



# In-depth Study on Protection of Traditional Knowledge, Traditional Cultural Expressions and Plant Genetic Resources



**RIS**

Research and Information System  
for Developing Countries

विकासशील देशों की अनुसंधान एवं सूचना प्रणाली

# In-depth Study on Protection of Traditional Knowledge, Traditional Cultural Expressions and Plant Genetic Resources

*by*

**T. C. James**

**Namrata Pathak**

**Apurva Bhatnagar**



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# Preface

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## **Prof. Sachin Chaturvedi**

Director General, RIS

**T**he global demand for traditional medicine and associated products has risen significantly. However, literature on ethical issues associated with usage such as informed consent of knowledge providers has been limited. For India this is a critical issue as its vast resource of traditional medicinal knowledge is used extensively and has been gaining attention in health debates.

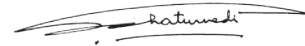
Traditional knowledge of medicine in the Indian context is closely associated with knowledge of plant genetic resources. More than 8000 species of medicinal plants are used as raw materials by the traditional medicine industry. Traditional cultural expressions in the form of crafts, languages, rituals, health practices, customs, handicrafts, textiles, songs, hymns, religious practices, art and architectural designs of local communities provide significant support to the protection of knowledge and natural resources. Hence protection to TMK entails protection of plant genetic resources and traditional cultural expressions.

The growth of biological resource and traditional knowledge dependent sectors like herbal and traditional medicine industry, has created challenges of sustainability and vulnerability of knowledge providers. On the other hand, legislations regulating access to natural resources hinder the growth of dependent industries. Research and innovation based on TK makes knowledge holders further vulnerable to misappropriation.

Against this backdrop, the Study on 'Protection of Traditional Knowledge, Traditional Cultural Expressions and Plant Genetic Resources' attempts to map the global and national instruments for protection of TK. It studies the key global platforms like World Intellectual Property Organization (WIPO) which negotiates a legally binding instrument for protection and the Convention on Biological Diversity (CBD) which emphasizes on fair and equitable sharing of benefits with TK holders. India is a major proponent of protection of TK at the international fora, including WIPO and CBD. It has been a trail setter with appropriate provisions in the patent law. In conformity with CBD, India has been one of the few countries with effective defensive and positive protection of TK and genetic resources in the form of legislations regulating access to biological resources, benefit sharing guidelines, and a digital library to establish TK as prior art abroad. India's efforts on designing Access and Benefit Sharing (ABS) mechanisms with users and knowledge providers of

biological resources has been studied and documented by RIS extensively. This study highlights issues associated with implementation of TK and biological resource protection legislations and offers recommendations for ensuring balancing interests of users and providers.

The interconnectedness of national and global legal regimes on TK protection and constant evolution of the debate calls for policy efforts towards adapting to changing requirements. I hope the study undertaken by Professor T. C James, Visiting Fellow; Dr Namrata Pathak, Research Associate; and Mr Apurva Bhatnagar, Research Assistant, RIS would help in shaping India's responses to global negotiations, particularly WIPO, on the one hand and create mechanisms to balance growth of traditional medicine industry with protection of TK and plant genetic resources on the other.



**Sachin Chaturvedi**

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# List of Abbreviations

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|        |  |
|--------|--|
| ABS    | Access and Benefit-Sharing   |
| AIISI  | American Institute for Indian Studies in India   |
| ASU    | Ayurveda, Siddha and Unani   |
| BDA    | Biological Diversity Act, 2002   |
| BDR    | Biological Diversity Rules   |
| BMCs   | Biodiversity Management Committees   |
| BR     | Biological Resource  |
| CBD    | Convention on Biological Diversity   |
| CGPDTM | Controller General of Patents, Designs & Trade Marks   |
| CIMAP  | Central Institute of Medicinal and Aromatic Plants   |
| CITES  | Convention on International Trade in Endangered Species of Wild flora and fauna                                |
| CSO    | Civil Society Organisations  |
| CTNBio | National Technical Biosafety Committee   |
| COP    | Conference of the Parties  |
| CSIR   | Council for Scientific and Industrial Research   |
| DNRs   | Designated National Repository   |
| DSI    | Digital Sequence Information   |
| DUS    | Distinctiveness, Uniformity and Stability Tests  |
| FAO    | Food and Agriculture Organisation  |
| FRA    | The Scheduled Tribes and Other Traditional Forest Dwellers (Recognition of Forest Rights) Act, 2006            |
| GIs    | Geographical Indications   |
| GMOs   | Genetically Modified Organisms   |
| GR     | Genetic Resources  |
| IBAT   | Integrated Biodiversity Assessment Tool  |
| ICAR   | Indian Council for Agricultural Research   |
| IGC    | Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore |
| IGNCA  | Indira Gandhi National Centre for Arts   |
| INTACH | Indian National Trust for Art and Cultural Heritage  |
| ISMs   | Indian System of Medicines   |
| IP     | Intellectual Property  |
| IUCN   | International Union for Conservation of Nature   |
| KVKs   | Krishi Vigyan Kendras  |



