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PROTECTING TRADITIONAL KNOWLEDGE AND SAFEGUARDING THE RIGHTS OF INDIGENOUS COMMUNITIES: AN APPRAISAL OF INDIA'S COMPLIANCE WITH THE NAGOYA PROTOCOL ON ACCESS AND BENEFIT SHARING

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ABSTRACT

Given India's rich biodiversity and immense wealth of traditional knowledge, it is indeed, one such country which has the required capacity to make new advancements especially in the fields of biotechnology and medicine. This paper acquaintances its readers with the significance of traditional knowledge and the role that indigenous and local communities have played through ages in conservation and evolution of this knowledge. This study provides an in depth analysis of key provisions relating to traditional knowledge and indigenous and local communities in two important international environmental agreements i.e. the Convention on Biological Diversity and the Nagoya Protocol on Access and Benefit Sharing. In continuation to the above discussion, this paper identifies existing legal gaps in the Biological Diversity Act of India (the Act of Parliament on access and benefit sharing in India) in context of protection of traditional Knowledge and safeguarding the rights of indigenous and local communities. This paper advocates that the indigenous and local communities have contributed significantly in conservation of traditional knowledge of the day and hence, their legal rights must be strengthened under the existing access and benefit sharing law of the country. In light of the fact that India has ratified the Nagoya Protocol, this study concludes that the current text of the

Biological Diversity Act falls short of fulfilling India's commitments under this international agreement in context of traditional knowledge and hence, the paper makes relevant suggestions in order to make domestic law of India fully compliant with the Nagoya Protocol's key provisions on traditional knowledge.

Key words: Access**,** Benefit Sharing, Biological Diversity, Biopiracy, Compliance, Indigenous, Legal Gap, Nagoya Protocol, Traditional Knowledge

Introduction

Traditional Knowledge (hereinafter TK) could in simple terms be described as man's understanding of nature through ages. This knowledge has travelled with humans and has been enriched over the course of time. Even though it is a property of human intellect but it cannot be said to be owned by a particular individual. Hence, it is regarded to be one of the most difficult concepts in terms of framing of an arrangement for its regulation and protection. TK continues to play its role in lives of indigenous and local communities (hereinafter ILCs) and is indeed an irreplaceable aspect of their living.

In addition to this, it would not be wrong to argue that the demand of products which have been derived from utilization of TK has been revived in lives of those residing in urban areas owing to rising awareness about healthy and sustainable ways of living. With this increase in demand, the tendency to produce and market products based on utilization of TK has increased manifolds amongst multi-national companies and business groups. The underlying issue in this process is the problem of Biopiracy i.e. total disregard by such users of the contributions that ILCs have made in conserving biological resources and TK associated with such resources over generations. This fact raises the concern of providing a well-designed access and benefit sharing legal framework both at the international and domestic levels to protect TK as well as to safeguard the rights of ILCs in this context.

Scope of the paper

Since the past two decades experts all over the world have been boggling their minds on the issue of ensuring proper protection for TK and related rights of ILCs who are possessors of this collection of knowledge. Such discussions have found place at several international fora and

during negotiations of various international agreements including World Trade Organization, World Intellectual Property Organization, Convention on Biological Diversity, Nagoya Protocol on Access and Benefit Sharing etc.

This paper shall provide an analysis of two major international environmental agreements i.e. the Convention on Biological Diversity and the Nagoya Protocol on Access and Benefit Sharing to the Convention on Biological Diversity. The analysis of the above two instruments shall only be in context of their key provisions on traditional knowledge and indigenous and local communities. In continuation to this, the paper shall look at the Biological Diversity Act of India to examine its compliance in light of India's international legal obligations under the Convention on Biological Diversity and the Nagoya Protocol on Access and Benefit Sharing. The existing regime on Access and Benefit Sharing (hereinafter ABS) in India includes other legal instruments like the Biological Diversity Rules, 2004, Access and Benefit Sharing Guidelines, 2014 and various state rules, but these instruments do not form part of this study. This study is a pure analysis of the text of the Biological Diversity Act of India, in context of its provisions on access and benefit sharing on traditional knowledge.

