Journal of Intellectual Property Rights
Vol 29, September 2024, pp 365-374
DOI: 10.56042/jipr.v29i5.5775

Challenges of State in Formulating Policies for Biological Resources Associated Traditional Knowledge in the Indian Context

Chaithanya E P[1] and Kavitha Chalakkal[2†]

[1]Department of Political Science, S N College, Nattika, Kerala – 680 566, India

[2]Interuniversity Centre for IPR studies, Cochin University of Science and Technology, Kerala – 682 022, India

Received: 23rd September 2023; revised: 20th June 2024

Over the centuries, communities have developed a close and unique connection with the lands and environments in which they live. They have established distinct systems of knowledge, innovations and practices relating to the uses and management of biological diversity on these lands and environment. Much of this knowledge forms an important contribution to research and development, particularly in the areas such as pharmaceuticals, agricultural and cosmetic products.This increasing economic importance of biological resources and related knowledge to these resources has made the allocation of property rights as one of the most contentious issues in the discussions concerning biodiversity management. But this new allocation does not recognize any property rights of holders over their knowledge. As far India is concerned one of the mega biodiversity countries of the world and also concentrated with indigenous people too. But existing legal framework does not confer positive protection, to the rights of traditional knowledge holders in the protection of traditional knowledge. In this context, the paper is going to look into the potential challenges faced by the State in the formulation of a law for protection of TK in India.

Keywords: Protection, Ownership, Traditional Knowledge, Biological Resources, India, IPR

Globalization has opened up the knowledge economy to the world and facilitated the free flow of knowledge and information. However, the movement of information was driven by the unequal distribution of economic and political power between developed and developing countries. The inclusion of a "global standard" in domestic intellectual property rights (IPR) is one example of how globalization has encouraged countries to be more open to global standardization of their national legal systems.The introduction of IPR to the regulation of access and benefit sharing of biodiversity, specifically on genetic resources has raised concerns over the loss of biodiversity and associated TK. Experience shows that knowledge that used to be in the public domain and transmitted from generation to generation has been privatized with the introduction of modern intellectual property protection, paving the way for depleting the raw material needed for the application of the knowledge that was available to the entire community.[1] Likewise, many other medicinal plant species and herbs known for curing more than one disease have been collected from the wild, and as a result, these species are under pressure due to over-collection from the wild.[2] However, the fact is that the main aim of IPR is to create a legal basis for the modern industry to 'access' the TK and its associated plant resources, claim an invention, and subsequently commercialize the product.[1] The misuse of valuable information with the help of technology saves time, money, and investment in the development of new technology, especially for modern biotechnology companies and other industries. This harmed the rights of TK owners and led to a demand for protection of TK through an international mechanism. Although the international community failed to reach a consensus on the same, this led to many more deliberations on this topic. It has been identified that even though neoliberalism brought many benefits to the population, these benefits have not reached the lower strata of society.

Scope for Protection of TK: Issues and Challenges in a Globalized World

In a globalized context, the mode for protection of TK was a serious question raised. Lack of protection for TK poses the risk of its disappearance since communities or the custodians who hold it may be impacted by the effects of globalization. It seems that the government must protect as well as preserve it.

†Corresponding author: Email: kavithachalakkal@cusat.ac.in

However, the State under globalization has changed its focus and shifted its ability to strengthen its capacity to effectively manage in a changing and complex situation. As discussed earlier, the State's role has changed from a 'hand on management and direct deliverer of service and goods' to a 'facilitator of an enabling environment and framework for private sector participation'.[3] The state's economic role has shifted to regulating financial institutions to ensure fair competition and maintain the safety and soundness of the financial system. In the globalised context, communities are struggling to establish their rights over their TK providing resources for future innovations. However, in this process, a share of such benefits would not accrue to the creators and holders of such TK. The two main options forwarded were whether TK is to be protected or preserved either through IPR regimes or through documentation, such as the Traditional Knowledge Digital Library (TKDL). Both these options have been identified with shortcomings such as increased public availability of the TK on one side and that the documentation of such knowledge may expose some form of misappropriation on the other hand. The protection and preservation do not have the same meanings in the context of TK. Preservation refers to nurturing and nourishing the already-existing traditional knowledge; it does not refer to preventing the inappropriate use of traditional knowledge, which does not fall under the purview of preservation. Positive protection and defensive protection are the two types of protection for TK that are now available. In reality, both international and national regimes place a greater emphasis on defensive protection, which only incrementally improves the characteristics of the patent system by allowing, for example, the use of TK databases as proof of prior art to refute a patent claim on such TK.[4] Unfortunately, communities are not protected in any way. Positive TK protection refers to safeguarding TK from exploitation and misappropriation, such as duplication, adaption, or usage by uninvited parties. Communities will benefit greatly from effective protection. Yet, no current statutory mechanism offering meaningful protection could be seen. Identifying an appropriate protection methodis one of the most fundamental issues of TK. Due to the diverse nature of TK, the mode of protection and who to be recognized as right holders is a major concern in many countries, including India.

