CHAPTER V

INTELLECTUAL PROPERTY (IP) PROTECTION OF BIODIVERSITY RELATED TRADITIONAL KNOWLEDGE IN INDIA

5.0. Introduction

The Biodiversity associated Traditional Knowledge has been one of the most contentious issues/concerns in the contemporary debates on intellectual property rights. The concerns are found to emerge from the lack of consensus on how to protect indigenous resources, as also due to the complexities involved in defining and classifying such resources within the framework of Intellectual Property Rights. Further, the IP protection of Traditional Knowledge acquired critical significance, rather emerged as a problematic area, in wake of the conclusion of the International Agreements such as the CBD and the TRIPS.

With the growing demands for the bio-products in the recent decades, commercialization of the Traditional knowledge associated with the biodiversity has been on growing pace all over the world. The erosion of the TK and bio-resources has adversely affected the livelihoods of Traditional Knowledge holding societies and also caused serious threat to the biodiversity. Hence the need for the protection of Traditional Knowledge and bio-resources has been raised and has become a topic of international debate. India and other Third World countries are bio-rich countries, the region’s countless varieties of plants, trees, and genetic material have innumerable potential applications. The knowledge of pan stimulated unprecedented race for access, possession and control by multinational companies, research laboratories, universities and various stakeholders. The value of biodiversity associated resources in the global market is astonishingly high, which would suggest the recent surge in bio-prospecting.
Intellectual property rights especially related to the protection of Biodiversity and Traditional Knowledge have been marred by the overlapping of the various Conventions. The highest level of divergence in this regard has been related to the TRIPS Agreement and the CBD. This Chapter shall review the Indian experience in the protection of Biodiversity associated Traditional Knowledge. Here, efforts have been made to examine as to how India has ensured compliance with TRIPS provisions on the one hand and initiated various legislative, legal, institutional and administrative measures taking recourse to the beneficial provisions in the CBD, such as Access and Benefit Sharing, Prior Informed Consent.

5.1. The Biodiversity associated TK: Issues and Challenges

Developing countries call for the harmonization of the Convention on Biodiversity and the TRIPS Agreement, so as to compel persons applying for IP protection over plant varieties to disclose information relating to; the source of origin of the plant varieties, proof that the indigenous community from which the TK originates consents to its exploitation, and that an Access and Benefit Sharing Agreement has been reached with the indigenous community, as required by the CBD and the Nagoya Protocol. This position is rejected by developed countries. The only logical explanation for this opposition by the latter may be that they encourage, and want to continue with bio-piracy (Dountio, 2009).

The Agreement merely allows individual countries the laxity to decide on how to protect plant varieties, making no allusion the CBD. Hence, developing countries, individually, are confronted with a problem that requires international cooperation to resolve. It is not as though developing countries are not capable of seeking solutions to their problems, the drawback lies in the fact that TK protection is an issue that concerns every country. Consequently, there is need to establish a bottom line on how these

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two blocs will make use of TK and equitably benefit there from, failing which the weak will lose to the strong as is the case today (Dountio, 2009).

5.1.1. Bio-prospecting and Bio-piracy: The Global Scenario

Though the term Bio-prospecting was in discussions for a long time, Bio-piracy is a new term, mostly controversial, that emerged in the wake of the CBD and TRIPS. Bio-prospecting is defined as the exploration of wild plants and animals for commercially valuable genetic and biochemical resources. Bio-prospecting is a fair enterprise based on certain legal conditions and benefit sharing. Bio-prospecting can help medical and other scientific research by collecting biological samples. Bio-piracy, on the other hand, occurs when corporations use the folk wisdom of indigenous people to locate and understand the use of medicinal plants and then exploit this knowledge commercially. Bio-piracy refers to the misappropriation and monopolisation of a traditional population's knowledge and biological resources, including the smuggling of diverse forms of plants and animals. Bio-piracy results in traditional populations losing control over their resources (Song, 2005). The term has gained popularity in use only over the past decade. Prior to that, research expeditions occurred regularly with the purpose of finding, collecting, and making use of the rich abundance of biological diversity worldwide with little to no legal repercussions (Gollin, 2004).

A rational definition of 'bio-piracy' would focus on activities relating to access or use of genetic resources in contravention to national regimes based on the CBD. Accordingly, a legitimate claim of bio-piracy will involve unauthorized access to a controlled genetic resource and using that resource in a manner that contravenes the national regime. In practical terms, this means that (a) the activity in question occurred after the CBD came into force and (b) the acts consist of a party gaining access without the consent of the source country, or in contravention to laws or regulations governing access to or use of genetic resources that the country has established (Ghidini, 2007).
This concept of bio-piracy stands in stark contrast to the claims of bio-piracy that are made with ever-increasing frequency by certain groups. For these groups, bio-piracy consists of an innovator gaining access to some genetic resource, making an invention, and filing a patent application. Indeed, some groups make lists of ‘examples’ of bio-piracy that consist merely of patent applications. It is hard to see how the filing of a patent application can, in itself, amount to bio-piracy (Ghidini, 2007).

The filing of a patent application presumes that something beyond the information relating to the genetic resource has been developed; namely, an invention. By attacking the innovative process itself, including efforts to obtain intellectual property protection for inventions arising out of the use of genetic resources, these groups will ultimately prevent or deter parties from even attempting to create benefits that could be shared under the CBD model. The CBD may require equitable sharing of the benefits from such an invention; if this does not take place, this could then reasonably be termed bio-piracy. However, the wrong does not lie in filing the patent application, but in failing to deal fairly with the parties that helped to create the opportunity for innovation (Paul, 2009).

### 5.1.2. A Case of Bio-piracy

The instances of Bio-piracy and its legitimisation through legal sanctions in the Developed Countries, and the US in particular have been quite disturbing to bio-rich developing countries. In 1980, the Supreme Court of the United States indirectly addressed the question of whether bacteria qualified as patentable subject matter. The Court explained that the relevant consideration was whether the invention was the product of human intervention. This decision paved the way for future applications containing eukaryotic organisms. The PTO adopted the policy of addressing patentability on a case-by-case basis according to the precedent established in Chakrabarty (Diamond Vs. Chakrabarty 447.US.303(1980)). Chakrabarty, a genetic engineer employed by General Electric, developed a bacterium from the genus Pseudomonas that was capable of breaking down crude oil. It was
suggested that the bacterium could be used for treating oil spills. With the organism originally rejected by the PTO as unpatentable subject matter, the issue eventually went to the Supreme Court. Ultimately, in a 5-4 ruling, the Court held in favour of Chakrabarty, stating alive, human-made micro-organism is patentable subject matter under Title 35 USC 101. Respondent's micro-organism constitutes a 'manufacture' or 'composition of matter' within that statute. Just because the subject matter of the patent is a living organism does not bar the subject matter from patent protection. In other words, the Court's holding set the stage for future courts as well as the PTO to give wide scope to their interpretation of patent laws (Henry, 2008).

The Supreme Court decision in Chakrabarty was vital for the progress of the biotechnology industry. The industry uses an abundance of natural discoveries, particularly living organisms, in most of the new products it develops each year. From pharmaceuticals to agricultural engineering, the active ingredients behind many of the most remarkable inventions are from plants and organisms discovered in the diverse ecosystems of smaller, less developed countries. Company representatives travel to remote locations looking for "undiscovered" traditional medicine that could possibly be commercialised for profit (Henry, 2008).

Indeed, in the ten years following Chakrabarty's victory, patents were extended in rapid order to isolated and purified genetic sequences, to man-made plants, and to animals. By the turn of the millennium, raw biological material increasingly moved from an open access or global commons good to a private or government-owned good (Safrin, 2007).

5.1.3. North-South Division and other Issues

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 tend 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). Furthermore, the indigenous communities are typically excluded from sharing results of the subsequent research. Often, no agreement between the countries takes place at all (Boyle, 1996). In some cases, the bond between TK and genetic resources is evident, 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 another 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). 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).

5.2. Intellectual Property Protection of Traditional Knowledge

One of the most contentious areas in the negotiations under the WTO and the CBD is on the matters related to the protection of biodiversity associated traditional knowledge. As a matter of fact, protections of such resources have been confronting a severe crisis primarily due to the provisions for
patenting of life forms enforced by the TRIPS Agreement. These provisions have found a place in the TRIPS Agreement primarily due to revolutionary breakthrough in the biotechnology industry which are under the monopoly control of multinational companies based in United States and Europe. It has been rightly argued that the challenges posed by biotech multinational companies have redefined the very notion of security (Sharma, 1995).