The next section of the paper provides a critical analysis of the key provisions of the Convention on Biological Diversity dealing with regulatory aspects of traditional knowledge.

The Convention on Biological Diversity and Traditional Knowledge

The Convention on Biological Diversity (hereinafter CBD) came into force in 1993. It came into existence as an action to address the rampant spread of Biopiracy during last quarter of the twentieth century with developing countries being at the receiving end. The Preamble of the CBD recognizes the desirability of sharing equitably the benefits arising from the use of TK. As mentioned earlier, TK plays a huge and significant role in deriving products from biological and natural resources. It reduces the frequency of experiments needed to arrive at a usable product and hence reduces the cost involved as well as saves the time. Therefore, this rising concern of sharing of the benefits arrived at by producers with the ILCs who have been the conservers of such precious knowledge over generations was given a place in the Preamble to the CBD text.

The CBD obligates the state parties to respect, preserve and maintain TK including innovations and practices of ILCs that are relevant in conservation and sustainable utilization of biological diversity. It brings them under the duty to promote the wider application of such knowledge and practices and to encourage the equitable sharing of benefits arising from their utilization. The State parties may fulfill this legal obligation by way of national legislations, regulatory and policy measures, executive decisions etc. The text makes this obligation subject to the national legislations of the State parties. Therefore, the pre-existing as well as future national legislations which might run contrary to this international legal obligation of preserving TK and encouraging the equitable sharing of benefits arising from the utilization of such knowledge can very well be a justification of non-fulfillment of it.

The CBD casts the legal duty upon the states to protect as well as encourage customary use of biological resources in accordance with traditional and cultural practices of ILCs with the overall purpose of ensuring conservation of biological diversity and sustainable use of its components. This provision although does not expressly uses the term Traditional Knowledge but impliedly it does have a significant manifestation of it. The text of this key provision of promotion of use of biological diversity in accordance with traditional and cultural practices of ILCs is a significantly wide phrase without any guidance provided for within the CBD for the State parties to indicate the manner or ways in which this obligation ought to be fulfilled.

The provisions on TK in the CBD text leave it to the state parties to act '*as far as possible*' and '*as appropriate*'. There is no set of standards or any sort of threshold as to the required 'possibility of domestic measure' or 'appropriateness of domestic measure' mentioned in the CBD text which the State parties need to attain in order to fulfill their commitments. In fact CBD herein, lost the opportunity to apply the principle of Common but Differentiated Responsibilities and to provide for a detailed and specified obligations as provided for in the international climate change law regime.

Likewise, the next section shall provide a critical analysis of the provisions related to TK and ILCs under the Nagoya Protocol on Access and Benefit Sharing to the CBD.

The Nagoya Protocol on Access and Benefit Sharing and Traditional Knowledge

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (hereinafter the Protocol) further advanced the third objective of the CBD i.e. the fair and equitable sharing of benefits arising from the utilization of genetic resources.

In order to achieve this objective, the Protocol undertakes to promote the use of genetic resources and associated traditional knowledge and to strengthen the opportunities for fair and equitable sharing of benefits.

Although the term 'Traditional Knowledge' does not finds a place in the title of the Protocol, but the Protocol creates a binding obligation for the state parties to undertake appropriate measures to share the benefits arising out of utilization of TK associated with genetic resources in a fair and equitable manner with the ILCs based upon mutually agreed terms. It is worth mentioning, that for the first time, the Protocol provides for intra-state sharing of benefits. It casts a duty upon the State parties to make it obligatory upon them by way of legislative, administrative or policy measures to share the benefits arising out of utilization of TK with ILCs belonging to it irrespective of such TK being utilized by a national or a foreign user. It also provides that such sharing of benefits has to be based upon mutually agreed terms. This brings the ILCs at par with the users within respective legal frameworks of their states in negotiations of the terms based on which benefits have to be shared. This is a major advancement from the CBD as the Protocol provides for a more detailed norm in this regard. This is indeed in furtherance of the opening statements of the Protocol wherein it restates that it is the right of ILCs to identify the rightful holders of their TK associated with genetic resources within their communities. One of the legal gaps within the Protocol is the lack of sufficient guidelines or an annex of model contractual clauses that could be framed on mutually agreed terms between the users and the ILCs of states. This is much needed as it would not be wrong to argue that ILCs lack the research and information required to put up their reasoned viewpoints during negotiations with the other party which is a much stronger one.