Ownership over TK is a controversial and complicated subject even after the conclusion of the CBD and Nagoya Protocol. Even though both have acknowledged, the owners of the TK are the indigenous people or communities, who preserved, conserved and developed the knowledge over generations. Notably, during the national implementation of the CBD and Nagoya obligations, the recognition of indigenous and local communities as the owners of the TK was not reflected in true spirit as envisaged in the international agreements. This was clear from the Indian position of not recognising indigenous people and instead standing firm on the proposition for the local community. It is matter of fact that India is a party to and a signatory to a number of international agreements that uphold the traditional community's right to self-determination and cultural identity, including the UN Declaration on the Rights of Indigenous Peoples (UNDRIP) in 2007, the International Convention on Civil and Political Rights (ICCPR) in 1966 and 1979, and the ILO Convention of 1957 and 1989.[5]

Interestingly, these international commitments did not find effective expression in the national laws, which allow only for consultation with the ILCs, with final authority for the grant of approval for access residing entirely with the national competent authority.[6] Article 7 of the Nagoya Protocol and other international legal instruments that recognize indigenous communities' right to control their knowledge are in conflict with Indian legislation because it denies the indigenous and local communities the ability to make decisions about the grant of access to their traditional knowledge, either directly or indirectly through BMC (Biodiversity Management Committee).[6] The non-inclusion of traditional knowledge holders in the process of agenda-setting and decision-making at the international, national and local levels and the lack of their practical capacity is one key reason for the non-effectiveness of existing or envisaged legal provisions.[7] One of the main reasons for the non-implementation of international commitments has been identified as the delay in the enforcement of the same at the national level and the deviation from the initially committed obligations. In that sense, the fight for a well-defined community rights system for the indigenous community or the knowledge holders remains and the debates continue on the need for the same for an effective regulatory framework.

India is one of the mega biodiversity countries and is rich in biological resources associated with TK. However, it has been pointed out that the current

legislative intervention in the country is more concentrated on facilitating scientific development and commercialization of new products based on TK, rather than protecting the knowledge holders and allegedly legislation is providing little protection per se for TK. It has been argued that many developing countries including India had a change in the protection of TK policy due to the political bargaining process that attempted to appease several different interest groups such as domestic industry and scientific community and local communities. The interests and preferences of these actors are directly or indirectly involved in the formulation of the law.In so doing, it may have led to the allocation of ownership rights in a manner that focuses on specific interests but overlooks general welfare. As of now, India does not have a specific or a sui generis legislation to protect such TK and its associated GR and the protection of TK and its elements, are spread across various laws, rules and regulations resulting in a fragmented approach, rather than integrated one for the treatment for conservation of biological resources and TK protection. Though some legislations such as the Biological Diversity Act, 2002 (BDA 2002); Protection of Plant Varieties and Farmers' Rights Act, 2001(PPVFRA); Patent Amendment Acts, 2002 and 2005, etc., exemplify some attempts to prevent misappropriation of TK, there is a lack of positive protection or a legal mechanism to protect TK and recognize property rights over TK. It has been forwarded that this fragmentation of law, affecting its implementation indicates the reluctance on the part of the Indian state to effectively enforce the legislation and to recognise ownership of TK-associated GR rests with the community and has compromised meaningful implementation of these acts in many respects.

Changing Role of the State and its Impact on the Protection of TK

Before the 1980s, the State and its bureaucracy remained deeply engaged in almost all social sectors, directly involved in economic production, distribution and exchange. In the past, the constitutional and officially proclaimed role of the state and bureaucracy was to address the basic needs and concerns (for example, food, health, education, transport) of common citizens, especially of the underprivileged sections of the population left out by the market forces. Recently, this direct role has been replaced by that of facilitating rather than directing economic activities and has initiated and implemented market-oriented policies, such as privatization and deregulation, while reinforcing the rationale that it would improve efficiency, growth, share ownership, technology, and market competition. Most of the current reform initiatives in India have emphasized the role of the state and its bureaucracy in managing these market-based standards and concerns, rather than developing overall societal progress.