## List of Abbreviations

|        |  |
|--------|--|
| LDCs   | Least Developed Countries                                      |
| LIP    | Law on Industrial Property                                     |
| LMOs   | Living Modified Organisms                                      |
| MoEFCC | Ministry of Environment, Forests and Climate Change            |
| MPGRs  | Medicinal Plant Genetic Resources                              |
| MTAs   | Material Transfer Agreements                                   |
| NBA    | National Biodiversity Authority                                |
| NGB    | National Genebank  |
| NBPGR  | National Bank for Plant Genetic Resources (NBPGR)              |
| NBSAPs | National Biodiversity Strategies and Action Plans              |
| NBTs   | National Biodiversity Targets                                  |
| NFSC   | National Folklore Support Centre                               |
| NGO    | Non-Governmental Organisations                                 |
| NMM    | National Mission for Manuscripts                               |
| NMPB   | National Medicinal Plants Board                                |
| NIPR   | National Intellectual Property Right                           |
| NSTDA  | National Science and Technology Development Agency             |
| NTCs   | Normally Traded Commodities                                    |
| PBR    | People's Biodiversity Register                                 |
| PGRs   | Plant Genetic Resources  |
| PIC    | Prior Informed Consent   |
| PPVFRA | Protection of Plant Varieties and Farmers Rights Act ,2001     |
| R&D    | Research and Development                                       |
| SBBs   | State Biodiversity Boards                                      |
| TCE    | Traditional Cultural Expressions                               |
| TM     | Trade Mark   |
| TMK    | Traditional Medicinal Knowledge                                |
| TKRC   | Traditional Knowledge Resource Classification                  |
| TSMs   | Traditional Systems of Medicine                                |
| TRIPs  | Trade-Related Intellectual Property Rights                     |
| UNCCD  | UN Convention to Combat Desertification                        |
| UNCTAD | United Nations Conference on Trade and Development             |
| UNO    | United Nations Organisation                                    |
| UNDRIP | United Nations Declaration on the Rights of Indigenous Peoples |
| VAP    | Value Added Products   |
| WDPA   | World Database on Protected Areas                              |
| WHO    | World Health Organization                                      |
| WIPO   | World Intellectual Property Organisation                       |
| WPPT   | WIPO Performances and Phonograms Treaty                        |
| WCL    | Western Coalfields Limited                                     |

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# Executive Summary

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**G**rowing commercial use of Traditional Knowledge (TK) based resources also makes them increasingly vulnerable to misappropriation and misuse by third parties. The interconnectedness of national and global legal regimes on TK protection and constant evolution of the debate calls for policy efforts towards adapting to changing requirements. The National Intellectual Property Right (NIPR) Policy, 2016, acknowledges that there is 'considerable unexplored potential for developing, promoting and utilizing traditional knowledge of India' and the need to reach out to the less visible Intellectual Property (IP) generators like the TK holders. International legal instruments for TK protection has been discussed in various global fora. These include the Convention on Biological Diversity (CBD) and the World Intellectual Property Organisation (WIPO), a specialized agency of the United Nations Organisation (UNO). Established in 2000, the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) at WIPO is a "forum where WIPO member states discuss the intellectual property issues that arise in the context of access to genetic resources and benefit-sharing as well as the protection of traditional knowledge and traditional cultural expressions.

At the WIPO IGC, a divide exists between demandeur countries (including India) seeking protection for TK, rights to knowledge holders,

and patent disclosure requirements and nondemandeur countries that view these provisions as hindering innovation. At these platforms, more specifically WIPO, India has been an active participant, advocating an international regime to prevent illegal bioprospecting and protecting rights of knowledge holders. India's possession of a rich biodiversity of plant genetic resources and associated TK of medicine on these resources is an important factor for this advocacy. As one of the 17 mega diverse countries in the world with over 47,000 species of plants, Indian Systems of Medicine (ISM) and traditional health practitioners have had knowledge of medicinal usage of more than 7000 plants species.

More than 90 per cent formulations of Ayurveda, Siddha and Unani (ASU) systems of medicine are plant based. Most of the knowledge associated with these systems have been preserved through a mixture of documentation and practice by local communities as well as through the cultural expressions demonstrated through rituals, languages, handicrafts, religious practices , songs and hymns. Lack of internationally agreed norms have hindered protection of these knowledge systems on one hand and encouraged appropriation of rights of knowledge holders on the other.

This report examines global deliberations on protection of TK, cultural expressions and

medicinal plant genetic resources , domestic legislations and programmes , associated challenges and recommends India's responses to the same. Section 1 studies protection of traditional medicinal knowledge. legislations and regulations. It covers the broader debate on the definition of TK , the challenges owing to the same. It maps India's domestic efforts in designing and implementing legislations related to TK, policies and programmes and civil society initiatives. It documents international regimes on TK protection and legislations by select countries with the aim of giving an overview of global efforts on the same.

Section II studies protection of medicinal plant genetic resources. This section studies both IPR protection and conservation strategies adopted. This includes international regimes like CBD, WIPO, WTO-TRIPS, CITES along with national conservation and IPR protection programmes. It examines more specifically access and benefit sharing (ABS)

provisions under the Biological Diversity Act 2002, implementation by the National Biodiversity Authority (NBA) and the response of stakeholders like AYUSH industry with respect to its implementation. Finally, it also documents conservation and IPR protection of plant genetic resources in select countries.

Section III studies protection of traditional cultural expressions. The wide and expansive definition of cultural expressions its relevance in protection of traditional medicinal knowledge have been examined through mapping of international conventions, organisations and international collaborative efforts like the Berne Convention for the Protection of Literary and Artistic Works, 1886, WIPO and WIPO-UNESCO Joint Initiatives . India's legal provisions in the form of key IPR legislations like The Copyright Act, 1957, The Geographical Indications of Goods (Registration and Protection) Act, 1999 The Trade Marks Act, 1999 etc that impact TCE protection have also been mapped.