The rapid growth of the biotechnology industry over the past two decades led many countries to recognise the vast economic potential of their genetic resources and indigenous knowledge with increasing demand for new biotechnological products. The global community is struggling to strike a balance between the interests of host countries, who seek remuneration for supplying genetic resources and traditional knowledge, and biotechnological inventors, who are pressing for free access, open markets, and stronger intellectual property rights protection (Sharma, 1995).

Industrialised countries, seeking to maintain incentives for new innovations through a strong intellectual property rights regime, viewed the wishes of many developing countries to assert sovereign control over their resources as barriers to free trade. (Sharma, 1995) In contrast, many developing countries viewed intellectual property rights as a tool for industrialised countries and multinational corporations to gain free access to their resources without sharing in the benefits derived from these resources. (Lesser, 1998) Consequently, developing countries began to assert their sovereign right to control the resources within their territorial jurisdictions.

Pharmaceutical corporations and Agribusiness companies increasingly rely upon these resources to engineer new drugs and genetically modified crops for sale in the international market. Developing countries, home to over eighty percent of the world's biodiversity, have become hotbeds for bioprospectors, searching for the next big breakthrough in medicine or agriculture. As a result of the high stakes involved in this multi-billion dollar industry, the global community, in seeking to facilitate the equitable
sharing of benefits, is struggling to strike a balance between the interests of biological suppliers and biotechnological inventors (Straus, 2000).

The Convention on Biological Diversity and the Agreement on Trade-Related Aspects of Intellectual Property Rights mirror the conflicting views of industrialised and developing countries concerning intellectual property rights. Industrialised countries view the CBD with a suspicious eye, as it precariously balances the sovereign rights of states with intellectual property protections. In turn, developing countries often viewed TRIPS as a tool for affording multinational corporations access to their resources without sharing in the benefits derived from them (Straus, 2000).

The conflict over intellectual property rights is partially the result of an unequal distribution in the location and wealth of the world's global biodiversity (Sharma, 1995). As a general rule, the richness in biodiverse natural resource is inversely related to latitude. Thus, the majority of the world's biological wealth is concentrated in the temperate regions of the globe (Kothari, 1994). Estimates indicate that nearly eighty percent of the raw genetic inputs used in biotechnology are from tropical developing countries (Straus, 2000). The uneven distribution of the earth's biological resources, coupled with the superior technology, economic leverage, and monopoly scientific knowledge of developed countries, have resulted in serious inequities in the global biotechnology trade.

5.2.1. The TRIPS, CBD and the IP Protection

As we discussed in the previous Chapter, the TRIPS Agreement, enforced in 1994, is capable of radically reshaping intellectual property law, especially with regard to genetic resources and biodiversity. Negotiations for the TRIPS agreement were an exhaustive process, and in the end both developed and developing countries compromised. Nonetheless, the TRIPS radically changed the face of international IP law. The TRIPS agreement provided "minimum standards for legal recognition of intellectual property rights" that were basically the standard levels already in place in most developed countries (Loew, 2006).
Indeed, the TRIPS was intended to standardise these differences in intellectual property protection between the nations of the global north and the global south. Because the United States, the European Union, and, to a lesser extent, Japan wield tremendous influence in the WTO, their voices drew the most attention in the process of drafting the TRIPS agreement. These nations were, in turn, influenced by the commercial interests of their corporate citizens. In fact, the TRIPS agreement was drafted and introduced in the Uruguay Round of the GATT by an American industry coalition, the Intellectual Property Committee (IPC), which conducted what it called "missionary work" to sell the idea to the international community (Bratspies, 2006).

The WTO negotiations succeeded in reshaping international trade because the process bundled previously unrelated areas into a single take-it-or-leave-it package. To participate in the global economy, states had to agree to abide by all the agreements that make up the WTO. Among the mass of terms were new intellectual property standards. By linking specified levels of intellectual property protection to previously unrelated trade issues, such as labour and environment, the TRIPS negotiation forced developing countries to sign on to higher standards of intellectual property protection than their state of development would otherwise have dictated (Salazar, 2000).

The TRIPS Article 27, entitled "Patentable Subject Matter," requires marked changes in the domestic patent law of many states. Under Article 27.1, states must ensure that patents "shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."

The most controversial portion of the TRIPS Agreement, Article 27.3, includes plants and animals within the inventions eligible for patenting or develop a sui generis plan for protecting these inventions (Bratspies, 2006).

According to the WTO, intellectual property rights are the rights given to people over the creations of their minds. Yet, the way TRIPS has been structured is against indigenous groups to claim any intellectual property
rights over the unmediated products of their traditional knowledge. As a result, indigenous and traditional knowledge is consigned to the global commons. This produces a striking imbalance, in the sense that modern scientific inventions are considered property and eligible for the full monopoly of TRIPS protections, while the creations of the mind of indigenous peoples are not (Bratspies, 2006).

In brief, the TRIPS Agreement made many promises for facilitating the equitable transfer of technology to developing countries. Although strengthened intellectual property protection enabled a handful of developing countries to obtain greater FDI than before the TRIPS Agreement, the overall impact of TRIPS on technology transfer has been dismal. Despite the predictions of many economists and scholars alike that increased intellectual property protection will result in technological development both domestically and abroad, the fruits of this transfer have yet to provide any substantial gains for most developing countries (Maskus, 2000).

The CBD represents a global framework aimed at protecting biodiversity. Although this agreement is largely an international treaty aimed at promoting the sustainable use of environmental resources, it also possesses important economic aspects that impact the application of intellectual property rights on the inputs of the biotechnological industry. The CBD approaches conservation based on the theory that what is perceived as having economic value tends to be used more efficiently, thus promoting the sustainable use of depletable resources (Lesser, 1998).

For many decades Developed Countries have combated the counterfeiting of their products abroad. They have called pirates all the foreign enterprises, no matter whether big or small, who reverse engineered and copied their intellectual creations in order to form their own industrial capacity and skills and decrease the technological gap dividing developed and developing countries. But ironically enough, the biodiversity and traditional knowledge (TK) issues seem to reverse the roles in the game. Almost all industrialised countries do not have Peru’s plant varieties or anything like the Indian Neem
tree, not to mention any shamanic knowledge associated to those natural resources (Ghidini & Arezzo, 2006).

The problems in the protection of biodiversity and TK stems from the circumstance that foreign researchers and scientists, backed by their own governments, take such resources without permission, and without granting any truly equitable sharing of benefits flowing from production of biodiversity-based drugs to the indigenous people, nor to their governments. Indeed, not only local natural resources and knowledge generate huge amount of profits to the exclusive benefit of such companies, but also, as Professor Boyle has pointed out, they often go back to their country of origin embedded in strong patents that impede the very local communities, who have long studied and cherished them, to keep using their own heritage and scientific culture (Ghidini & Arezzo, 2006).

The best way of protecting those communities in a way consonant to the principles expressed by the Convention on Biological Diversity is to grant them some form of entitlement to protect their tangible and intangible knowledge against its misappropriation. As already mentioned in the previous chapters, in 1992 the United Nations Conference on Environment and Development convened in Rio de Janeiro and created the CBD. Generally, the CBD established sovereign national rights over biological resources and committed member countries to conserve them, develop them sustainably, and share the benefits resulting from their use (Gervais, 2004).

Over the centuries, many samples of unique genetic resources have been taken from their original country of origin to collections in industrialised nations. Many unique biological resources have yet to be catalogued or even discovered. These resources, which are concentrated in developing countries of high biodiversity, remain in demand as sources of leads for new products, or for scientific collections. (Laird & Kate, 2002) This demand has led many biodiversity rich developing countries to exercise their rights over biological resources established by the CBD by enacting national laws and rules to protect their resources. The extension of developing countries’ laws to require
informed consent and benefit-sharing as preconditions to access to biological resources has resulted in contractual arrangements between biodiversity source countries and biotechnology and pharmaceutical corporations seeking access to the biological resources. These agreements are variously referred to as either biodiversity prospecting agreements or access and benefit sharing agreements (Gollin, 1999).

While national legislation relating to biological resources and biodiversity prospecting agreements is intended to protect countries' rights to their biological resources, it has also added new legal complexities. Intellectual property experts have not been extensively involved in the establishment of such rules, with the result that they are of limited practicality. While some biodiversity prospecting agreements may be fairly straightforward, many provide negotiated royalty payments in exchange for access and sample collection, and other agreements involve complex negotiations regarding the sharing and value of locally acquired and/or pre-existing indigenous knowledge regarding a developing country's biological resources (Barber et al., 2002). The source countries may place a high value on these contracts in monetary, environmental, and political terms. Thus, legal representation that can adequately and appropriately handle the intellectual property issues that arise in the context of biodiversity prospecting agreements is crucial.