The successive governments in India have endorsed and embraced market-driven programs such as structural adjustment guided by neo-liberal principles, since the 1980s. This also ensured a conducive business atmosphere for the local and foreign private capital. In the case of India, it is obvious that the very nature of the State has also changed towards a more market-biased, neo-liberal mode of governance. This transition in the role of the State and bureaucracy in India, under the influence of the contemporary globalization process, has serious implications for various sections of society[1] and has also influenced policy-making in various sectors of the legal system, including the laws relating to the protection of TK. The changes in the character of the State and its mechanisms, particularly the establishment and expansion of knowledge induced into market mechanisms, including fictitious commodities, and the 'duty' of States to maintain this 'new' form of market exchange.[8] The major dimensions of the contemporary globalization process that have affected the role of the State and its bureaucracy include the following:

i. The globalization of market ideology;
ii. The globalization of the emerging neo-liberal State; and
iii. The globalization of the business-like administrative model.[9]

The introduction of modern market systems and intellectual property into this 'common and shared property' of the communities invariably disturbed the existing traditional modes of economic and social activities and reshaped economic power relations. The process of commodification of bio-resources and associated TK, through international trade and IPR regimes, is a consequence of liberalism and neo-liberalist policies. It has been observed that even though the State should be intervening in the market to prevent the use of knowledge as 'monopolistic commodities' as occurred with the patent regime, it

could not further this principle due to the pressure from market forces. Similarly, due to their TRIPS and CBD commitments, States were under an obligation to promote IPR-related laws, which led not only to the commoditization of knowledge but also "integration of knowledge and intellectual labour into production the appearance of severe social costs undermined the attempt to present IPRs as a neutral and technical market solution, allowing the reassertion of a politics of IPRs".[8]

Protection of Traditional Knowledge in India: Issues and Challenges

A self-regulating market and its associated fictitious commodities require State intervention by establishing a set of rules for the proper function of neoliberal market mechanism, where private property must be guaranteed and incentives must be given to compete for scarce resources. This should be understood in the context of wider transformations that took place during the 1970s and 1980s that ushered in a more intensive regime of valorisation and competition in world markets, prompting many developing States to see the biodiversity within their territories as a resource whose utilisation would enhance their income and as a key component of their growth regimes.[10] This new growth regime was with the vision of transforming India into a globally competitive economy.

In the late 1980s, India asserted that Plant and Genetic Resources (PGRs) is a sovereign property, as a defensive-assertive state strategy, which aimed simultaneously at resisting acts of biopiracy fuelled by nationalist indignation against neo-colonial expropriation and at making India a competitive player in global agricultural and biotech markets. By realizing its potential, India became a new priority area for biotechnology-related knowledge and globally competitive with a better capacity for converting genetic resources into wealth. This is also reflected in the Indian negotiations over PGRs in key international forums. For instance, to support India's emerging modern biotech sector, India insisted during the CBD negotiations, on both moving toward a property regime based on the principle of national sovereignty over genetic resources and making access to them dependent on the transfer of biotechnologies developed in frontier economies.[11]

From the 1990s onwards competitive biotech sector emerged as a new growth regime that is capable of generating ecological surplus has invited the attention of policymakers of various political persuasions to considerit as a powerful enabling technology that will not only revolutionize India's agriculture but also help establish India as a knowledge superpower in the world. This new growth regime, though it offered support to indigenous rights at various international fora, did not result in actual and effective realization at the domestic level and focused more on ecological surplus creation *vis-à-vis* other players in the global market. This impact was also visible while challenging the U.S. Patent Office on turmeric and basmati rice. Although this improved India's credentials as the protector of national genetic resources, it was alleged that India fought these cases exclusively on issues of interestof theIndian exporters rather than of the farmers dependent on such crops who saw no benefits from the legal challenges.[12] Legal protection of traditional knowledge has never been on the agenda of Indian law-makers, irrespective of the fact that India is one of the nations, which is rich in this knowledge base and many communities and industries have been surviving on this. It is only the CBD and the conclusion of the TRIPS that led Indian policymakers to look at the problems concerning the protection of traditional knowledge in India.[13] India has a mixed record of its effective implementation of laws against the misappropriation of TK and biological material at the national level. However, India had successfully challenged and revoked patents on Neem, Basmati and Turmeric. However, these opposition proceedings did not emerge as a significant strategy in the protection of traditional knowledge against misappropriation in the domestic system.[12] It is interesting to note that, most of the biopiracy of Indian traditional knowledge was first challenged by the civil society and the government reacted after the public demand.The Scheduled Tribes and Other Traditional Forest Dwellers (Recognition of Forest Rights) Act of 2006 is another legislation that deals with TK rights. The aforementioned Act contains a particular section that acknowledges the communities' property rights; however, it is still unclear how to uphold and establish these rights. The Act is in controversy due to its ineffective implementation. It has been stated that the above said legislation made no recognition of community rights, who have significantly contributed for of biological diversity and inevitable for the great majority of rural people's means of subsistence. At the

same time, the Act provided a vast array of initiative to protect the existing knowledge either through document or to catalogue all over the Indian subcontinent. It is interesting to note that India emerged as a great promoter of for the new growth regime either through setting up appropriate property regimes or investing in biotechnological R&D and high-tech clusters, which are not necessarily benefit the knowledge holders of TK.

