiversity reveals that it is located mostly in the global south. The countries in Asia, Africa and South America account for major chunk of such resources. The region's countless varieties of plants and trees are viewed as a treasure trove of genetic material with innumerable potential applications. The knowledge of pan genetic resources and its application in almost all walks of production have stimulated unprecedented raise for access, possession and control by multinational companies, research laboratories, universities and various other stake holders. The value of biodiversity associated resources in the global market astonishingly high which would suggests that recent surge in bioprospecting.

Indigenous communities and local have been the custodians of biodiversity associated traditional knowledge and resources. However, the commercial application of such resources has come to threaten not only the reckless exploitation of such resources but have become an affront on the very traditions livelihood and culture of Indigenous communities.
Most legal regimes award the mantle of "property," with its attendant rights, only to the tangible goods produced by indigenous cultures, paying no attention to the contexts in which those goods were produced and used. This compartmentalisation under the western Cartesian worldview in a way facilitates the transfer of wealth from indigenous cultures to multinational corporations. However, these patents raise benefit sharing issues, because the raw material often comes from developing countries, while the resulting profit from the patent remains with the developed world corporation that performed the research. Some developing countries also have moral and cultural objections to patents on living organisms viewing this as theft and labeling it "bio-piracy," because developed countries did not recognise IPR in wild PGRs or TK bodies of know-how and skills that have been developed by local communities over generations.

Globalisation has exponentially increased the chances of acquiring first-hand information about the knowledge that indigenous peoples have and the intrusion of western styles in their traditional cultures and the exploitation of natural resources in their territories—a typical behavior of the western actor—have produced emigrations as well as the consequent subsuming of indigenous peoples as a whole. TK about ecosystems, specifically regarding medicinal plants and animals, has become the "green gold" of transnational corporations, representing increasingly important economic advantages for just a few.

Ethnobotanical knowledge is a foundation for the pharmaceutical and other related industries but benefit-sharing arrangements are comparatively rare. There is large outcry from the indigenous people that the scientific community uses their knowledge to amass millions of dollars from the market without their consent and proper return. In the recent past, this process has been legitimised with the institutionalisation of IPR. So there is direct link between biodiversity associated knowledge and market as the scientific community heavily depended on former for the new lead.

From this viewpoint, TK solves a market failure problem by providing incentives to invest in potential paths of research. Indigenous
creation of TK is not driven by the incentives of a market economy; local communities do not aim at obtaining exclusive rights to exploit their innovations, as such knowledge is generally shared within the community. There is a merit in recognising the dynamic interplay that exists between the contours of creativity within TK 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 is also true that with increase in population, general health and education levels, the ability of traditional systems to sustain the economic and social aspirations may not be easy.

Some aspects of TK systems contain most of the elements that make a scientific proposition valid. TK is differentiated from formal Western knowledge on the following characteristics. First, TK is transmitted through oral traditions, such as songs, idioms, and riddles. Second, TK is "embedded in culture and is unique to a given location or society." Indigenous knowledge, therefore, is dynamic and varies within and between societies as well as within and between generations. Third, TK is holistic. It is both "a way of life" and a "worldview" which defines the relationship between individuals and the community as well as humans' relationships vis-à-vis nature, place, and spirituality.

TK in pedagogic sense is a way of knowing of a community or a culture. This knowledge is considered indigenous despite being contemporary. In order to cope with the complexity of ecological change, some people in the community specialise by knowing more and more about less and less. Such specialised expertise requires focusing, targeting and steering strategies on specific themes or aspects of nature. Hence, there is a need for rewarding not only TK but also contemporary innovations. It is indigenous because the meanings as well as the categories of sense making are generated internally within a cultural community.

It is very important to understand that different indigenous and local communities develop knowledge systems through oral languages. Hence, the conservation of language or oral tradition become a crucial factor for conserving taxonomies because each word, conceptually speaking in the
context of a natural resource, is a category. There is no reason why negotiations on geographical indications should be restricted only to wines and not include TK as well as contemporary innovations of local communities and individuals.