The concerns of developed and developing countries resulted in various concessions that are reflected throughout the text of the CBD. In Article 16, for example, the CBD consistently acknowledges the importance of intellectual property rights and stipulates that these rights be honored. Nevertheless, Article 16 places conditions in adherence to intellectual property rights by requiring mandatory technology transfer and benefits-sharing obligations when necessary to meet the goals of the CBD. The end result was an international agreement that arguably fell short of meeting the expectations of both developed and developing countries because of its compromised and often ambiguous language (Maskus, 2000).
Despite the shortcomings of the CBD, the agreement marked a crucial starting point for addressing the concerns of intellectual property rights and the trade of biotechnological products. By acknowledging the importance of intellectual property rights and the goal of equitably sharing the benefits derived from utilising the genetic materials of developing countries, the CBD came close to striking a balance between the divergent views of the developed and developing world (Maskus, 2000).

5.2.2. TRIPS versus CBD: The Areas of Conflict or Cooperation

There are few laws and regulations in force at present that have been explicitly enacted to govern access to genetic resources or to clarify the questions related to private versus community rights. Most countries face significant challenges regarding the administrative competencies and jurisdictions for regulating access to genetic resources, particularly given the contradicting and mutually conflicting directives of the major international treaties. Although the CBD predates the TRIPS, it is not clear which treaty takes precedence when conflicts occur; while the TRIPS has enforcement and penalty provisions, the CBD does not, but both treaties have equal nominal authority. Thus the dearth of legal, institutional, and scientific capacity to deal with these complex biodiversity, trade, and intellectual property rights issues has been exacerbated by the lack of clarity within the international policy framework.

Article 16(5) of the CBD, in fact, recognises that the IPR can have a negative effect on the implementation of the CBD provisions, and thus, urges Parties to cooperate to ensure that IPR are supportive and do not run counter to the CBD objectives. The discussions raised under the TRIPS Council have dealt with the relationship with the CBD, as well as the review of Article 27.3(b) of the TRIPS. Nonetheless, developing countries argue that they feel consistently exploited because of structural imbalance between countries rich in biological diversity and those strong in technological and legal instruments. They contend that the CBD is intended to conserve and use biological diversity of developing countries on a long-term basis, while
TRIPS Agreement is intended to provide private property rights over products and processes. According to the developing countries' standpoint, TRIPS Agreement influences the provisions of the pre-existing CBD in the access to genetic resources, the fair and equitable sharing of benefits from the utilisation of genetic resources, and the respect for traditional knowledge held by the indigenous communities (Gervais, 2003).

Based on the principle of national sovereignty enshrined in the CBD, countries have the right to regulate access of foreigners to biological resources and knowledge, and to determine benefit sharing arrangements. TRIPS enables persons or institutions to patent one country's biological resources (or knowledge relating to such resources) in countries outside the country of origin of the resources or knowledge. In this manner, TRIPS Agreement facilitates the conditions for misappropriation of ownership or rights over living organisms, knowledge and processes. The sovereignty of developing countries over their resources, and over their right to exploit or use their resources, as well as to determine Access and Benefit Sharing arrangements have been compromised (Gervais, 2003).

Developing countries argue that Article 15.1 of the CBD recognises the sovereign rights of States over their national resources and that national government might determine access to genetic resources. Also, under the Articles 14.4 and 14.5, the CBD simply submits access to genetic resources to the "prior informed consent" of the party on mutually agreed terms aimed at sharing the benefits arising from the utilisation of such resources. However, on the contrary, it is said that biological resources should be subject to private intellectual property rights under the TRIPS Articles 21 and 27. Thus, developing countries assert that the conflict arises on the primacy of national sovereignty in the CBD that countries have the right to prohibit patents on life forms, and TRIPS requires provisions of intellectual property rights on life forms (Gervais, 2003).

The most distinct aspect of the CBD is that it recognises the sovereign rights of states over their biodiversity and knowledge, and thus gives the state
rights to regulate access, and this in turn enables the state to enforce its rights on arrangements for sharing benefits. Access, where ever granted, shall be on mutually agreed terms (Article 15.4), shall be subject to prior informed consent (Article 15.5). Further, the countries providing the resources should fully participate in the scientific research (Article 15.6) and, most importantly, each country shall take legislative, administrative or policy measures with the aim of sharing in a fair and equitable way the results of research and development, and the benefits arising from the commercial and other utilisation of genetic resources with the contracting party providing such resources. Such sharing shall be upon mutually agreed terms (TWN, 2001).

Under the TRIPS, there is no provision for the patent holder on claims involving biological resources or related knowledge to share benefits with the state or communities in countries of origin. In fact, there is little that a country of origin can do to enforce its benefit-sharing rights, if a person or corporation were to obtain a patent in another country based on the biological resource or related knowledge of the country of origin. While a legal challenge can be launched, such legal cases are prohibitively expensive. Even if a state has the resources to legally challenge a patent in another country, it may not have the resources to track down and challenge every patent that it believes to be a case of bio-piracy against it, nor is there a guarantee of success. Thus, if the patent laws, the administration of approvals, or the courts of a particular country operate in a context that is favourable to granting such patents, there is little that can be done by a country of origin to ensure that bio-piracy does not take place, or that if it takes place that it can get a remedy (Paul, 2009).

In the preamble to the TRIPS Agreement, it is recognised that “intellectual property rights are private rights”. Patents confer exclusive rights on its owner to prevent third parties from making, using, offering for sale, selling or importing the patented product, and to prevent third parties from using the patented process. As mentioned earlier, in the TRIPS Agreement, the award of IPR over products or processes confers private ownership over the
rights to make, sell or use the product or to use the process (or sell the products of that process). This makes it an offence for others to do so, except with the owner’s permission, which is usually given only on license or payment of royalty (Gervais, 2003).

IPR, therefore, have the effect of preventing the free exchange of knowledge, of products of the knowledge, and their use or production. This system of exclusive and private rights is at odds with the traditional social and economic system in which local communities make use of, and develop and nurture, biodiversity. For example, seeds and knowledge on crop varieties and medicinal plants are usually freely exchanged within the community. Knowledge is not confined or exclusive to individuals but shared and held collectively, and passed on and added to from generation to generation, and also from locality to locality (Gervais, 2003).

The CBD has several provisions that acknowledge this and also that aim at protecting community rights, the key provision being Article 8(j). However, the contribution and nature of community knowledge and community rights are not recognised in the TRIPS agreement. Instead, the patent system endorsed by TRIPS favours private individuals and institutions, enabling them to acquire “rights”, including rights over the products or knowledge, whose development was mainly carried out by the local communities. TRIPS and the enactment of patent laws relating to biological materials in some countries have facilitated the misappropriation of the knowledge and resources of indigenous and local communities, and the number of “bio-piracy” cases has been increasing at a rapid rate. This misappropriation is counter to the principles and provisions of the CBD that oblige countries to recognise local community rights and fair benefit sharing. Indeed, one of the main objectives of establishing the CBD was to counter the possibility of misappropriation or “bio-piracy”, whilst one of the effects of TRIPS has been to enable the practice of such misappropriation (Gervais, 2003).
5.2.3. Towards a Review of the TRIPS and the CBD

In the review of the TRIPS (which has been provided for in Articles 27.3(b)), amendments should be made in Article 27.3(b) to bring the scope of exclusion of biological materials and processes in line with environmental and ethical considerations as well as the need for preventing bio-piracy; and an interpretation can be made that the sui generis option for plant varieties can include the protection of traditional knowledge and local community rights, in line with the CBD.

Amendments can also be made to the TRIPS Agreement, in the context of the review under Article 71.1, to strengthen the obligations of developed countries to ensure the transfer of technology to developing countries, as well as to operationalise the implementation of technology transfer. Consideration can also be given to revise TRIPS to allow for exclusion or relaxation of standards of the IPR relating to environmentally-sound technologies, and to technologies that relate to the use of biodiversity. This would bring the TRIPS more in line with the spirit of the CBD, and with the provisions in Article 16, including those dealing with technology transfer on concessional and preferential terms, as also and with the need to ensure that IPR are supportive of and do not run counter to the CBD objectives (Gervais, 2003).