Challenges in Formulating Policies for TK Protection: Owners of TK

The complexity of TK is further increased by technical problems like the issue of collective ownership and the methods of rights enforcement. In the Indian context also, questions such as who is the owner and holder of TK and for whose benefit shall TK be “protected” exist and the legal framework has not adequately addressed these issues. Defining the owner of TK remains fairly difficult in the Indian context due to its diverse nature. Thus, it can be seen that it is essential to devise a fair and effective mechanism for the protection of TK, which would also address the interest of different stakeholders in the protection of TK.

A crucial step in determining the range of TK protection is creating a *sui generis* system for its protection through national law and allowing legislators to specify the subject of rights. Countries, with diverse and different stakeholders, have different attitudes and priorities towards defining the subject matter and scope of TK protection. Without a clear definition of ownership and identification of communities, the scope of TK protection cannot be determined and is difficult to implement.

One of the challenges before the government is the ‘ownership’ of TK and the concept of ownership, which raises issues when applied to collectively created works like TK linked to GR. Several difficulties are presented because TK is a collective product and has a trans-generational nature. The trans-generational nature means that successive generations have immensely contributed tothe sustenance of the knowledge and therefore it becomes a factor in determining a right holder or an inventor in the case of TK. Thus elders, clans, families or individuals, could be considered as traditional custodians or holders of such knowledge rather than owners of such knowledge.

In Article 8(j) of the CBD, indigenous and local communities are given legal status rather than the holders of collective rights, and it is implied that traditional knowledge should be connected to or associated with indigenous and local communities and preserved following custom.[14] It's interesting to note that when describing the relationship between local or indigenous communities and their TK, the definition uses the word "held" rather than "owned," implying that they are merely custodians of it rather than its true owners.[15] But following the CBD and the principle of sovereignty in customary international law, it is up to the State to decide who owns and has the right to dispose of TK. By using domestic law, sovereign states can specify, based on the types, distribution, and current possession of the TK, whether a specific piece of TK belongs to an individual, an individual(s), a group, or the state. Both the CBD and the Nagoya Protocol have drawn criticism for their use of "soft language," particularly for giving the state priority over the rights of knowledge holders over their TK and for remaining silent on the issue of local and Indigenous communities' IPR. Toprevent undermining the function and further disempowerment of those in charge of managing biodiversity locally, it is imperative that the relationship between state rights and those of local communities be clearly defined if states are to assume sovereignty over natural and biological resources.

The CBD mandated that state legislation cannot change or weaken clauses like "prior informed consent" (PIC) as stated in the CBD text. The domestic application of this CBD principle requires owner identification for the proper PIC process. In order to guarantee effective communal rights while also fulfilling the obligations acquired through adherence to international conventions, national legislation must define the relationship between governments and local communities over their resource within their territory in accordance with the international principle of sovereignty. It would be based on the creation and application of clearly defined mechanisms for the participation and management of local community rights for a State to act as the custodian of local community resources. The CBD Secretariat has outlined a number of actions that governments may take to carry out the enunciated principles, including the State's recognition of communal rights, the State's recognition of appropriately defined indigenous property rights, including the ability to control access to genetic

resources within their territory, control over production and marketing, access to the formal legal system, access to financial and technical resources, and the modification of national laws.

India claimed that its position should be to ensure agreement on sovereign rights over genetic resources and the aforementioned "rights of local communities" in the context of TK protection. India has consistently argued that it is challenging to identify the creator and holder of TK in various countries like India because of the complexity of the resources. As a result, in India, the State makes decisions, manages resources, and grants PIC for resource access. Due to the uneven distribution of knowledge and biological resources, which are geographically dispersed and not constrained by political boundaries, it is difficult to identify the owners of genetic resources in this context. In Section 41(2) the Act provides that the NBA and the SBB shall “consult” the BMC when making a decision relating to the utilization of biological resources or knowledge associated with it that is in the territorial jurisdiction of the BMC.[16] Even though Article 7 of the Nagoya Protocol refers to the “prior and informed consent or approval and involvement” of indigenous and local communities, it can be inferred from this discussion that the Indian Act denies the traditional community the authority to determine who has direct or indirect access to their traditional knowledge through the BMC. The NBA, a bureaucratic entity oblivious to the problems and difficulties encountered by indigenous and local populations, makes all decisions in India about ABS. It is also important to note that the Nagoya Protocol talks of prior and informed consent of indigenous and local communities in case their traditional knowledge is accessed and not the prior and informed consent of the government of the country where indigenous and local people reside.[17]However many of these applicants appear to have accessed the resources or knowledge not directly but through various intermediaries including local markets. Given the widespread availability of biological resources and traditional knowledge, it is a significant challenge for the NBA to identify the local rights holders/benefit claimers thereby causing undue delays in the processing of the ABS applications.[18]As there is no systematic data on how much and to what extent TK exists widely within a country or across borders, it may not be possible to identify any, or even all, of the potential TK holders in this situation. The Prior informed consent (PIC) could be obtained from the actual suppliers of the resource and associated TK, who are qualified to negotiate benefits and rights, in cases where the TK is widely dispersed throughout the nation and there are numerous known potential communities that can lay claim to the TK.