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# Introduction

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The establishment of a new separate Ministry of AYUSH on 9 November 2014 followed by the announcement of a new National Intellectual Property Rights (IPRs) Policy on 12<sup>th</sup> May, 2016 gave a great impetus to India's domestic and international efforts on promoting Traditional Knowledge of which the principal content of commercial value is the Traditional Medicine Knowledge. The National IPR Policy, 2016 envisages undertaking "an in-depth study to determine the appropriateness and extent of applying the existing laws to protecting TK Genetic Resources (GR) and Traditional Cultural Expressions (TCEs), and to propose changes required, if any." (Action Point 3.6). The vision statement of the Policy, among others, visualises promotion of traditional knowledge and biodiversity resources. The Policy recognises that there is considerable unexplored potential for developing, promoting and utilizing traditional knowledge which is a unique endowment of India (Objective 2). In another part of the Policy, it is stated that it is important to protect such knowledge, be it oral or in codified form, from misappropriation while providing space and environment for dynamic development of traditional knowledge for benefit of mankind (Objective 3). Besides the National IPR Policy, 2016, a renewed policy emphasis on protection of TK and associated sectors such as Traditional Systems of Medicine

(TSMs) has led to initiatives that would lead to better clarity on the subject on one hand and provide multidimensional solutions on the other.

The above-mentioned measures/initiatives are a response to domestic requirements as well as the challenges associated with the global governance frameworks on TK. At the international fora such as WIPO, new deliberations call for study of country specific provisions for protection of TK. The Nagoya Protocol further redefines the issues related to protection, access and benefit sharing related to TK.

In light of the above developments, a reassessment of the existing legal protection mechanisms for TK, GR and TCE is expected to bring to fore the needed clarity on the pros and cons of India's initiatives for protection of the related sectors till date and any further initiatives/legal measures that may be required in context of domestic and international compulsions. This will serve to strengthen India's TK and associated sectors on the one hand and on the other the policy outcomes as a result of the suggestions of the study will showcase Indian initiatives on protection of TK, thereby setting the global framework for emulation by other countries. Accordingly, this study was undertaken.

## Objectives of the Study

The broad objectives of the study are:

- To examine the adequacy of legal provisions presently available for protecting TK, GR and associated traditional knowledge, and TCEs in India, including in the digital world;
- To assess their adequacy to prevent misappropriation and biopiracy;
- To examine the underlying relationship and any overlap between different legislations;
- To propose changes required in the existing laws, if any;
- To propose broad areas of new laws and regulations, if any, required; and
- To suggest policy measures, including legal instruments and guidelines.

## Scope of the Study

- All existing Indian legislations, both central and state, which have direct or indirect provisions relating to protection of TK, GRs and TCEs.
- All existing Indian Rules and Regulations which have direct or indirect bearing on protection of TK, GRs and TCEs.
  - » WIPO IGC documents, particularly the following:
  - » WIPO Questionnaire on TK and India's responses<sup>1</sup>
  - » The Protection of TCE : Draft Articles (IGC , 34<sup>th</sup> Session)
  - » The Protection of TK : Draft Articles (IGC , 34<sup>th</sup> Session)
  - » Consolidated document relating to IP and Genetic Resources (IGC , 34<sup>th</sup> Session)
- An overview of legal provisions in select countries like China, Thailand, South Africa, Peru, Chile, Mexico, Ecuador and Brazil regarding TK, GR and TCEs.
- An overview of current global developments in the area of TK, GR and TCEs in fora such

as Convention on Biological Diversity (CBD) including Nagoya Protocol.

Later, in the light of periodic guidance from the FITM Board, certain focus shifting was done to adapt the study to the current requirements of Ministry of AYUSH and the Traditional Medicine industry in the country.

## Research Methodology

The study was mostly based on literature survey and analysis of primary source material, namely, the legal texts and governmental instructions, judicial pronouncements, international agreements and treaties, documents of international organisations. Secondary sources of reference included published research work in the form of books, monographs, articles and papers including conference papers, discussion papers and policy briefs. Several consultations with the AYUSH industry contributed significantly to the understanding of the issues that were affecting them and making the study accordingly relevant to the industries' requirements.

## Issues being studied

The study explores the Indian policy and legal provisions and key international instruments on Intellectual Property Rights of TK, TCEs and medicinal plant genetic resources (MPGRSs). The WIPO being a principal platform where international efforts are going on to create one or more new legally binding instrument(s) aimed at according *sui generis* IPR protection to TK, TCEs and plant genetic resources. The discussions so far have led to the development of three draft legal instruments, one each on TK, TCE and GR. In India also the subjects do not fall under a single Ministry; in fact, the subject 'TK' as such does not figure in the list of business allocated to different Ministries, but parts of TK linked with some other topics appear under different Ministries. For example, issues relating to "TK associated with biological resources"

are with the Ministry of Environment, Forests and Climate Change (MOEF&CC). At the same time, the major portion of TK is that relating to Traditional Medicine, as per the current norms, which is with the Ministry of AYUSH. Ministries of MOEF&CC and Ministry of Science and Technology (Department of Biotechnology) are both concerned with genetic resources, one as the source regulator and the other as the research regulator and researcher too. Even other Ministries who have biochemistry or biotechnology or pharmaceutical research institutions are also concerned with GR. Ministry of Agriculture can lay claim for agriculture related TK. The Department of Industrial Promotion and Internal Trade handles the negotiations at WIPO, being the Department dealing with WIPO matters. The Ministry of Tribal Affairs has a claim over TK and TCE of scheduled tribes. TCEs mostly

fall under the domain of Ministry of Culture, though the interests of other Ministries cannot be ruled out because of the TCEs relating to specific areas such as traditional medicine. Between TK and TCE uniform practices are rare and beneficiaries may differ. GR has a lot to do with research and already separate international protocols exist for the same. In view of this complex background, this study is divided into three parts, each focussing on one of the three topics. However, they are complementary and not exclusive. But, specifically because of the complementarities and because many of the documents and laws being examined are spanning across either two or three of the topics, there will be some repetitions also.