In a review of the CBD, Article 16 CBD could be amended to remove the tensions in it, so that the important objectives and principles of access to and transfer of technology to developing countries are not so constrained, as with the present CBD, by the references to the need to be consistent with adequate and effective protection of IPR and international law. The obligations on technology transfer can also be strengthened and the implementation made more operational.

One should also recognise that the present provisions in the CBD on access to genetic resources now place the onus of implementation on national policies and legislation. However, measures by national authorities are insufficient to enable effective implementation of access and benefit sharing
arrangements. For example, in its national legislation, a state may require as part of its access contract that the collector cannot patent a product or knowledge originating in that state (or that such a patent can be applied for only under certain conditions or benefit-sharing arrangement). But to be able to monitor or effectively implement that condition, that state would require the cooperation of patent authorities or biodiversity authorities of other states. Further, an international protocol would be required to establish guidelines and standards for access and for fair and equitable sharing of benefits, as well as to establish international cooperation to facilitate implementation of the access and benefit-sharing arrangements (TWN, 2001).

5.3. The IP Protection of Biodiversity Associated TK: Global and Regional Initiatives

The Biodiversity, as discussed earlier, 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.

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 with, 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 is a deceptive argument from the perspective of the CBD. 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.

5.3.1. Global Institutional Initiatives

The WIPO has given serious consideration to the possible extent of the protection of indigenous knowledge through various forms of intellectual property rights, 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). According to the 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 (WIPO,1999).
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 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).

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).

Given this perceived incompatibility between the 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 the intellectual property law, traditional knowledge is designed not to confer economic benefits to
individual creators but is intended for common appropriation. ‘Consequently, it does not make sense to try to fit it within the rigidities of national intellectual property law’ (Mugabe, 1998).

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. 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 and 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 (Kuruk, 2007).

5.3.2. Regional Initiatives

One of the earliest comprehensive regional sui generis instruments on the traditional knowledge protection has been 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. The 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 (Gervais, 2003).
For the grant of access to the 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 (Gervais, 2003).

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 (Kuruk, 2007).

The 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 the 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).
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 to 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).

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 (CIPR, 2001).

The decision requires any application for a process or product patent obtained from or developed on the basis of the traditional 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,"

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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 (Kuruk, 2007).

5.3.3. National Initiatives

The 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 legal acquisition
of elements of the heritage from the relevant traditional owners (LIP, 1998).

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 (Kuruk, 2007).

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 (Kuruk, 2007).
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).

5.4. The Biodiversity Concerns in India

India is the seventh largest country in the world and Asia’s second largest nation with an area of 3,287,263 square km, it has a land frontier of some 25,200 km and coastline of 7,516km. India is one of the top twelve mega-diversity countries and has two of the total eighteen biodiversity hotspots in the biodiversity rich areas of the Western Ghats and Eastern Himalayas (CES, 2006).

India is a party to the Convention on Biological Diversity (CBD) which came into force on 29 December 1993. As already discussed earlier, it has three main objectives namely, the conservation of biological diversity, the sustainable use of its components and fair and equitable sharing of benefits arising out of the utilization of genetic resources. The CBD envisages that the benefits accruing from commercial use of TK have to be shared with the people responsible for creating, refining and using this knowledge. Art 8(J) of the CBD provides for respecting, protecting and rewarding the knowledge, innovation and practices of local communities (CES, 2006).

Traditional Knowledge is essentially culturally oriented or culturally based, and it is integral to the cultural identity of the social group in which it operates and preserved. In India Traditional Knowledge is an open-ended way to refer to 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.

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. The conservation of language or oral tradition becomes a crucial factor for conserving taxonomies because each word, conceptually speaking in the context of natural resources is a category (Blackent, 2010).

India is a fortunate country for having rich and varied heritage of Biodiversity. It has a variety of habitats ranging from tropical rainforests to alpine vegetation and from temperate forests to coastal wetlands. The two hotspots of Biodiversity in India are the Western Ghats and the Eastern Himalayas. In 1980s, around 18 biodiversity hotspots were identified. Of the estimated total 14 million species, only 3.7 million have been described till now. The distribution of all these species is highly uneven. About seven percentage of the world's total land area is the home to half of the world's species. The tropics alone account for 6 million species. India contributes significantly to this latitudinal biodiversity trend. Even with just 2.4 percent of the world's area, India accounts for 7.68 percent of the species which number around 90,225.

India has not done well to conserve its rich biodiversity, which is considered most diverse in the world. The National Biodiversity Action Plan maintains that 41 percent of India's forest cover is at different levels of degradation and the country is making limited use of is 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 (NBA, 2007).

India has already lost more than 41 percent 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 unsustainable methods being adopted that ignored traditional management practices (Blackent, 2010).

### 5.4.1. Bio-piracy and other Concerns

The term ‘indigenous’ describes tribes or semi-tribal populations in independent countries who live in the country prior to colonization or conquest by immigrants from outside the country or geographical region in question. These populations became increasingly marginalized after the conquest, which gradually led them to develop particular social, economic, and cultural lifestyles distinct from those of the national mainstream.

The indigenous knowledge, as already discussed earlier, is interchangeably referred as traditional knowledge, local knowledge, traditional ecological knowledge, folklore, traditional bio-cultural contribution and traditional bio-culture knowledge of knowledge developed by local people through direct interactions between human beings and nature. It is the knowledge that the locals use in their everyday lives as they strive to sustain their livelihoods (Blakeny, 2010).

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, as there is no fear of such knowledge being stolen, and thus local people have not been completed to codify it in a written form (WIPO, 2003).

Traditional knowledge has always been an easily accessible treasure and thus has been vulnerable to misappropriation, particularly; it related to the treatment of various diseases has provided leads for development of biologically active molecules by the technology rich countries. Bio-piracy of codified Indian traditional knowledge continues, since, this information exists in regional languages, and there exists a language barrier due to
which the patent offices are unable to search this information as prior art, before granting patents. Formulations used for the treatment of human ailments from traditional knowledge are time-tested since they have been in practice for centuries. The reliability of the traditional medicine systems coupled with the absence of such information with patent offices, provides an easy opportunity for interlopers for getting patents on these therapeutic formulations derived from traditional medicine systems (Blakeny, 2010).

5.4.2.1. The Case of Turmeric:

The rhizomes of turmeric are used as a spice for flavouring Indian cooking. It also has properties that make it an effective ingredient in medicines, cosmetics and dyes. As a medicine, it has been traditionally used for centuries to heal wounds and rashes. In 1995, two expatriate Indians at the University of Mississippi Medical Centre (Suman K. Das & Hari Har P. Cohly) were granted a US Patent (no.5, 401,504) on use of turmeric in wound healing (Rao & Guru, 2003).

The Council of Scientific & Industrial Research (CSIR), India, New Delhi filed a re-examination case with the USPTO challenging the patent on the grounds of existing of prior art. The CSIR argued that turmeric has been used for thousands of years for healing wounds and rashes and therefore its medicinal use was not a novel invention. Their claim was supported by documentary evidence of traditional knowledge, including ancient Sanskrit text and a paper published in 1953 in the Journal of the Indian Medical Association. Despite an appeal by the patent holders, the US PTO upheld the CSIR objections and cancelled the patent. The turmeric case was a landmark Judgment case as it was for the first time that a patent based on the traditional knowledge of a developing country was successfully challenged. The US Patent Office revoked this patent in 1997, after ascertaining that there was no novelty; the findings by innovators having been known in India for centuries (Ghidini & Emannuela, 2010).
5.4.2.2. Neem:

Neem extracts can be used against hundreds of pests and fungal diseases that attack food crops; the oil extracted from its seeds can be used to cure cold and flu; and mixed in soap, it provides relief from malaria, skin diseases and even meningitis. In 1994, European Patent Office (EPO) granted a patent (EPO patent No.436257) to the US Corporation W.R. Grace Company and US Department of Agriculture for a method for controlling fungi on plants by the aid of hydrophobic extracted Neem oil (Ghidini &Emanuela, 2010).

In 1995, a group of international NGOs and representatives of Indian farmers filed legal opposition against the patent. They submitted evidence that the fungicidal effect of extracts of Neem seeds had been known and used for centuries in Indian agriculture to protect crops. In 1999, the EPO determined that according to the evidence all features of the present claim were disclosed to the public prior to the patent application and the patent was not considered to involve an inventive step. The patent granted on was Neem was revoked by the EPO in May 2000. EPO, in March 2006, rejected the challenge made in 2001 by the USDA and the chemicals multinational, W. R. Grace to the EPO's previous decision to cancel their patent on the fungicidal properties of the seeds extracted from the Neem tree (Udgaonkar, 2002).