When the resource and its associated TK are used by communities outside of one country, things get more complicated. For instance, the natural distribution of resources, like that of basmati and turmeric, spans multiple nations, making the TK associated with these resources common. This brings up the question of who should gain from the agreement, and it may not be appropriate to demand the consent of the entire community or nation. It mandates that all access requests be made known to member nations, perhaps through a clearinghouse mechanism, whether they have been approved or denied. It mandates that all access requests, regardless of whether they have been granted access or denied, be communicated to member countries, possibly through a clearing house mechanism. It also enables member nations to talk about benefit sharing when resources are present in multiple members.However, Article 11 of the Nagoya Protocol, which states that the same genetic resources are found in situ in more than one country, contemplates the issues of trans-boundary cooperation.[19] Additionally, cooperation is required when a resource is shared by multiple indigenous and local communities. Even in the instance of the first IRCC issued by India, it was given for the use of the TK of the Siddhi group, whose origins in Africa are disputed. So, it is questionable in this context how the Indian government can give such a certificate to a non-Indian group. The first IRCC was issued by the Competent National Authority (CNA) of India, on 27 March 2015, for a PhD student at Kent University, UK, to access ethno-medicinal knowledge of the Siddi community from Gujarat for research purposes.[20] Since then, IRCC issued the number started to increase up to 3436 by 4 August 2023.[21] In India, IRCCs were granted to domestic users seeking patents for commercial applications, usually based on a combination of various biological resources.[20] It is not clear what kind of benefit communities are getting from this certificate and no data is available regarding the benefit sharing arising from this certificate to communities. There is a definite need to see that the benefit sharing is realized fairly and equitably.

However, it would ultimately be up to each of these nations' domestic laws to decide whether or not to establish common ABS decisions and show solidarity and uniformity of practice among such nations. This highlights the requirement for creating international minimum standards for genetic resources access and benefit sharing. The BDA doesn't make it obvious how the transboundary provisions work. When such resources and associated knowledge are spread across States, it is unclear how the Indian states will handle access and benefit-sharing agreements.

Identification of Communities in the Indian Context

Land and related knowledge have historically had a strong connection to indigenous identity, and they are characterized by a communal relationship to resources, as well as to social and spiritual well-being. Due to complex collective ownership, it is challenging to properly identify and trace the knowledge holders even though this identity is linked to both the natural and livelihood of Indigenous Peoples. It is interesting to note that dynamic nature of culture, changes over time, and geographical dispersion across communities and nations, defining the ethnic and cultural boundaries of an indigenous group is difficult. It can be difficult to define what constitutes an indigenous person, whose PIC should be sought, and with whom. This is due to factors like social, legal, and political ambiguity as well as cultural heterogeneity. *Hansen* and *VanFleet* have thus classified the knowledge claims in this context as known and used by an individual; known and used by a group of people or a community; or diffused widely and in the public domain.[22] TK can be seen in India in the following forms:

a) Knowledge that is practiced and preserved by particular communities, particularly tribal groups, institutions, or families frequently found in particular territories of the country. Different traditional techniques are used to transmit this knowledge from one generation to the next.

b) Knowledge that has no particular community, institution, or family acting as its custodian but is used to support the livelihoods of numerous people dispersed throughout India.

Figure 1 shows that traditional knowledge in India falls into the following categories: secret, sacred, narrowly diffused, and widely diffused. The

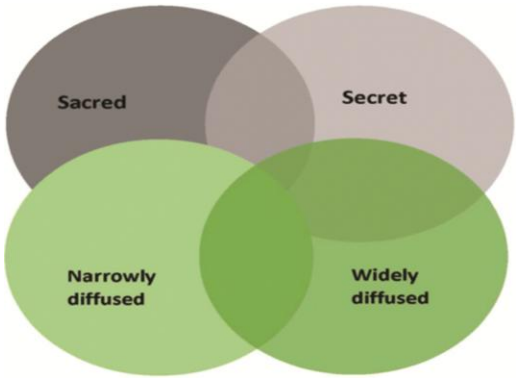

Fig. 1— Representation of tiered and differentiated approach to TK/TCEs
Source: Chidi Oguamanam, 2018

classification's main goal is to distinguish between the more limited types of rights for commonly used TK and TCEs.[22]