But can patent law actually provide promising solutions? WIPO has given serious consideration to the possible protection of TK through various forms of IPR, including copyright, patents, plant varieties, industrial designs, and trademarks. As a practical matter, however, it may be difficult to protect TK through IPR due to problems fitting TK into "certain accepted notions of IP relating to ownership, originality, duration, fixation, inventiveness and uniqueness," among others. 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 rarely if ever taken into account when patent regulations are reformed. The difficulty of applying IPR laws to TK, innovations and practices arise from the consideration of the TK 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 true 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 IPR and TK, the case has been made for the development of a sui generis regime specifically adapted to the nature and characteristics of TK. The argument for adopting a separate instrument for TK is based on the recognition that TK is created, owned, and utilised differently. The establishment of a sui generis regime, however, poses a number of complex conceptual and practical issues, including the definition of subject matter of protection, goals for protection, requirements of protection, extent of rights to be conferred, the title holders (individuals or communities), modes of acquisition, and duration and enforcement measures.
One of the earliest comprehensive regional sui generis instruments on TK is the African Model Law for the Protection of the Rights of Local Communities, Farmers, Breeders and Regulation of Access to Biological Resources (African Model Law) adopted by Council of Ministers of the Organisation of African Unity (OAU) in June 1998. The African Model Law reaffirms the sovereignty of the State and people over their biological resources and provides for the establishment of a National Competent Authority to administer the instrument's provisions. Like the African Region, the Pacific Region has developed a sui generis framework entitled Model Law for the Protection of Traditional Knowledge and Expressions of Culture (Pacific Model Law). The Pacific Model Law recognises as traditional owners and as holders of traditional cultural rights individuals, clans, or groups in whom the custody or protection of the TK or expressions of culture is entrusted in accordance with customary law and practices. In addition to traditional cultural rights, the owners also enjoy moral rights in TK.

In September 2000, the Andean Community adopted Decision 486 on a Common Intellectual Property Regime, which sought to create a sui generis system for TK. Under Decision 486, the Andean Community member states undertook to safeguard and respect "their biological and genetic heritage, together with the TK of their indigenous, African American, or local communities."

In addition to the regional frameworks discussed above, some national measures are equally noteworthy. For example, Panamanian legislation on the intellectual property rights of indigenous communities subjects "the rights of use and commercialisation of the art, crafts and other cultural expressions based on the tradition of the indigenous community, to the regulation of each indigenous community approved and registered in the DIGERPI or in the National Copyright Office of the Ministry of Education." Ecuador's Law on Intellectual Property of 1998 provides that protection given to industrial property should ensure the protection of the country's biological and genetic heritage. In 1997, the Philippine Congress passed the Indigenous Peoples Rights Act that recognises rights of indigenous peoples
to ancestral domains, self-governance and empowerment, social justice and human rights, and cultural property.

So far, the 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 TRIPS agreement. There is, however, a third aspect to this struggle over TK 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. Both of these regimes potentially conflict with indigenous claims and aspirations to group ownership of these same biological materials.

Customary law, as the system of rules and customs that governs conduct and rights in such groups, would therefore be relevant to any analysis of rights and obligations under TK provided for under the sui generis models. Aboriginal customary law also recognises procedures for the conduct and resolution of disputes, and "responsibilities for land and for objects and ideas associated with land." An important characteristic of customary law is its dynamism. Customary law is not static, and its rules change from time to time to reflect evolving social and economic conditions. Accordingly, one cannot seek to understand TK without reference to customary law which is the system within the scope of rights in such knowledge is determined. The link just noted between TK and customary law confirms the relevance of customary law as the primary regulatory mechanism over uses of TK.

This link also suggests that solutions to TK issues drawn from customary law are likely to be more successful than the western oriented top-down approaches reflected in current international instruments on TK. As a corollary to this fundamental right of ownership, custodianship, or other relevant right in TK 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.
Unlike the limited period of protection for IP rights, customary law rights in TK are held for an indefinite period. Accordingly, the Pacific Model Law provides that such rights "continue in force in perpetuity." 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.

There have been several cases of bio-piracy of TK from India. It includes, as discussed in this chapter, the misappropriation of resources related Indian herbal plants such as neem, turmeric, Aswagandha, Karela, Jamun, Brinjal, etc. Many of these claims with minor modifications in methods of extraction and processing could amount to bio-piracy of the centuries old TK of Indian system of medicine. There is also the view that the TRIPS Agreement permits patenting of organisms that encourages 'bio-piracy'. Whilst the corporations stand to make huge revenues from this process, the local communities are unrewarded and in fact face the threat in future of having to buy the products of these companies at high prices.

In this regard the legislative initiatives made in India especially the Protection of Plant Varieties and Farmers Rights Act 2001 and Biodiversity Act 2002 merit serious attention. The PPVFA was appreciated by various stake holders especially for its classification of plant varieties into three protectable categories: (a) New Varieties, (b) Extant varieties, and (c) Farmers' Varieties. The extant variety typology itself was introduced to protect traditional knowledge and indigenous rights. Section 28 of the Act provides that the Government, as the owner of the extant varieties, enjoys the rights to determine their production, sale, marketability, distribution, importation or exportation. The objective is to protect biodiversity by empowering the government to negotiate with entities that require biodiversity materials for creating biotechnology innovations. The Act also provides for benefit sharing which may provide ample scope for protection of biodiversity related traditional knowledge in India.
In brief, the discussion in this chapter reveals that there is ample scope for devising appropriate regional and national regulatory framework for the protection of biodiversity associated traditional knowledge. Having learned from its own experience in bio-piracy, India has initiated certain solid measures PPVFA, Biodiversity Act and TKDL. However, legal initiatives need to be supplemented with adequate administrative and participatory measures.