#### **Endnote**

1. As received from the International Cooperation Section, Ministry of AYUSH, New Delhi on 29th August, 2017





# Traditional Knowledge of Biodiversity and Medicine in India

As one of the 17 mega diverse countries in the world (with over 47,000 species of plants),<sup>1</sup> Indian Systems of Medicine (ISM) and traditional health practitioners have had knowledge of medicinal usage of more than 7000 plants species.<sup>2</sup> More than 90 per cent formulations of Ayurveda, Siddha and Unani (ASU) systems of medicine are plant based. In the past, several cases of IP misappropriation of Indian TK have been documented. Examples include patents granted on wound healing properties of turmeric<sup>3</sup> and fungicidal properties of *neem*<sup>4</sup>. More recently, efforts to claim copyright over yoga postures<sup>5</sup> and attach a trademark to Yoga<sup>6</sup> have been reported, implying that in the absence of an international regime on TK, this misappropriation may continue. The integration of TK into business models as in the case of Yoga and the use of IPRs and commercialisation generate further dilemmas for traditional communities.<sup>7</sup> Challenges to protection of TK exist both domestically and internationally. Despite several Indian legislations related to protection of TK, instances of misappropriation remain.<sup>8</sup> More crucially, many forms of TK remain legally unprotected and vulnerable to misappropriation in foreign jurisdictions. The WIPO being a principal platform there efforts are on to create a legally binding instrument, aimed at according IPR protection to TK, TCEs and plant genetic resources. But the discussions so far have led to the development of three draft legal instruments, one each on TK, TCE and GR.

## Definition and Characteristics of TK

An accepted definition on TK is yet to evolve at the international level. Major international conventions like the CBD, WTO and ITPGRFA have not defined TK. Countries of Africa, however, have attempted a definition under the framework of the Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore within the Framework of the ARIPO which was adopted by the Diplomatic Conference of ARIPO at Swakopmund (Namibia) on August 9, 2010. According to this definition, Traditional Knowledge is “any knowledge originating from a local or traditional community that is the result of intellectual activity and insight in a traditional context, including know-how, skills, innovations, practices and learning, where the knowledge is embodied in the traditional lifestyle of a community, or contained in the codified knowledge systems passed on from one generation to another. The term shall not be limited to a specific technical field, and may include agricultural, environmental or medical knowledge, and knowledge associated with genetic resources”.<sup>9</sup> While this definition is quite wide ranging, it limits the TK to local or traditional communities and may pose problems for systematised knowledge systems like Ayurveda and other such knowledge which may be wide-spread and may not even be bound national territories.



WIPO defines TK as ‘*knowledge, know how, skills and practices that are developed, sustained and passed on generation from generation within a community, often forming a part of its cultural or spiritual identity*’.<sup>10</sup> At the same time, the IGC Glossary gives a broad description of the subject matter of TK as generally including the “intellectual and intangible cultural heritage, practices and knowledge systems of traditional communities, including indigenous and local communities.”<sup>11</sup> TK in a broad definition may include the content of knowledge itself as well as in TCEs including distinctive signs and symbols associated with TK. Narrowly it refers to the ‘knowledge resulting from intellectual activity in a traditional context’. It can be found in a variety of contexts including agricultural, scientific, technical, ecological and medicinal knowledge. A 2007 draft of the IGC describes the scope of the subject ‘TK’ in a detailed descriptive way as under:

“The content or substance of knowledge resulting from intellectual activity in a traditional context, and includes the know-how, skills, innovations, practices and learning that form part of traditional knowledge systems, and knowledge embodying traditional lifestyles of indigenous and local communities, or contained in codified knowledge systems, passed between generations. It is not limited to any specific technical field, and may include agricultural, environmental and medicinal knowledge associated with genetic resources.”<sup>12</sup>

This description includes almost all the elements that pro-TK protection groups have been demanding to be included under TK (James:2019). It also specifically accounted for codified knowledge contained in the ancient texts of ISMs. The relationship of TK with intellectual property is that innovations based on TK may benefit from patent, trademark

and geographical indications protection or be protected as a trade secret or confidential information. However, TK as such is knowledge that has ancient roots, is often oral, is not protected by conventional intellectual property systems. Lack of a commonly accepted definition of TK has been a serious impediment towards IPR protection of these systems. What is to be realized is that TK is not static but dynamic, both temporally and spatially, with each successive generation adding to or deducting from the knowledge passed down to it by the previous generation. It is also dynamic in a spatial sense as different communities may develop received knowledge differently. This is reflected in the definition in the current text (though with brackets) of IGC:

Traditional Knowledge refers to knowledge originating from indigenous [peoples], local communities and/or [other beneficiaries] that may be dynamic, and evolving and is the result of intellectual activity, experiences, spiritual means, or insights in or form a traditional context, which may be connected to land and environment, including know-how, skills, innovations, practices, teaching, or learning.<sup>13</sup>

What is crucial in this definition is that “it is developed in a traditional way as different from laboratory based research” (James:2019). The expression ‘connected to land and environment’ is vast in scope and may include knowledge about the use and properties of certain minerals and metals which are traditionally been used in AYUSH systems.

## Value of TK

TK related to biological resources is valuable for several reasons, but all this is not being reflected in direct commercial value terms. In tangible terms, this is reflected in the global herbal medicine market mostly consisting of

products derived from traditional medicine related knowledge systems. The market is expected to register a CAGR of 5.88 per cent to reach USD 1,29,689.3 Million till 2023.<sup>14</sup> The market value of the commercialisation of plant species is indicated by the demand for products derived from these plants, price of products sold, and that contribution the plant makes. A large number of plant species that were traditionally used by local communities have now been commercialised. Similarly, the global handicrafts market, mostly an expression of traditional cultural expression of respective countries, reached a value of US\$ 526.5 billion in 2017.<sup>15</sup> Otherwise too, TK has both a short term and long term commercial value, the former for the survival of those in subsistence economies dependent on biodiversity for their day to day survival and the latter for the global economy as a whole as a valuable source of information for the commercial use of the components of biodiversity. However, direct commercial value of such knowledge may not always be affirmed.