In countries like India, which are rich in TK and have many layers and levels of TK, the "tiered approach" to protecting TK may have some benefits. This is so that it can determine which forms the national government can represent and which ones need more protection.[23] As a result, the indigenous community, which has kept it a secret and out of the public sphere, would be granted an exclusive right (strong right). In circumstances where TK could not be directly attributed to a local community, the Indian delegation has argued for including national authorities within the definition of beneficiaries.[24] Additionally, it has been argued that specific types of undisclosedor narrowlydisseminated knowledge require additional protections, such as exclusive control and use, respect for particular cultural norms and moral rights, and fair benefit sharing.[23] In cases where it is appropriate, a nation-state must be given fiduciary responsibility after consulting with local populations. Because of this, nation-states' responsibility to protect collectively owned knowledge and their fiduciary duty to indigenous communities are crucial. After the policy is implemented, the mechanism would ensure that the stakeholders would share benefits in a stratified manner. India may experience some immediate benefits from using this paradigm, including the following.

(i) A specific and positive mechanism can be adapted to act as a standard;
(ii) Uniformity in accessing benefit sharing amongst the stakeholders;
(iii) The element of clarity would be introduced effectively;

(iv) Avoid a multiplicity of benefit-sharing laws and regulations;
(v) Enable the indigenous peoples to exercise their rights over their culture, communities and ancestral practices, which uphold the promises undertaken to achieve in the UNSDGs.[24]

Additionally, India still faces difficulties in identifying the owners of knowledge because the term "indigenous people" as a whole is not recognised. It is interesting to note further that there are also countries that say that the concept of indigenous people is irrelevant to them because all of their population is indigenous. The term "local communities" has been used by India in place of "indigenous" in its legislative framework. It is interesting to note that India supported the 1957 ILO Convention on Indigenous and Tribal Population from the start, even though it only used the term "Indigenous" at the time because the term did not yet link issues like rights and empowerment, and the emphasis at the time was on integrating indigenous and tribal people into the larger social system. But when issues of focus shifted, India felt the need for clarification of the relevance of the term in the Indian context. India has not yet ratified the updated 1989 Convention and remains with the 1957 Convention.[23]The Indian representative in the UN Working Group's meeting in 1993 at Geneva supported such a perspective by saying that "the term 'indigenous' was not adequate for the Indian scenario as"its entire population had been living on its land for several millennia, all these people were indigenous, and any attempt to make a distinction between indigenous and non-indigenous would be artificial".[25]In this context, it also has to be noted, many indigenous communities in India are not recognized as 'scheduled tribes'- as per the Indian Constitutional scheme, making the procedure "more of a political, than a legal process".[24] Additionally, it should be noted that without these rights, communities are unable to enforce PIC and assert control over GR on their property. The knowledge holders are also wary because local communities' rights to their TK or resources are not recognized by the law.In India, the question of "who are the people indigenous to India" is still open to debate. This flaw effectively creates obstacles to the ownership, use, and reaping of benefits from biological resources and knowledge. It has been reported that successive Indian government attitudes seem to run contrary to the true spirit of the CBD and Nagoya agreements, which made clear that the indigenous peoples are owners of such resources. So, it is very clear from the above discussion that Indigenous perspectives are thus rarely heard in the Indian debate over TK. In this situation, the State is unable to divide its responsibilities and bargain its commitments to specific communities, such as indigenous rights. This effort is crucial in the formulation of an effective regulatory framework as the lack of 'knowledge owners'' identification may result in many issues.Firstly, the role of national legislation in protecting TK owners may be diminished; secondly, the healthy exploitation, dissemination, and development of the cultural assets in TK may be hampered; and third, unnecessary transaction costs may be created during the processes of exercising, enforcing, and transacting TK rights, particularly when the users (buyers) and providers (sellers) of TK are from different countries. Fourth, when it comes to PIC and benefit sharing, distributive justice may be compromised, resulting in disputes between unidentified right holders.[26]

Traceability and Related Benefit-Sharing Concerns

It is challenging to pinpoint the origin of bio-resources due to the complicated movement of those resources across geographies. Due to a lack of traceability on the origin of accessed biological resources, several SBBs are currently struggling to distribute benefits to the communities and BMCs even though users have shared the benefits with them.[27, 2] When the source of the material is unknown, the money remains in the State Biodiversity Fund and must be used for biodiversity promotion, research, and conservation projects. It is troubling that so few commercial ABS agreements have been reached in India, which points to a lack of demand for GRs among potential users as well as onerous access rules as reasons for the underwhelming results. Different stakeholders have pushed for an easy mechanism to access the same to overcome these obstacles.Finding the originator and holder of TK is challenging when resources are obtained from the Himalayas and Western Ghats of India, despite increased concern over the protection of TK for benefits. Hence, knowledge is quickly disseminated to a vast number of communities both inside and beyond the nation. Due to this, those nations are having trouble establishing legal frameworks to recognize TK