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>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.J. Mar go Pvt. Ltd. (Kamataka, India) to build first commercial facility for producing neem biopesticides. Margo Biocontrols is the subsidiary dealing with neem and other biopesticides. Demonstrations begin against Grace in India.</td>
</tr>
<tr>
<td>Year</td>
<td>Event</td>
</tr>
<tr>
<td>------</td>
<td>-------</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 Famam 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>Biosys 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>Biosys 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 &quot;non-core&quot; business and seeks buyer.</td>
</tr>
<tr>
<td>2001</td>
<td>Mitsui purchases Thermo Trilogy and creates a subsidiary, CertIs, 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>


5.4.2.3. The Case of Basmati Rice

The Case of Basmati Rice has forever been one of the most discussed and debated issue in the context of traditional knowledge protection vis-a-vis bio-piracy related to India. Rice Tec. Inc. had applied for registration of a mark “Texmati” before the UK Trade Mark Registry. Agricultural and
Processed Food Exports Development Authority (APEDA) successfully opposed it. One of the documents relied upon by Rice Tec as evidence in support of the registration of the said mark was the US Patent 5,663,484 granted by the US Patent Office to Rice Tec on September 2, 1997 and that is how this patent became an issue for contest (Udgaonkar, 2002).

This US utility patent was unique in a way to claim a rice plant having characteristics similar to the traditional Indian Basmati Rice lines and with the geographical delimitation covering North, Central or South America or Caribbean Islands. The US PTO granted the patent to Rice Tec on September 2, 1997. The said patent covered 20 claims covering not only novel rice plant but also various rice lines; resulting plants and grains, seed deposit claims, method for selecting a rice plant for breeding and propagation. Its claims 15-17 were for a rice grain having characteristics similar to those from Indian Basmati rice lines. The said claims 15-17 would have come in the way of Indian exports to US, if legally enforced (Ghidini & Emannuela, 2010).

Evidence from the IARI (Indian Agricultural Research Institute) Bulletin was used against claims 15-17. The evidence was backed up by the germplasm collection of Directorate of Rice Research, Hyderabad since 1978. CFTRI (Central Food Technological Research Institute) scientists evaluated the various grain characteristics and accordingly the claims 15-17 were attacked on the basis of the declarations submitted by CFTRI scientists on grain characteristics.

Eventually, a request for re-examination of this patent was filed on April 28, 2000. Soon after filling the re-examination request, Rice Tec chose to withdraw claims 15-17 along with claim 4. Biopiracy of traditional knowledge is not limited to India alone. In fact, there have been several examples from other countries where traditional knowledge bio-piracy has become a concern (Rao & Guru, 2003).
## List of Bio-piracy of India’s Traditional Knowledge

1. **Basmati Rice:** Patented by Rice Tec, Texas USA in 1997 as aromatic rice. Recently on challenges by APEDA, withdraw four claims of its uniqueness. The use of term ‘Basmati’ by Rice Tec 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 to rice varieties grown in India.

2. **Turmeric:** Patent granted to University of Mississippi medical Center (for wound healing) in the US, was revoked on challenges by CSIR.

3. **Neem:** Patent granted to WR. Grace & Co. UK and US department of Agriculture was vacated on Challenge.

4. **Karela, Jamum and Brinjal:** Patented granted to Cromak Research Inc. US on edible herbal compositions compromising the mixtures of the above to reduce sugar levels.

5. **Pepper:** Patent granted by US patent office.

6. **Aswagantha:** Patent granted to Relive International Inc. as a supplement for healthy joints, US patent office also granted a dozen patents on Aswagantha centered findings.

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

8. **Hessian (Jute Cloth):** Patent granted to UK firm by the European Patent Office, patent revoke on challenges by Jute Industrial research Association of India.

9. **Ginger:** Us patent Office granted patent on eight ginger formulation.


5.5. National Initiatives

The Constitution of India provides fundamental rights to equality, equal opportunity, right to life and personal liberty and to conserve distinct language, script or culture. The Directive Principles enjoin the State inter-alia to direct its policy towards securing that the ownership and control of material resources of the community is so distributed as to sub-serve the common good.

Article 243 of the Constitution of India enables the State to make laws to empower Panchayats to deal with certain matters including schemes of economic development and social justice. The areas in which the Panchayats could implement such schemes include agriculture, social forestry and farm forestry, minor forest produce and maintenance of community assets (Kaushik, 2002).

5.5.1. Biodiversity under the Indian Constitutional Framework

India has a great diversity of people and cultures and the sustainable use and equitable sharing of benefit have been part of the traditional life styles and ethos of the people. This is reflected in Indian forms of worship, rituals, food habits, philosophy and culture. Reverence for plants and animals in India guided traditional people to even sacrifice their lives to protect biological diversity (Ramesh, 2006).

In independent India, the need to conserve biodiversity integrating the needs people was identified as a priority even in the early years of planning and development. The Government of India, as early as 1952, enunciated the National Forest Policy with the aim of conserving a third of the forest cover in the country. The Wild Life (Protection) Act was the first major step taken by the Government of India to protect Wild Life in the Country. Environmental protection and the conservation of natural resources in the context of poverty alleviation emerged as key national priorities in India in the wake of the 1972 Stockholm Conference on Human Environment (Ramesh, 2006).
Between the Stockholm Conference and Rio Earth Summit 1992, India developed a stable organizational structure for environment and wildlife protection in the country. India’s concern and commitment towards environmental conservation were reinforced in 1976 by the 42nd amendment of the Constitution of India. Article 48 under the Directive Principles of State Policy and Article 51a (g) of the Fundamental Duties in the Constitution states that ‘the State shall endeavour to protect and improve the environment and to safeguard forests and wildlife in the country and its protect and improve the natural environment including forests, lakes and rivers and wildlife and to have compassion for the living creatures’ (Ramesh, 2006).

In 1980, a Department was setup, till this time environment and forests were the concern of the Ministry of Agriculture and the Department of Science and Technology. The Forest Act which came into force in 1980 had stringent provisions for preventing diversion of forest land for any other purpose. In 1985, the Department of Environment was upgraded as a full-fledged Ministry of Environment and Forests. The Environmental (Protection) Act 1986 set out and operates to formulate and carry out environmental policy at the national level. The Forest (Conservation) Act was amended in 1988 to include provisions to allow certain developmental activities in and around forest areas (NBA, 2007).

5.5.2. Important Acts Relevant to Biodiversity

The Indian Forest Act 1927 is a colonial legislation enacted mainly to enable the state to acquire ownership over forests and their produce and specifically to facilitate trade and timber. The Wildlife (Protection) Act 1972, amended in 1983, 1986 and 1991, for the protection of wild plants and animals, regulates hunting, trade and collection of specific forest products. Certain tribes are however allowed to collect or possess specifies plants for their bonafied personal use. The revised act also provides a licensing system to regulate cultivation and trade of specifies plants in pattern similar to the
trade in fauna. Licenses are required to declare their stocks and follow prescribed procedures (Ramesh, 2006).

The National Wildlife Action Plan 1973, identified broad goals of establishing a network of representative protected areas and developing appropriate management systems which take into account the needs of local peoples and conservation requirements outside protected areas. The National Forest Policy as amended in 1989, stressed the sustainable use of forests and the need for greater attention to ecological fragile, but biologically rich mountain and island ecosystems (Ramesh, 2006).

The Forest (Conservation) Act, 1980, amended in 1988, primarily deals with using forest lands for non-forestry purposes, mainly industry and mining. It requires the state governments to acquire the approval of the central government before it gazettes a reserved forest, leases forest land to a private person or corporation or clears it for the purpose of reforestation. Implementation of this Act has reduces the annual rate of diversion of preset lands for non forestry purposes to 16,000 hectares a year (Ramesh, 2006).

The Environment (Protection) Act, 1986 empowers the central government to take appropriate measures for the purposes of protecting and improving the environment. In accordance with this act, the central government has issues a number regulations affecting sectors such as hazardous and chemical wastes, genetically engineered micro-organisms, and industrial development of costal zones (NBA, 2007).

The Foreign Trade (Development and Regulation) Act 1992, is designed to stimulate sustained economic growth and enhance the technological strength and efficiency of Indian agriculture, industry and services. The Central Government regulates the import and export of goods by means of a negative list of imports or a negative list of exports, depending on the situation, Import and export are prohibited restricted through licensing or routed through specified agencies. Provisions of the conventions on International Trade and Endangered Species of Wild Fauna and Flora (CITIES) are also implemented through this act (NBA, 2007)
5.5.3. Traditional Knowledge Protection through the Framework of IP

The 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.