Intangible value of TK is related to biological resources. It includes its contribution to conservation and promotion of such resources in light of increased depletion and extinction threats. In most cases, these may be embedded in the cultural, economic and social practices associated with biodiversity. Indigenous communities have therefore reiterated that the land and territory, and diversity contained within them are infused by a variety of values, social, cultural, spiritual and economic.<sup>16</sup>

There is a large literature on TK and some initial where also made attempts to estimate the value of goods and services which rely on the use of TK have been estimated.<sup>17</sup> In a quantitative analysis of the patent landscape, Robinson and Raven<sup>18</sup> compiled a list of 321 plant species with known Indigenous uses; 66 species were mentioned in the title or abstract of a patent in WIPO's database, and more than 1,300 patents were returned. The traditional medicine sector in countries of the

global South is heavily dependent on TK of medicine documented or orally transmitted through generations. However, there is no documentation of the economic value of TK or the market value of TK contained in IP instruments *per se*.

## Issues in Protection of TK

The lack of clear allocation of rights and obligations are one of the main bottlenecks in bringing out an effective protection and validation of TK. This is further complicated by the divide between the providers and users of these resources. Most key jurisdictions in the Global North, including those with considerable indigenous populations, have not adopted a TK protection mechanism. Almost all domestic legislation<sup>19</sup> and all regional frameworks<sup>20</sup> on the TK protection are in countries and regions that seem to be net exporters of TK and genetic resources.

## International Instruments in Protection of TK

The protection of traditional knowledge in general began as part of a larger discussion on the conservation of biodiversity resources. While the CBD and WTO deliberations do not specifically refer to TK codification or disclosure, the WIPO IGC facilitated substantial discussion focusing on the need to save TK from loss through documentation.

### Convention on Biological Diversity

The CBD is one of the first international conventions to mention traditional knowledge<sup>21</sup> and has since become the principal international instrument explicitly acknowledging the role of traditional knowledge and local communities as knowledge holders in biodiversity conservation and its sustainable development. The Convention was signed by 150 States during the Rio "Earth Summit" in June 1992 and entered into force on 29 December 1993. The CBD does not specifically call for the protection of TK. The

scope of the traditional knowledge covered by the Convention is confined to genetic materials. For the purposes of TK protection, the key sections of the CBD include Articles 8(j), 10 (c), 15 and 18 (4)<sup>22</sup>. These provisions are more aspirational than substantive in that they use qualified language including the phrases “as far as possible and as appropriate” and “subject to national legislation.”<sup>23</sup>

In its Article 8(j), the CBD recognizes indigenous and local communities’ contribution to biodiversity conservation, calls for respect and support for their knowledge, innovations and practices, and confirms indigenous people’s rights over the knowledge they hold. The other relevant articles, i.e. Articles 10 (c), 15 and 18 (4),<sup>24</sup> provide a general obligation for cooperation in the promotion and conservation of biodiversity and the ability of states to design systems for the sharing of benefits arising from the use of such biodiversity resources and knowledge<sup>25</sup>. All these are subject to the existence of national legislation. TK is also recognised in Article 16 as a vital ‘technology’ for effective practices of conservation and sustainable use of biodiversity.

The Convention’s significance is that it is the first move towards international dialogue on TK protection. It functions as a framework instrument which requires supplementary documents to be implemented. As one of the steps in elaborating on the CBD, working groups and meetings of the Conference of the Parties (COP) managed to produce two instruments: The Bonn Guidelines (2002) and the Nagoya Protocol (2010).

*The Bonn Guidelines (2002):* The Bonn Guidelines (on access to genetic resources and the fair and equitable sharing of the benefits arising from their utilization) are an important step in elucidating the CBD. It is a voluntary system proposed to help member countries in developing legislation and contractual regimes for access to benefit sharing from

the use of genetic resources and TK. Several member states, especially developing, and Least Developed Countries (LDCs), have used the system to establish national ABS mechanisms. The Guidelines, through its Section C (16,d(ii)) promoted a discussion on the requirement of disclosure of origin of source countries/communities in procedural and substantive patent law instruments. The disclosure of origin requirement pertains to a patent application which, directly or indirectly, has used a genetic resource or TK in developing the invention. Following the inclusion of such a standard in the Bonn Guidelines, the disclosure requirement was incorporated in the (procedural) Patent Cooperation Treaty and the (substantive) Patent Law Treaty.

*The Nagoya Protocol (2010):* The Nagoya Protocol, adopted at the 10<sup>th</sup> COP in 2010 and which entered into force in 2014, expands upon the CBD provisions establishing a substantive regime governing Access and Benefit-Sharing (ABS). Earlier, at the 2004 COP meeting of the CBD, the Ad Hoc Open-ended Working Group on Access and Benefit-sharing mandated member states to work on an instrument that would elaborate on Articles 8(j) on TK, and Article 15 on access and benefit sharing. The purpose of the Protocol is to provide legal certainty and clarity in implementing the CBD’s third objective – access to genetic resources and the fair and equitable sharing of benefits arising from their utilization.<sup>26</sup> The Protocol is binding on the states that have ratified it, and this is one of the key achievements. So far, 124 countries have ratified the Protocol.<sup>27</sup> Highlights include Global Clearing-House, and Multilateral Access and Benefit Sharing mechanisms. The ABS Clearing House (ABSCH) enables those who are using, or intending to use, genetic resources under the sovereignty of Contracting Parties to be aware of, and comply with, relevant laws and regulations. The ABSCH plays a key role in the issuance of Internationally Recognized Certificates of Compliance. These

include access to genetic resources and TK based on PIC and MAT, mandatory benefit-sharing obligations, recognition of community protocols and customary use of GRs and TK among indigenous and local communities, and compliance and monitoring measures. Here it may be noted that although the Protocol recognises customary laws of indigenous people and local communities on biodiversity and TK, it subjects such laws to domestic laws of signatories.