In addition to this, the Protocol provides that the TK associated with genetic resources should be accessed with the prior and informed consent of the ILCs holding such knowledge or their prior

approval and with their involvement for accessing it. This access of traditional knowledge must be based on mutually agreed terms. This provision goes beyond the text of CBD by requiring the State parties to lay down norms within their domestic legal systems to regulate the access to TK including norms requiring the prior informed consent or involvement of the ILCs. The State parties are required to provide for such appropriate measures which could be in the nature of legislative, policy or executive measure in accordance with their domestic laws.

It can fairly be seen that in recognition to the larger role that ILCs have played in conserving and evolving TK, the Protocol provides for a two-fold role of ILCs. Firstly, it makes the informed consent of ILCs a mandatory requirement before access of TK that is held by such ILCs and secondly, as mentioned earlier, states are required to provide measures for equitable and fair sharing of benefits arising out of utilization of TK with the ILCs and ensure that mutually agreed terms in this regard have been established.

There can be instances where a particular TK associated with genetic resources is shared by ILCs belonging to different state parties as neither biological resources nor TK follow the political territorial boundaries carved by states. The Protocol requires such state parties to take measures to cooperate with each other with the involvement of their ILCs in furtherance of equitable and fair benefit sharing arising out of utilization of access to genetic resources and TK associated with such resources.

The Protocol lays down specific provisions for participation of ILCs during various stages of access and utilization of TK. For instance, it makes it obligatory upon state parties to take into consideration *effective participation* of ILCs while establishing mechanisms to inform potential users of TK about their obligations. In addition to this it also requires State parties to make an effort to *support* the development of community protocols in relation to access to TK, model contractual clauses for sharing of benefits etc. undertaken by their ILCs. The State parties could introduce various governmental schemes or provide for appropriate legal or policy frameworks in furtherance of the same.

The Protocol requires the State parties not to restrict, *as far as possible*, the continuing customary usage and exchange of TK within and amongst its ILCs. It shall be interesting to look

at the statutory decisions or frameworks in cases where such exchange of genetic resources and the ever vital TK comes in conflict with the economic interests of potential users.

The Protocol makes it obligatory for the state parties to set up national authorities on access and benefit sharing. One of the main functions of such an authority shall be to inform the user applicants seeking access to TK, *where possible*, about the legal procedures of that state regarding the requirement prior informed consent of ILCs and the establishment of mutually agreed terms including sharing of benefits.

Not only the Protocol provides for provisions during the access and benefit sharing of TK associated with genetic resources but it also lays down norms dealing with compliance mechanisms in order to keep a check as to whether the TK that has been accessed and utilized has been done so in accordance with the procedures laid down in the domestic laws framed in consonance with the legal obligation created under the Protocol. In this regard, it lays down a binding obligation on user countries which are largely the developed nations to take measures *as appropriate* in order to ascertain that the users belonging to their jurisdictions have complied with the access and benefit sharing requirements of the provider countries including the requirements of prior informed consent and mutually agreed terms in all cases where access to TK is involved.

Apart from the above stated key provisions, the Protocol creates a legal obligation for the State parties to raise awareness about the importance of TK and related access and benefit sharing issues within their jurisdictions.