5.5.3.1. 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 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 (Dutfield, 2002).

(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.

(iv) 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 skeptical 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 (Dutfield, 2002).

Supporters of patents argue that ‘traditional knowledge’ cannot be registered under patents. While patent law generally supports such a defense, ‘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).

5.5.3.2. 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 (Dutfield, 2002).

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 (Dutfield, 2002).

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).
5.5.3.3. Trade Secrets

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 (Dutfield, 2002).

An experimental project based in Ecuador and supported by the Inter-American 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 bio-prospecting 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)

5.5.3.4. Geographical Indications

The TRIPS Agreement intended the introduction of the GI Act as a means to protect French makers of wines and champagnes, and to give 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 (Dutfield, 2002).

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 (Dutfield, 2002).
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 (Eiland, 2007).

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" (Eiland, 2007).

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 (Dutfield, 2002).

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, handmade 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 (Dutfield, 2002).

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 (Eiland, 2007).

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).

5.5.4. Major Indian Legal Initiatives

To conserve the biodiversity and counter the problem of bio-piracy, India has enacted three Legislations in the Parliament. They are;


(2) The Biological Diversity Act 2002

(3) The Patent Amendment Act 2005

5.5.4.1. The Protection of Plant Varieties and Farmer’s Right Act (PPVFR), 2001

Indian Parliament passed the PPVFR Act in 2001 with the objective of intellectual property protection of plant varieties and protection of rights of farmers. The farmer’s right arises from their role in conserving, improving and making available plant genetic resources for the development of new plant varieties. And it is to stimulate investment in plant breeding research, promote development if new plant varieties, growth of seed industry and availability of high quality seed and planting material to farmers for an accelerated agriculture development. The Act has 97 sections stacked in 11 chapters. The notified rules have 76 sections, arranged in nine chapters with four schedules and 45 forms.

The objectives of the Protection of Plant Varieties and Farmers’ Rights Act are (Ravi, 2004):

1. To stimulate investments for research and development both in the public and the private sectors for the developments of new plant varieties by ensuring appropriate returns on such investments;

2. To facilitate the growth of the seed industry in the country through domestic and foreign investment which will ensure
the availability of high quality seeds and planting material to farmers; and

3. To recognize the role of farmers as cultivators and conservers and the contribution of traditional, rural and tribal communities to the country’s agro biodiversity by rewarding them for their contribution through benefit sharing and protecting the traditional right of the farmers.

The Protection of Plant Varieties and Farmers Right Act 2001 (PPVFR Act) seeks to protect the right of farmers and breeders on plant varieties. The act recognizes the individual and community roles played by farmers in the improvement and conservation of varieties. Under the PPVFR Act, Plant Breeders Rights (PBR) on a plant variety is established by registration of the variety, the persons become its PBVR Holders (Venkittaraman&Latha, 2008). The PBR holder can be one person, a group of community or an Institution. The PBR holder alone has the exclusive right to produce, sell, market or distribute the seeds or planting material of that variety. PPVFR Act has provisions with regard to researcher’s rights, benefit sharing between breeders and farming or tribal communities who have contributed to genetic diversity used by the breeder and establishment of national gene fund to promote conservation (Venkittaraman&Latha, 2008).

The farmers rights as defined in the PPVFR (Venkittaraman&Latha, 2008):

1. A farmer who has bred or developed a new variety shall be entitled for registration and other protection in like manner as a breeder of a variety under this Act;

2. The farmers’ variety shall be entitled for registration of the application contains declaration as specified in clause (h) or sub-section (1) of section 18;

3. A farmer who is engaged in the conservation of genetic resources of land races and wild relatives of economic plants and their improvement through selection and preservation shall be entitled
in the prescribed manner for recognition and reward from the Gene Fund. Provided that material so selected and preserved has been used as donors of genes in varieties registrable under this Act;

4. A farmer shall be deemed to be entitled to save, use, sow, re-sow, exchange, share or sell his farm produce including seed of a variety protected under this Act in the same manner as he was entitled before the coming into force of this Act.

5.5.4.2. Biological Diversity Act, 2002

The Act states that a member country should facilitate access to its genetic resources by other parties on mutually agreed terms, but that access requires a PIC of the country providing the resources. It also provides for an equitable sharing of any benefits arising from the commercial use of these resources or any TK associated with the biological resources subject to domestic legislations. In response to its obligation under the Act after ten years of negotiations and discussions with all the stake holders, India has enacted the Biological Diversity Act in 2002 (Datta, 2002).

The Act mainly deals with access to genetic resources by foreign companies, individuals or organizations. The National Biodiversity Authority (NBA) was set up under section eight of the act to deal with requests for access to genetic resources by foreigners and to related research out of India and to determine benefit sharing arising from the commercialization.

The other salient features of the Act are (Datta, 2002):

- To regulate access to biological resources of the country equitable share in benefits arising out of the use of biological resources;
- To conserve and sustainable use of biological diversity;
- Setting up of National Biodiversity Authority (NBA), State Biodiversity Board (SBB) and Biodiversity Management Committees. (BMC’s);
• NBA and SBB are required to consult BMCs in decisions relating to bio-resource / related knowledge within their Jurisdiction;
• To respect and protect knowledge of local communities traditional knowledge related to biodiversity;
• To secure sharing of benefits with local people as conservers of biological resources and holders of knowledge and information relating to the use of biological resources;
• All foreign nationals/organizations require prior approval of NBA for obtaining biological resources and/or associated knowledge for use;
• Indian scientists/individuals require approval of NBA for transferring results of research to foreign nationals/organizations;
• Conservation and development of areas of importance from the standpoint of biological diversity by declaring them as biological diversity heritage sites;
• Protection and rehabilitation of threatened species;
• Involvement of institutions of State Government in the broad scheme of the implementation of the Biological Diversity Act through constitution of committees;
• Protect India’s rich biodiversity and associated knowledge against their use by foreign individuals and organizations without sharing benefits arising out of such use and check Biopiracy;
• Indian Industry needs prior intimation to SBB to obtain bioresource. SBB has right to restrict if found to violate conservation and sustainable use and benefit sharing;
• Provisions for notifying heritage sites by State Government in consultation with local body;
• Creation of National, State and Local Biodiversity Fund and its use for conservation of biodiversity;
• Prior approval is needed from NBA for IPRs in any invention in India or outside India on Bio-resources;
The Act also prescribes some special provisions for the protection of TK. For instance, chapter II of the Act regulates access to biological diversity. The Act prohibits ‘certain persons’ from obtaining any biological resources occurring in India or knowledge associated there to for research or for commercial utilization or for bio-safety and bio-utilization (Venkittaraman & Latha, 2008). According to this provision, no person shall apply for any IPR, by whatever name called, in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of the NBA.

The procedure for the access and other purposes mentioned in the Act are provided to ensure effective, efficient and transparent access procedures through written agreements and applications in prescribed formats. The NBA, through appropriate consultation mechanisms shall dispose of the application and communicate its decision to grant access or otherwise to the applicant within a period of six months from the date of receipt of the application. The Authority is required to communicate the grant of access to the applicant in the form of a written agreement duly signed by an authorised official. The rule 14 of the Biodiversity rules, 2004 also stipulates the Authority to provide reasons in writing in case of rejection of an application and give reasonable opportunity to the applicant for appeal. The Authority shall publicize the approval granted through print or electronic media and also shall monitor the compliance of the conditions agreed by the party and the applicant when approval for grant for access was accorded. The access procedure is only regulatory in nature but is not prohibitive in any manner to any applicant irrespective of their nationalities, affiliations, origin, etc.

The Act also providers for revocation of the approvals granted to an applicant only on the basis of any complaint or suo moto under the following conditions (Venkittaraman & Latha, 2008):

(1) Violation of the provisions of the Act or conditions on which the approval was granted;

(2) Noncompliance of the terms of the agreement;
(3) Failure to comply with any of the condition of access granted;

(4) On account of overriding public interest or for protection of environment and conservation of biodiversity rules.

After having withdrawn the access permit, the Authority is required to send an order of revocation to the concerned Biodiversity Management Committee (BMC) and the State Biodiversity Board to prohibit the access and to assess the damage, if any, caused and steps to recover the damage.