### **The UN Convention to Combat Desertification (UNCCD)**

The UNCCD provides for the protection of TK in the ecological environment as well as the sharing of benefits arising from any commercial utilization. Article 16 (g) of the Convention reads, “subject to their respective national legislation and/or policies, exchange information on local and traditional knowledge, ensuring adequate protection for it and providing appropriate return from the benefits derived from it, on an equitable basis and on mutually agreed terms, to the local populations concerned.” This is a clear statement recognising the rights of local people over their TK and also their right to get appropriate benefits from the commercial exploitation of such knowledge. Further Article 17 (c) talks about research support to protect, integrate, enhance and validate traditional and local knowledge, know-how and practices ensuring that the owners get benefits from any commercial utilization. Similar statements are made in Article 18.2, and 19.1(e) also. This Convention also talks about making inventories of TK. Annex II of the document relating to Regional Implementation Annex for Asia, in Article 6 (b) talks about preparing inventories of technologies, knowledge, know-how and practices, as well as traditional and local technologies and know-how and promoting their dissemination and use. There are 197 countries who ratified the Convention showing a general acceptance of the treaty; India ratified

the Convention on 17 December 1996. United States of America which has not yet ratified the CBD is also a member of UNCCD.<sup>28</sup>

### **WTO and TRIPS**

The WTO was established in 1995 following the decade-long Uruguay Round of multilateral trade negotiations. The preamble to the *Marrakesh Agreement Establishing the World Trade Organization* identifies the ‘need for positive efforts designed to ensure that developing countries, and especially the least developed among them, secure a share in the growth in international trade commensurate with the needs of their economic development’. Given the value of traditional knowledge to many developing countries and their indigenous populations, settling the treatment of traditional knowledge within the WTO agreements can be seen as especially important for developing countries and as a process in which developing countries may need special consideration. The Trade-Related Intellectual Property Rights (TRIPs) Agreement which forms part of the World Trade Organization (WTO) agreement is the instrument that outlines the intellectual property rights and obligations of member countries. TK, which is dominant in countries of the Global South, is not recognised under the TRIPs agreement. There is a “profound silence around the protection of indigenous and traditional knowledge”<sup>29</sup> in the agreement. The expressed wish of countries from the Global South includes TK protection as an integral part of the obligation under the TRIPs Agreement or agreements of similar scope.<sup>30</sup> In response, developed countries seem to have engaged in a ‘regime-shifting’ strategy by remitting TK protection discussions to the WIPO.<sup>31</sup> Mega diverse countries such as Brazil and India call for the amendment of the TRIPs Agreement to include a mandatory ‘disclosure of origin’ requirement for member states.<sup>32</sup> Most developed countries have not been keen on amending the TRIPs agreement. For instance, the



US as the most influential member of the WTO, objects to the TRIPs council's jurisdiction over TK protection. However, a limited disclosure of origin requirement, the violations of which do not have severe implications for patent holders, seems to enjoy popular support.<sup>33</sup>

### United Nations Conference on Trade and Development (UNCTAD)

While the TRIPs Agreement is silent on protecting TK, the UNCTAD, in its eleventh session in 2004 adopted the Sao Paulo Consensus recognising that “lack of recognition of intellectual property rights for the protection of traditional knowledge and folklore ” is an issue of particular concern for developing countries in international trade. It also identified TK as a potential means to poverty alleviation. It also made a firm commitment in para. 88 that “full attention and support should be given to the protection, preservation and promotion of traditional knowledge, innovation and practices.” It also exhorted the UNCTAD to undertake analysis of the development dimension of protection of traditional knowledge, genetic resources, and folklore and fair and equitable sharing.<sup>34</sup>

### World Health Organization (WHO)

Unlike TK, *per se*, or TK associated with biodiversity, TK related to health had drawn international attention quite early. The WHO recognized the relevance of traditional medicine as a source of primary health care as early as 1978 in the Primary Health Care Declaration of Alma Ata. The Declaration in para sub-para 7 of Para VII declares that primary health care, *inter alia*, relies at local level on traditional practitioners “suitably trained socially and technically to work as a health team and to respond to the expressed health needs of the community”.<sup>35</sup>

The various international organisations and the ensuing deliberations in these highlight that the international community is quite concerned about protection of TK, particularly of

traditional medicinal knowledge. Declarations and commitments have been made in various global fora for protection and for ensuring fair and equitable sharing of the benefits out of its commercial utilisation with the communities concerned. They are also equally clear about prior informed consent for such access. At the same time, it is a fact that there is no real consensus on a comprehensive legal instrument for the same, although efforts are going on the WIPO.

## Traditional Knowledge Protection in India

This section covers Indian Policy Regulations, Institutions, Initiatives and National Policies that affect biodiversity and associated traditional knowledge.

*National Biodiversity Action Plan*<sup>36</sup>: There are two mandatory unqualified obligations of CBD on all Parties, i.e. preparation of National Biodiversity Strategies and Action Plans (NBSAPs)<sup>37</sup> and National Reports.<sup>38</sup> India has updated its second generation NBSAP 2008 by developing 12 National Biodiversity Targets (NBTs) in consultation with stakeholders, which are included in Addendum 2014 to NBSAP 2008<sup>39</sup>. The Action Plan has very specific provisions for protection of TK such as developing *sui generis* system for protection of TK and related rights including IPRs (Point 48), documenting bio-resources and associated knowledge (Point 120), promoting and strengthening TK and practices (Point 130), and harmonising provisions concerning disclosure of source of biological material and associated knowledge used in the inventions under the Patents Act, Protection of Plant Varieties and Farmers Rights Authority (PPVFRA), and Biological Diversity Act (BDA), to ensure sharing of benefits by the communities holding TK, from such use (Point 138).