owners and safeguard their rights to it. In India, communities with GR and TK ties may be found both inside and outside of the country. For instance, the Himalayan region is dispersed among India's neighbouring nations, and the Western Ghats' resources are dispersed among its several Indian states.For instance, resources like Turmeric, Ginger and other food, medicinal plants and animals found in Himalayas are common in TK connected with GR.Other nations with their sovereign rights have the same species and the knowledge that goes with it. Since the species and knowledge can be found in several communities, it is difficult to determine ownership over the associated knowledge even within the same country. This makes benefit sharing a challenge. Another example is the Normally Traded Community (NTC) list, which includes many important species and is regarded by the government as a common traded commodity. For instance, resources are taken from the wild and the original owners are hard to find. When agricultural universities use modified varieties derived from the parental lines of community holders and the same community then uses the hybrid variety created by such institutions and it is difficult to share benefits under such circumstances.Till date it has not been solved by any ABS laws, particularly in Indian law. It is clear from the discussion above that ownership ambiguity and disputes regarding biodiversity and TK make the system complex and reckless. In the Biodiversity Amendment Act 2023 however, it won't have any real impact on issues involving the safeguarding of traditional knowledge. It would just change how things are implemented, with no changes to the underlying concepts or TK-related policies.

Conclusion

India is one of the mega biodiversity countries and is rich in biological resources associated with TK. However, it is to be pointed out that, India does not have a specific sui generis legislation to protect such TK and its associated GR, and the protection of TK and its elements are spread across various laws, rules, and regulations resulting in a fragmented approach rather than integrated one for the treatment for conservation of biological resources and TK protection. It is a matter of fact that the existing legislations are not sufficient to protect indigenous knowledge since they are based on the protection of individual property rights. Thus, there is space for a sui generis law for the protection of TK associated with TK. The aim of incorporating a sui generis system in India for the protection of T.K could be achieved by modifying certain features of the existing intellectual property regime to accommodate the unique characteristics of its subject matter, i.e. traditional knowledge along with understanding the policy requirements, beneficiaries and examining the concept of equitable sharing and the principle of PIC. Such a system can help legal rights associated with T.K and T.C.E and thereby create space for access and benefit-sharing to protect the diverse set of knowledge and information that Indian indigenous communities hold. It has been forwarded that this fragmentation affecting its implementation indicates the reluctance on the part of India to effectively enforce the legislation and to recognise ownership of TK-associated GR rests with the community. It has been argued that many developing countries including India had a change in the protection of TK policy due to the political bargaining process that attempted to appease several different interest groups such as domestic industry and scientific community and local communities. The interests and preferences of these actors are directly or indirectly involved in the formulation of the law. In so doing, it may have led to the allocation of ownership rights in a manner that focuses on specific interests but overlooks general welfare. In the case of India, it is obvious that the very nature of the State has also changed towards a more market-biased, neo-liberal mode of governance. This transition in the role of the State and bureaucracy in India, under the influence of the contemporary globalization process, has serious implications for various sections of society and has also influenced policy-making in various sectors of the legal system, including the laws relating to the protection of TK.

References

1 Javed, G, Priya R & Deepa V K, Protection of traditional health knowledge: International negotiations, national priorities and knowledge commons, *Society and Culture in South Asia*, 6 (2020) 100, https://doi.org/10.1177/2393861719883069.

2 Kala C P, Dhyani P P & Sajwan B S, Developing the medicinal plants sector in northern India: Challenges and opportunities, *Journal of Ethnobiology Ethnomedicine* 32 (2006), https://doi.org/10.1186/1746-4269-2-32.

3 Jordan J, Globalisation and the role of State, 2013, 79, https://repository.up.ac.za/bitstream/handle/2263/24284/02chapters4-5.pdf.

4 Poorna R L, Preservation and protection of traditional knowledge – Diverse documentation initiatives across the globe, *Current Science*, 107 (2014) 1241, https://www.currentscience.ac.in/Volumes/107/08/1240.pdf.

5 Gupta M, Right of indigenous communities to prior informed consent under Article 7 of the Nagoya Protocol and a comparative analysis of its implementation by India and Bhutan, *International Journal on Minority and Group Rights*, 28 (2020) 56, https://www.jstor.org/stable/27001631.

6 Gupta M, Right of indigenous communities to prior informed consent under Article 7 of the Nagoya protocol and a comparative analysis of its implementation by India and Bhutan, *International Journal on Minority and Group Rights*, 28 (2020) 58, https://www.jstor.org/stable/27001631.