The NBA gives Indian nationals/researchers permission to access biological resources. It will also lay down some conditions as to how any benefits that arise should be shared with local communities. The Act provides that benefit sharing may include monetary payment, technology transfer or joint ownership of IP rights, but this is not an exhaustive list. The Act, subject to Section 21 and rule 20 of the Biodiversity rules, insist upon including appropriate benefit sharing provisions in the access agreement on mutually agreed terms related to access and transfer of biological resources or knowledge occurring in or obtained from India for commercial use, bio-survey, bio-utilization or any other monetary purposes (Venkittaraman & Latha, 2008). The Authority shall develop guidelines and shall notify the specific details of benefit sharing formula in an official gazette on a case-to-case basis. The suggested benefit sharing measures may include, monetary benefits such as realty, joint ventures, technology transfer, product development and non-monetary benefits such as education and awareness raising activities, institutional capacity building, venture capital funds, etc.

With the assistance of NBA, eighteen State Biodiversity Boards have been formed by state governments. Several BMC have also been constituted by SBBs. The main function of the Biodiversity Management Committee (BMC) constituted under each local body as per section 41(1) of the Act and Rule 22(1-11) of biodiversity rules (2004), is to prepare People’s Biodiversity Registers, which shall contain comprehensive information on the availability and knowledge of local biological resources and medicinal or any other traditional knowledge associated with them. Other important
functions of the BMC are to advise the SBBs and NBA on matters for granting approval, maintain data about the local vaids and practitioners using the biological resources, besides maintain a register containing information on access to biological resources and knowledge granted, details of collections fee received and details of benefit sharing derived along with the mode of sharing (Venkitaraman & Latha, 2008).

NBA has set up eight expert committees to prepare guidelines on different issues. The guidelines for the collaborative research projects have been approved and published in the government’s official gazette, however, guidelines on issue like normally traded commodities, intellectual property rights, traditional and tribal knowledge, microbial diversity, etc are in the line for approval (Venkitaraman & Latha, 2008).

5.5.4.3. The Patent (Amendment) Act, 2005

With the adoption of TRIPS Agreement in 1995, India had to amend its patent laws to fulfill its obligations under TRIPS Agreement. Accordingly in 2005, India enacted the Patent (Amendment) Act and introduced product patent along with some provisions relating to TK. The change made to the definition of the term ‘patent’ which means a patent granted for an invention under the Act section 2 (1) (m) and specification of ‘invention’ which are not patentable in section 3 of the act which states that ‘a mere new use for a known substance’ (section 3 (d)) and ‘an invention’ which, in effect, is traditional knowledge or which is and aggregation or duplication or known properties of traditionally known component or components Section 3 (p) will not be an invention (Venkitaraman & Latha, 2008).

The inclusion of the new provisions of patent opposition proceedings which can be done on limited grounds under Section 25(1) of the Act as: (Venkitaraman & Latha, 2008): Where an application for a patent has been published but a patent has not been granted, any person may, in writing, represent by way of opposition to the Controller against the grant of patent on the ground of:
(a) Patentability including novelty, inventive step and industrial applicability, or

(b) Non disclosure or wrongful disclosure mentioning in complete specification, source and geographical origin if biological material used in the invention and anticipation of invention by the knowledge, or oral or otherwise available within any local or indigenous community in India or elsewhere.

Inclusion of the provisions for the opposition of a complete patent specification of an invention which was publically known or publically used in India before priority date of that claim (Section 25(3d)).

The reason for the inclusion of all the above provisions is to defy the challenges of misappropriation of the TK which is already in the public domain in India or its use is known to the Indian communities or individuals from the time immemorial. One inference can be drawn from these provisions that all of them are defensive in nature, which can help to oppose the patent granted for the invention whose source and geographical origin of biological material used or the knowledge, oral or otherwise is available within any local or indigenous community. Benefit sharing is not the concern of the Act (Venkitaraman & Latha, 2008).

5.5.5. Institutional Initiatives

In addition to the aforesaid legal initiatives, various institutions have been constituted at the national level to augment the protection of Biodiversity and Traditional Knowledge in a more comprehensive manner. Following is a brief discussion of some of these institutions.

5.5.5.1. The National Biodiversity Authority (NBA) (2003)

The National Biodiversity Authority (NBA) was set up in 2003 at Chennai by the Government of India to implement the different provisions of the Biological Diversity Act 2002 (BD Act) and Biological Diversity Rules, 2004. The BD Act provides a legal mechanism for establishing sovereign rights over the Indian biodiversity and its conservation, protection against
misappropriation, regulation of access and sustainable use of biodiversity and associated knowledge (NBA, 2008).

The BD Act, 2002 is implemented engaging decentralized regulation of activities through Biodiversity Management Committees (BMCs), State Biodiversity Boards (SBBs) and the NBA, each with well-defined functions within their respective jurisdiction. Accordingly, it is being operated at national, state and local levels, as a three-tier system. A significant progress has been made in implementing the Act and it is believed that with the support, cooperation and partnership of different stakeholders, the implementation process will reach new heights. It will provide an exemplary mechanism for meeting the various provisions of the Act.

At the top of the hierarchy is the National Biodiversity Authority which will deal with matters relating to requests for access by foreign individuals including non resident Indians, institutions or companies and all matters relating to transfer of results of research to any foreigner; imposition of terms and conditions to secure equitable sharing of benefits and approval for seeking any form of intellectual property rights in or outside India for an invention based on research or information pertaining to a biological resource obtained from India. The NBA has also been given the authority to take any measures necessary to oppose the grant of intellectual property rights in any country outside India or knowledge associated with the biological resources derived from India (NBA, 2008).

The NBA is a body corporate having perpetual succession and a common seal with the power to acquire, hold and dispose of property, both movable and immovable and to contract and shall by the said name sue and sued (Section 8(2)). The NBA consists of a Chairperson, ten ex-officio members and five non official members (Section 8(4)). The NBA has the fund called the National Biodiversity Fund which will be used to distribute benefits to the stakeholders, conservation and promotion of biological resources and socio-economic development of areas accessed to obtain biological resources (Section 27) (NBA, 2008).
5.5.5.2. The State Biodiversity Board (SBB)

At the state level, State Biodiversity Board has the authority to deal with matters relating to access by Indians for commercial purposes and restrict any activity which violates the objectives of the conservation, sustainable use and equitable sharing of benefits. In the case of Union Territories, the NBA shall perform all the functions of the SBB and the NBA has been vested with the power to delegate any and all of the powers to a person or a group of persons specified by the Central Government (NBA, 2008).

The SSB also has a body corporate having perpetual succession and a common seal with the power to acquire, hold and dispose of property, both movable and immovable and to contract and shall by the said name sue and sued (Section 22(3)). The SBB consists of a Chairperson, five ex-officio members and five non-official members. The SSB also have a fund called the State Biodiversity Fund which will be used for management and conservation of heritage sites, compensating and rehabilitating people affected by notification of heritage sites, conservation and promotion of biological resources and socioeconomic development of areas accessed to obtain biological resources (NBA, 2010).

5.5.5.3. The Biodiversity Management Committee (BMC)

The Biodiversity Management Committee will be set up by institutions of self government in their respective areas for conservation, sustainable use, and documentation of biodiversity and chronicling of knowledge relating to biodiversity. The BMC shall consist of a chairperson and note more than six persons nominated by the local body, of whom not less than one third should be women and not less than 18% should belong to the scheduled castes/tribes. The BMC shall be consulted by the NBA and the SBB on matters related to use of biological resources and associated knowledge within their jurisdiction. A fund called Local Biodiversity Fund will be constituted at every area notified by the State Government, presumably at all places where a BMC is established (NBA, 2008).
5.5.5.4. The Biodiversity Heritage Sites

The duty of the Biodiversity Heritage is that, any areas of biodiversity importance can be notified to the State Government, after consultation with the local bodies. The State Government is also empowered to make rules in consultation with the Central Government for the management and conservation of all the heritage sites (Ramesh, 2006).

5.5.6. Additional Institutional Initiatives

Intellectual Property Rights are often considered synonym to patents or at best patents, trademark and copyrights. Awareness still remains an unfulfilled goal in spite of efforts made by so many agencies. There is a need to adopt different means such as contact programmes, print media, bulletins, internet, videos etc. Awareness by itself is of little use if the State does not create and provide suitable systems to enable scientists, technologists, industries and even the State to protect their rights. The departments like Atomic Energy, Space and DRDO and agencies like CSIR have their in house system for looking after their needs of IPR (Ravi, 2008).