*National Forestry Policy (2016 draft)*: National Forestry Policy (2016 draft)<sup>40</sup> provides that special communities at the *Gram Sabha* level

be created to take over management of forests. The plans prepared by the *Gram Sabhas* for their forestlands would also have to be vetted by the forest department based on the rules prepared for the same, such as wider management plans that the forest department prepares.<sup>41</sup> The draft Policy provides for the involvement of TK holders in the management of certain aspects of forest management (Point 4.7.6). A revised Draft National Forest Policy, 2019 has been finalized.

*National Wildlife Action Plan 2017-2031*: The National Wildlife Action Plan (2017-2031) is the third, the first two having been implemented from 1983 to 2001 and from 2002 to 2016. Some of the key features of the Plan are conservation of threatened species of flora especially local endemics and highly traded species such as medicinal plants and orchids, identification and validation of TK available in various parts of the country and use of mobile technology to develop 'Digital Field Guides' for easy identification of various wildlife goods and their derivatives.<sup>42</sup>

*National Environment Policy, 2006* : Among others, the National Environment Policy, 2006 calls for enhancing and conserving environmental resources which includes biodiversity and traditional knowledge (Section 5.2)<sup>43</sup>, and utilize TK for environment conservation and 'unlocking the value of genetic diversity', encourage cultivation of traditional varieties of crops and traditional water conservation efforts, among others. It calls for harmonising the Patents Act, 1970 with the Biological Diversity Act, 2002.

*National Intellectual Property Rights Policy 2016 (National IPR Policy)*: Although India does not have a national policy on TK, the National IPR Policy contains specific recommendations on TK. In fact, by including TK protection within the ambit of the IPR Policy, India has raised the level of protection that it would like the holders of such knowledge to that of the owners of other IPRs. The Vision Statement

of the Policy itself talks about the role of IP to promote, inter alia, traditional knowledge and biodiversity resources. The Policy also mentions the necessity to create awareness of TK, GR and TCE & Folklore. (p.8). Holders of TK, TCE & folklore are one of the target groups for the same (p.9). It also acknowledges that there is considerable unexplored potential for developing, promoting and utilizing TK which it considers as a unique endowment of India. It is gratifying to note that the policy advocates that activities for promotion of TK have to be conducted with effective participation of TK holders (p.11). It made a very specific action point that India's rich TK should be promoted with effective involvement and participation of TK holders who should be provided necessary support and incentives for furthering the "knowledge systems that they have nurtured from the dawn of our civilization" (p.14). In regard to the Traditional Knowledge Digital Library (TKDL), the policy has recommended expanding its ambit and using it in future for R&D. It also recommended documenting oral TK with adequate precautions as to maintaining its integrity and with safeguards to prevent misappropriation (p.13).

Apart from the recommendations on the general TK, the Policy takes note of the TM. It makes detailed observation that

"India is rich in traditional medicinal knowledge which exists in diverse forms in our country. Amongst them, well developed systems like Ayurveda, Yoga & Naturopathy, Unani, Siddha, Sowa-Rigpa and Homeopathy have immense economic value. It is important to protect such knowledge, be it oral or in codified form, from misappropriation, while providing space and environment for dynamic development of traditional knowledge for the benefit of mankind." (p.15).

This succinctly puts India's overall approach to TK as for the benefit of all humanity but that it should be protected from misappropriation. Hence the Policy recommends that India should engage actively and constructively at various international fora to develop legally binding international instruments to protect TK, GR and TCE, obliquely referring to the three draft legal texts before the WIPO IGC.

While speaking about the benefits of IP reaching holders of TK, the Policy also is aware of issues that the AYUSH industry is facing with regard to BDA and recommends formalisation of a consultation mechanism for harmonious implementation of the BDA.

Overall, the National IPR Policy has made a good number of recommendations for protecting TK though it has not recommended a separate legislation for the same. The Policy should serve as guiding principles for policy and law makers.

### Civil Society

Non-Governmental Organisations (NGOs) and Civil Society Organisations (CSOs) have played an important role in protecting TK, with conservation of genetic resources being undertaken by institutions like M.S. Swaminathan Research Foundation, Gene Campaign and Navdanya. Research, documentation, promotion and advocacy on TK protection has been undertaken by Kalpavriksh, the Society for Research and Initiatives for Sustainable Technologies and Institutions (SRISTI), Deccan Development Society, CUTS international, ATREE and Centre for Indian Knowledge Systems. The role of grassroots organisations and civil society has been critical in the development of the narrative on TK protection and also in legislations related to TK protection such as Biological Diversity Act and Protection of Plant Varieties and Farmers' Rights Act.

### Biodiversity Related Legislations

India does not have any separate legislation on protection of TK and also biological resources. The law on the subject is scattered over a number of legislations, each one addressing separate aspects and administered by different Ministries. A list of such legislations which directly or indirectly protect TK and BR is presented below:

1. The Fisheries Act 1897
2. The Destructive Insects and Pests Act, 1914
3. The Indian Forest Act, 1927
4. The Agriculture Produce (Grading and Marketing) Act, 1937
5. The Indian Coffee Act, 1942
6. The Import and Export (Control) Act 1947
7. The Rubber (Production and Marketing) Act, 1947
8. The Tea Act, 1953
9. The Mining and Mineral Development (Regulation) Act 1957
10. The Prevention of Cruelty to Animal Act, 1960
11. The Customs Act, 1962
12. The Spices Board Act, 1986
13. The Seeds Act, 1966
14. The Patents Act, 1970
15. The Wildlife (Protection) Act, 1972
16. The Marine Products Export Development NBA Act, 1972
17. The Water (Prevention and Control of Pollution) Act, 1974
18. The Tobacco Board Act, 1975
19. The Territorial Water, Continental Shelf, Exclusive Economic Zone and other Maritime Zones Act, 1976
20. The Water (Prevention and Control of Pollution) Cess Act, 1977