7 Sarma U K & Barpujari I, Revisiting the debate on intellectual property rights and traditional knowledge of biodiversity:Accommodating local realities and perspectives, *The International Indigenous Policy Journal*, 3 (2012) 1, http://ir.lib.uwo.ca/iipj/vol3/iss4/1.

8 Chakkri C & May C, The Polanyian perspective in the era of neoliberalism: The protection of global intellectual property rights, *Journal of Population and Peasant Studies*, 19 (2010) 111, https://so03.tci-thaijo.org/index.php/jpss/article/view/84688.

9 Shamsul H M, Impacts of globalization on the role of the state and bureaucracy in Asia, *Administrative Theory & Praxis*, 20 (1998) 477, http://www.jstor.org/stable/25611308.

10 Muzaka V & Serrano O R, Teaming up? China, India and Brazil and the issue of benefit-sharing from genetic resource use, *New Political Economy*, 25 (2019) 8, https://kclpure.kcl.ac.uk/portal/files/106675693/Teaming_Up_China_India_MUZAKA_Publishedonline1March2019_GREEN_AAM.pdf.

11 Muzaka V, Stealing the common from the goose: The emergence of Farmers' Rights and their implementation in India and Brazil, *The Journal of Agrarian Change*, 21 (2021) 366, https://doi.org/10.1111/joac.12398.

12 Krishnaswamy S, Access to knowledge and traditional protection: The Indian experience in Ramesh Subramanian and Lea Shaver*(eds.), Access to Knowledge in India: New Research on Intellectual Property, Innovation & Development*, Bloomsbury, London, 2011.

13 Gopalakrishnan N S, Protection of TK: The Need for a *Sui Generis* Law in India, *The Journal of World Intellectual Property*, 5 (2002) 730, http://onlinelibrary.wiley.com/doi/10.1111/j.1747-1796.2002.tb00179.x/epdf.

14 Article 8(j) of UN Convention on Biodiversity, 1992.

15 Kariuki F, Notion of 'Ownership' in IP: Protection of traditional ecological knowledge *vis-a-vis* protection of T K and Cultural Expressions Act, 2016 of Kenya, *Journal of Intellectual Property Rights*, 24 (2019) 90, https://nopr.niscpr.res.in/bitstream/123456789/54175/1/JIPR%2024(3-4)%2089-102.pdf.

16 Gupta M, Right of indigenous communities to prior informed consent under Article 7 of the Nagoya Protocol and a comparative analysis of its implementation by India and Bhutan, *International Journal on Minority and Group Rights*, 28 (2020) 17, https://www.jstor.org/stable/27001631.

17 Gupta M, Right of indigenous communities to prior informed consent under Article 7 of the Nagoya protocol and a comparative analysis of its implementation by India and Bhutan, *International Journal on Minority and Group Rights*, 28 (2020) 19. https://www.jstor.org/stable/27001631.

18 Access and benefit sharing experiences from India, http://nba.org.pdfABS-Factsheets.

19 Article 11 of Nagoya Protocol, 2010.

20 Martyniuk E & Haska A, Implementation of the Nagoya Protocol in livestock sector: What have we learnt so far?*Animals (Basel)*, 11 (2021) 7, doi: 10.3390/ani11082354.

21 Internationally Recognized Certificates of Compliance (IRCC) https://absch.cbd.int/en/countries/IN.

22 Stephen H A & VanFleet J W, A Handbook on issues and options for traditional knowledge holders in protecting their intellectual property and maintaining biological diversity, (2003) 44, http://www.icimod.org/resources/353.

23 Chakrabarty S P & Kaur R, A primer to traditional knowledge protection in India: The road ahead, *Liverpool Law Review*, 42 (2021) 421, https://link.springer.com/article/10.1007/s10991-021-09281-4.

24 Javed, G, Priya R & Deepa V K, Protection of traditional health knowledge: International negotiations, national priorities and knowledge commons, *Society and Culture in South Asia*, 6 (2020) 109, https://doi.org/10.1177/2393861719883069.

25 James T C, International discussions on indigenous people and India, *RIS-Discussion paper*, 272 (2022) 5, https://www.ris.org.in/sites/default/files/Publication/DP%20272%20T%20C%20James%20English.pdf.

26 Zhang C, How is the owner of "Traditional Knowledge Right"? A perspective of international law and the case of China, *Journal of Legal, Ethical and Regulatory Issues*, 21 (2018) 4, https://www.abacademies.org/articles/how-is-the-owner-of-traditional-knowledge-right-a-perspective-of-international-law-and-the-case-of-china-7175.html.

27 Bhartiya S, Good practice of access and benefit sharing, *Indo-German Biodiversity Program*, https://www.giz.de/de/downloads/giz2019-good-practices-access-and-benefit-sharing.pdf.