The fact that strikes one's mind while reading the text of the Protocol is that although it does provide a provision for the monitoring of the utilization of genetic resources, it does not do the same for the utilization of TK. A valid argument in this regard is that as the Protocol provides for designation of check points by the State parties in case of genetic resources, such check points could have also been designated in cases where TK is accessed and one such check point could be the Intellectual Property Registration Office. At this stage, a requirement within the domestic legislations of countries could be inserted wherein users would be required to disclose

information on access to TK and could be required to show that they have complied with the procedural requirements of PIC and MAT of the provider country.

Although the terminologies used in the Protocol seem to be weak but the above discussed provisions of the Protocol are believed to be drafted in good faith and a hope that state parties would endeavour with a honest commitment to protect TK and honour the rights of their ILCs.
After looking at the key provisions of CBD and the Protocol TK, the next section shall bring forward an analysis of relevant sections of the Biological Diversity Act of India with respect to TK.

The Biological Diversity Act and Traditional Knowledge

The Biological Diversity Act of India, 2002 (hereinafter the Act) was enacted in furtherance of India's international obligations under the CBD in order to give effect to the said Convention. In line with the objectives of the CBD, one of the purposes of the Act is to provide for fair and equitable sharing of benefits arising out of the use of biological resources and ***knowledge***.

India's in depth understanding and its appreciation to the contribution made by the ILCs becomes evident in opening part of the Act wherein it recognizes *creators and holders of knowledge and information relating to the use of biological resources* as benefit claimers. This is a significant advancement in legal drafting wherein law itself provides that the ILCs have a legal right to claim benefits arising out of utilization of traditional knowledge, held by them and relating to purpose for which a biological resource is being used. By way of this section, the ILCs can sue the users and the relevant authorities including the state itself in a court of law in case their right as benefit claimers is being violated.

The Act provides a safeguard against the misappropriation of TK by foreign users by laying down the access route to biological resources as well as knowledge associated thereto through the National Biodiversity Authority (hereinafter the NBA). That is to say, if a non-Indian user wishes to access Indian biological resources or knowledge associated thereto, he/she can do that only with the prior approval of the NBA. This provision gives effect to the aim of conservation of biological resources by providing protection to TK and biological resources of the state against the menace of bio-piracy.

The Act provides an opportunity for NBA to act as a designated platform to review that the laws and regulations with respect to access to TK have been complied by users including the requirements on sharing of benefits. The term i.e. used in the Act is '*information on biological resource obtained from India'* which can very well be broadly interpreted to include TK associated with such biological resource. In this regard, seekers of intellectual property rights (hereinafter IPRs), in any part of the world, in cases where in their invention is based on any research or information on a biological resource obtained from India need to obtain the prior approval of the NBA before applying for grant of IPR for that particular invention.

This provision is indeed a fine attempt to monitor the compliance with the Act. An important observation in this regard is that the text of the Act provides NBA with the power to impose benefit sharing fee or royalty while granting such approvals and it also mandates NBA to dispose of the application for permission within ninety days from the date of receipt. Hence, in case of non-fulfillment of benefit sharing requirements imposed on users, NBA stands in a position not to grant approval to such requests.

The Act provides for sanctions in cases where IPR applicants fail to seek and obtain prior approval of NBA before filing an IPR application in any jurisdiction or deliberately fail to disclose that such invention is based on information on biological resource obtained from India. But the underlying concern is regarding the timely awareness about such omission.

The only alternative provided to the NBA in this regard is that it may, on behalf of the central government, take measures necessary to oppose grant of IPRs in any jurisdiction on any biological resource obtained from India or TK associated with such biological resource that is derived from India. Similarly, no foreign user is allowed to transfer the TK associated to biological resource which is a subject matter of approval of the NBA except with its permission. The Act lays down sanctions in case of violation of the same. Assuming jurisdiction over a foreign entity and enforcing the judicial decisions of one's own country over that entity brings into play the rules of private international law which vary from country to country. Therefore, such sanctions might not turn out to be effective in practical situations.