5.5.6.2. Patent Facilitating Centre (PFC)

The Department of Science and Technology has set up the Patent Facilitating Centre at the Technology Information Forecasting and Assessment Council (TIFAC) in 1995 as a new small initiative to address the need of awareness creation among scientists, helping them to protect their inventive and original work through IP laws and also act as a watch dog. The PFC came to be known for its capability to raise issues and bringing new information and knowledge about IPR in public domain. Starting with the revelation of the turmeric patent to the whole country, it brought to notice many other patents using some of our well known plants and traditional knowledge (Ravi, 2008).

The PFC has organized 305 IPR awareness workshops all over the country independently and also in association with Ministry of Small Scale Industries, Department of Atomic Energy, Department of Space and ICMR. In the
process almost 35000 scientists, technologists and policy makers have been sensitized from about 500 universities, colleges and R&D institutions and 800 industries. The PFC has been organizing advanced level of training programmes with CII and attorney firms and also workshops cum retreat on topics such as public private partnership in IPR management (Ravi, 2007).

The PFC brought out Ekaswa A and Ekaswa B databases on the patent applications filed in India and the patent applications accepted by the Patent Office. There are twenty Patent Information Centres (PIC) that have been set up by the PFC in 20 States namely; Assam, Andhra Pradesh, Chattisgarh, Goa, Gujarat, Haryana, Himachal Pradesh, Jammu and Kashmir, Karnataka, Kerala, Madhya Pradesh, Manipur, Punjab, Rajasthan, Sikkim, Tamil Nadu, Tripura, Uttar Pradesh, Uttrakhand and West Bengal (Mathew, 2013). These PICs are helping scientists, technologists and policy makers in their respective States by creating awareness and extending help for protecting their inventions. The PFC is the only window available in the country, which provides full technical, legal and financial support for inventions emanating from educational institutions, including schools and colleges, and government departments. It has so far filed 260 patent applications in India and other countries from about 55 universities/academic institutions and many of them have been granted (Mathew, 2013).

5.5.6.2. Other Centers/Cells

Many government departments, educational institutions and PSU have started their IPR Cells. Prominent among the government departments / agencies are Department of Biotechnology, Ministry of Telecommunications and Information Technology, Indian Council of Medical Research, Indian Council of Agricultural Research, ISRO, Department of Atomic Energy, Defense Research and Development Organization and Indian Council of Forest Research. IITs at Delhi, Mumbai, Kharagpur and Roorkee have also set up their cells and evolved their IPR policies (Mathew, 2013).

Ministry of Science and Technology issued the guidelines ‘Instructions for Technology Transfer and Intellectual Property Rights’ in March 2000, which
would help in enhancing the motivation of scientists, research Institutions and universities in projects funded by the Department of Science and Technology, Department of Biotechnology, Department of Scientific and Industrial Research and Department of Ocean Development.

The salient features of the guidelines are (Mathew, 2012);

- Institutions shall be encouraged to seek protection of intellectual property rights in respect of the results of R&D. They may retain the ownership of such IPR. Here Institutions mean any technical, scientific or academic establishment where research is carried out through funding by the central or the state governments;
- The Institutions shall take necessary steps to commercially exploit patents on exclusive or on non-exclusive basis;
- The owner institution is permitted to retain the benefits and earnings generated out of the IPR. The institution may determine the share of inventor(s) and other persons from such actual earnings. However, such share shall be limited to one third of the actual earnings;
- IPR generated through joint research by institution(s) and industrial concern(s) through joint efforts can be owned jointly by them or as may be mutually agreed to by them through a written agreement. The institution and industrial concern may transfer the technology to a third party for commercialization on exclusive/ non-exclusive basis. The third party, exclusively licensed to market the innovation in India, must manufacture the product in India. The joint owners may share the benefits and earnings arising out of commercial exploitation of the IPR;
- The owner institution shall set apart not less than 25% of the revenue generated from;
- IPR to create a Patent Facilitating Fund which shall be utilized by the institution for updating inventions, filing new patent applications
and protecting IP rights against infringement, and for building competency in the area of IPR and related issues;

- The Government shall have a royalty free license for the use of the Intellectual property for the purposes of the Government of India.

This is a major departure in the approach and policy towards managing inventions in India by the Ministry of Science and Technology. In order to have a uniform policy of the government in this respect, it may be useful to have a suitable law in this regard. It is obvious that with more and more autonomy to research institutions in regard to IPR and technology transfer, these institutions, and the scientists working there would have stronger motivation to invent products and processes, which are required by the market (Mathew, 2013).

5.5.7. Documenting the Traditional Knowledge

Documentation of TK in an organised manner started as early in 1982. Number of government institutions are involved in this work such as the Council for Scientific and Industrial Research (CSIR), National Botanical Research Institute (NBRI), Central Drug Research Institute (CDRI), National Institute of Immunology (NII), Tropical Botanical Garden and Research Institute (TBGRI), National Medicinal and the Aromatic Plant Institute (NMAPI). The opening up of the globalised market, external pressures from TRIPS and the emergence of a significant interest group within the country that supports the new market and IPR regimes have led India to attempt to be in the forefront through pioneering initiatives in this arena in the rush to garner an advantageous position in the global market (Mathew, 2013).

5.5.7.1. Traditional Knowledge Digital Library (TKDL)

The Indian government set up the Traditional Knowledge Digital Library (TKDL), an electronic database, to document public-domain information about medicinal plants including traditional systems such as Ayurveda, Unani, Sidha, Naturopathy and folklore. The information is then classified under Traditional Knowledge Resource Classification (TKRC), an
information retrieval system linked to International Patent Classification (IPC). This is to make the information available worldwide to national patent office’s through the IPC system to establish Indian rights to that knowledge so that they are not awarded patents since a claim could be laid then that the knowledge is already in the public domain.

The genesis of TKDL dates back to the Indian effort on revocation of patent on wound healing properties of Turmeric at the USPTO and anti-fungal properties of Neem at EPO. In 2000, the TKDL expert group estimated that about 2000 wrong patents concerning Indian systems of medicine were being granted every year at international level, mainly due to the fact that India’s traditional medical knowledge existing in languages, such as Sanskrit, Hindi, Arabic, Urdu, Tamil etc. was neither accessible nor comprehensible for the patent examiners at the international patent office’s (Mathew, 2013).


These unique international Access Agreements are expected to have long-term implications on the protection of both traditional knowledge and global intellectual property systems in view of the fact that in the past, patents have been granted at various patent offices on the use of over 200 medicinal plants due to the lack of access to the documented knowledge in public domain. Also, 40-50 patent applications based on Indian traditional knowledge are awaiting grant of patent at any point of time.

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The National Innovation Foundation (NIF) of India, established in 2000 by the Department of Science and Technology, Government of India, provides institutional support in scouting, spawning, sustaining and scaling up grassroots innovations and helping their transition to self-supporting activities. NIF established the National Register of Innovations and Unique Traditional Knowledge (NRITUK). These innovations are to be supported for incubation and conversion into viable business opportunities. Society for Research and Initiatives for Sustainable Technologies (SRISTI), a nongovernmental initiative based in Ahmedabad in Gujarat established in 1993, promoted the ‘Honey Bee Network’ to document and promote innovations through entrepreneurship (Mathew, 2013).

The Honey Bee database of 12,000 innovations collected and documented by SRISTI would be part of the National Register of Innovations to be managed and supported by NIF. Grassroots Innovations Augmentation Networks (GIANs) in various geographic regions have been established to link up innovations, investments and enterprises. Input of formal science and technology, design, handholding support for project planning and management, finance and marketing intelligence to enable transition of an innovation into product and then into enterprise. The National Biodiversity Act also indicates village or community biodiversity chronicles/ registers to be carried out at a national level (Mathew, 2013).

5.6. Summary

The Protection of biodiversity associated Traditional knowledge 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.
Discussion on the 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. These region's have countless varieties of plants and trees that 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 is astonishingly high which would suggest the recent surge in bioprospecting.

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.

The Indian experience reveals that until the advent of TRIPS Agreement, the IPR protection in the country has served well the interests of the people and society on the one hand and the legitimate interests of the right holders on the other. Implementation of the TRIPS Agreement in India, as in the case of other developing countries, did experience a variety of challenges, the intensity of which was felt high in the realm of protection of indigenous and traditional knowledge as well as biodiversity resources.

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.

Indian experience reveals that the national level, number of initiatives have been made to protect Traditional Knowledge and biodiversity. National Biodiversity Authority, National and State Biodiversity Boards, Biodiversity Management Committees and Biodiversity Heritage Sites.

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. TDKL is one of the prestigious initiatives to protect Traditional Knowledge and prevent bio-piracy. However, legal initiatives need to be supplemented with adequate administrative and participatory measures.