As it is said, it is always right to nip it in the bud i.e. it is easier to sort out issues, the earlier they are addressed. Therefore, the law must require simultaneous fulfillment of mutually agreed terms (hereinafter MAT) while access is being granted. This point of view is supported by the language of the Act itself as it provides that the NBA, while granting approval must ensure that equitable sharing of benefits is secured. Such access must be continuously monitored and discontinued in case of failure of complying with MAT provisions by a user. Timely actions shall go a long way in saving the government of the pain and costs involved in opposing grants of IPRs at later stages in cases of non-compliance.

An important omission with respect to TK is reflected in the provision on prior intimation to state biodiversity boards for obtaining biological resources. Therefore, in situations where a company registered in India obtains the biological resource and also TK associated with such biological resources for commercial utilization, it needs to give prior intimation to the concerned state biodiversity board only with regard to biological resource and not TK. This provision stands weak on three grounds. Firstly, the Indian users need to give a prior intimation only which is quite different from seeking prior approval of the NBA by foreign users. Although, it is the function of SBBs to regulate commercial utilization of biological resource, by granting of approvals, and they have power to prohibit or restrict any such activity but the above requirement of 'prior intimation' leaves a doubt in the mind of readers as to the over-all interpretation of the text. Secondly, such prior intimation is needed only with respect to biological resource even if an access to TK has also been made by the concerned user. And thirdly, this provision provides a veil for foreign users to function and might lead to turning the other well drafted provisions designed to contain bio-piracy as futile. It can be concluded that the Act provides mechanisms for inter-country sharing of benefits but does not provides for intra-country sharing of benefits between national users and ILCs.

The language of the Act is such that it allows sharing of benefits arising out of utilization of TK based on mutually agreed terms, only in situations where the user is a non-national. Clearly, this keeps the users belonging to India beyond the obligation of equitable and fair sharing of benefits arising out of utilization of TK associated with biological resources. This stands in denial of rights of benefit claimers including the ILCs which have been conserving biological resources and enriching TK since time immemorial. Within this parameter of applicability of benefit

sharing provisions only to foreign users, one of the advancements made by this law is making the ILCs who are benefit claimers, a party in the negotiation of the MAT based on which benefits are to be shared in a fair and equitable manner. This provides the ILCs an opportunity to put forward their valid concerns and issues during the negotiation process and ensure that their share of benefits is just and fair. The non-applicability of benefit sharing provisions to the national users and lack of requirement of prior intimation to the State Biodiversity Boards where access to TK is made raises serious issues on effectiveness of this law. Such legal gaps tend to be heavily misused. In addition to this, the State Biodiversity Boards (hereinafter SBBs) lack any concrete function entrusted to them by the text of the Act with respect to sharing of benefits. As the Indian users come within the regulatory regime of SBBs, sharing of benefits between Indian users which might be a top grade research or technical institution or a huge profit making business group and the marginalized ILCs does not exist at least in the text of the Act.

Although, several state rules contain provisions for grant of approvals by state biodiversity boards in context of access to biological resources and associated knowledge, but the lack of a legal backing under the national law casts a shadow on efficiency, legal certainty and predictability aspects of the Act as far as TK and rights of ILCs is concerned.

The Act does provide that NBA as well as SBBs shall consult the Biodiversity Management Committee (hereinafter BMCs) while making decision with respect to biological resources and TK associated with it but it no where provides for criteria to be a member of BMCs. Therefore, members of various ILCs (ILCs in India are largely the scheduled tribes) might or might not find a place in a BMC of their locality. This might lead to concerns of such communities being unheard. Therefore, it should be made mandatory in the national law for a member of a scheduled tribe or ILCs of that particular locality to be associated with BMCs, whether by being a member of it or in some other effective capacity.

The Act, as is mentioned earlier, was enacted more than a decade before the Protocol came into effect and in furtherance of aims and objective of the CBD. As India has ratified the Protocol and the Act is the law on access and benefit sharing in India, its compliance need to be tested on the standards laid down in the Protocol. In this regard, the next section shall be examining the compliance of the Act with the Protocol, strictly, in context of TK.

Compliance of the Biological Diversity Act with the Nagoya Protocol in context of Traditional Knowledge

From the previous sections, it is quite evident that there is a significant legislative gap between binding obligation provided under the Protocol, and the Biological Diversity Act of India. In order to be fully compliant with the Protocol, it is required that the Act must provide for fair and equitable sharing of benefits in context of TK irrespective of the fact of user being national or a non-national. In other words, domestic legislation must provide for inter-state as well as intra-state sharing of benefits arising out of utilization of TK associated with biological resources. In addition to this, such sharing of benefits must be based on MAT and ILCs must be a party to such MAT, as is provided for in the Act but only in cases where NBA is authorized to grant approvals. This must be extended to other situations as well.

In light of the binding obligations under the Protocol, the domestic law must also provide for a provision on requirement of prior informed consent of ILCs who are holders of TK before granting approval for access of TK by the NBA and MAT between the users and ILCs must be established in this regard.

Also, the compliance and monitoring mechanisms provided for in the Act need to be strengthened in light of the Protocol requirements. The Act must provide for effective and proportionate measures to address situations of non-compliance with respect to access and benefit sharing norms of the country. In addition to this, the central government might time to time come up with certain policies and schemes to safeguard interests of ILCs by supporting conservation of their customary practices; raise awareness about the importance of TK in the country and take initiatives towards capacity building in terms of institutions as well as human resource to protect country's TK.

India could look forward to cooperation with adjoining countries having same TK as well as biological resources as that of India with the involvement of respective ILCs in order to give effect to the objective of the Protocol. Such collective approach might prove helpful in effective protection of TK and raising the bargaining capacity of provider countries including that of their ILCs during the actual course of access and benefit sharing negotiations with respect to TK.

Conclusion and Suggestions

The geographical location and climatic conditions of India makes her a mega-diverse country and she provides site for three major Biodiversity Hotspots of the world. She has been and continues to be home of several local and indigenous communities whose livelihoods and sustenance are dependent on nature to a very large extent. These communities are the store house of TK i.e. the nature's secrets whether such knowledge be related to skin care, health, energy, medicinal herbs, clothing, shelter, daily needs etc. Today, when the global economics has turned towards consumption and usage of natural products and there is a boom in the field of biotechnological research, it is required on India's part to leave no stone unturned to protect its TK. In light of the CBD and the Nagoya Protocol, the domestic legal and regulatory framework of India in context of TK need to be strengthened with the main focus on laying down norms on Prior Informed Consent, Mutually Agreed Terms, and Compliance. Apart from this, the Government of India may endeavour to bring about policy or administrative measures as provided for in the Protocol in order to enhance effective participation of ILCs in the decision making process with respect to access and benefit sharing process involving TK. The Government of India may provide for model text for the Indian bilateral access and benefit sharing treaty to be signed with user countries containing model contractual clauses on benefit sharing and an effective dispute resolution system on the lines of model text for the Indian bilateral investment treaty. This would provide a sense of predictability and certainty to users from such user countries which shall in turn strengthen the ABS trade regime of the country. Such treaties would also provide an umbrella protection to the interests and rights of ILCs as well as the state itself in case of non-compliance by users.

The Protocol is indeed an opportunity for developing countries which are rich in biodiversity and TK and it gives ample space to State parties to pursue the obligations enshrined in it. It has been nearly three years that the Protocol has come into force and five years since India ratified it, therefore, there is an urgent need for law makers to make necessary amendments to the Biological Diversity Act in light of legally binding obligations enshrined in the Protocol. This paper endeavours to make a point that it has been a long time that the subject matter of access and benefit sharing with respect to TK has taken a back seat and it is much required on the part of legislature to review the current domestic ABS legal regime on TK in light of the Protocol in order to provide proper protection to country's TK and safeguard the rights of her ILCs.

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