21. The Maritime Zones of India (Regulation and Fishing by Foreign Vessels) Act 1980
22. The Forest (Conservation) Act, 1980
23. The Air (Prevention and Control of Pollution) Act 1981
24. The Agricultural and Processed Food Products Export Development NBA Act 1985/1986
25. The Environment (Protection) Act, 1986
26. The Species Act, 1986
27. The National Dairy Development Board, 1987
28. Rules for the manufacture, use/import/export and storage of hazardous microorganism/genetically engineered organisms or cells, 1989
29. The Foreign Trade (Development and Regulation) Act, 1992
30. The Protection of Plant varieties and Farmer's Right (PPVFR) Act, 2001
31. The Plant Quarantine (Regulation of Import into India) order 2003
32. The Food Safety and Standards Act, 2006
33. The Scheduled Tribes and other Traditional Forest Dwellers (Recognition of Forest Rights) Act, 2006
34. The National Green Tribunal Act 2010

While these legislations touch upon some aspect or other of the AYUSH industry, there are few legislations that are of serious concern for the industry. A brief overview of the major legislations which affect commercial activities and research in Traditional Medicine related areas follows:

#### **The Forest Conservation Act, 1980**

One of the early legislations that has impact on certain aspects of TK protection issues is the Forest Conservation Act, 1980. The provisions of this Act restrict and regulate the de-reservation of forests or use of forest land for non-forest

purposes without the prior approval of Central Government. The Act lays down the prerequisites for the diversion of forest land for non-forest purposes.<sup>44</sup> Most of the TK is linked with medicines and agriculture. While the Act may not directly regulate those activities, it affects certain issues particularly relating to medicinal plants, an essential ingredients in TMs. Medicinal plants are the major raw materials of ISMs and the traditional knowledge about their properties and uses form the principal portion of TM knowledge system. As per the Section 2 of the law, 'de-reservation of forests or use of forest land for non-forest purpose' requires prior approval of the Central Government and 'non-forest purposes' include cultivation of 'horticultural crops of medicinal plants'. It thus restricts the powers of state governments for clearing forest land for purposes of cultivation of medicinal plants.

The legislation may be seen as being aimed, *inter alia*, at conservation and protection of medicinal plants. The Act was amended in 1988 and revised and comprehensive rules and guidelines were issued in 1992.

#### **The Protection of Plant Varieties and Farmers' Rights Act, 2001**

The Protection of Plant Varieties and Farmers' Rights Act, 2001, (PPVFRA) was enacted to fulfil India's obligations under Article 27 (3)(b) of the TRIPS Agreement. It recognises the role of farmers as cultivators and conservers, and the contribution of traditional, rural and tribal communities' knowledge in the country's agrobiodiversity by making provisions for benefit sharing and compensation and also protecting the traditional rights of the farmers, including protection for the rights of the producers of new varieties of plants in the traditional way of breeding.<sup>45</sup> Among other provisions for recognition of TK of farmers, it stipulates benefit sharing<sup>46</sup>, recognition and reward (through the Gene Fund) for farmers engaged in the 'conservation of genetic resources of land races and wild relatives of economic plants



and their improvement through selection and preservation’.

*Protection of Plant Varieties and farmers Rights’ Authority:* The Protection of Plant Varieties and Farmers’ Rights Authority (PPVFRA) is also an agency concerned with protection of TK. The main functions of the Authority with relevance to protection of TK are:

- Documentation, indexing and cataloguing of farmers’ varieties;
- Registration of extant varieties;
- Maintenance of the National Register of Plant Varieties;
- Maintenance of the National Gene Bank.<sup>47</sup>; and
- Recognizing and rewarding farmers, community of farmers, particularly tribal and rural community engaged in conservation, improvement, preservation of plant genetic resources of economic plants and their wild relatives.<sup>48</sup>

### **The Biological Diversity Act, 2002<sup>49</sup>(BDA)**

This is the principal legislation that discusses TK protection, albeit restricted to TK associated with biological resources.

The BDA was enacted to fulfil India’s obligations towards CBD and is one of the important legislations on protection of TK. The BDA, along with the Biological Diversity Rules, 2004 (BDR) and the Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014, provides the main access related legislation in India. It does not refer to TK *per se*; the provisions refer to TK as one ‘associated with .... Biological Resource (BR) which is derived from India’<sup>50</sup>. The provisions which are applicable to ownership of BR are also applicable to TK.

*Access Provisions:* The BDA delineates the conditions under which persons, commercial firms, and other institutions can access biological resources occurring in India and the knowledge associated with the BR, for

research or for commercial utilisation or for bio survey and bio utilisation.<sup>51</sup> Given India’s federal structure, the BDA establishes a three-tier system for regulating access to biological resources, at national, state and local levels. The access provisions have paradoxically impacted the sector most dependent on TK, i.e. the AYUSH industry, particularly MSME sector, and researchers. The related issues will be highlighted in subsequent sections.

*Benefit Sharing:* The BDA also contains elaborate provisions for benefit sharing arising out of utilisation of the biological resources.<sup>52</sup> The National Biodiversity Authority (NBA) is vested with regulating activities and issuing guidelines for benefit sharing<sup>53</sup>. Benefit claimers are defined as “conservers of biological resources, their by-products, creators and holders of knowledge relating to the use of such biological resources, innovations and practices associated with such use and application”<sup>54</sup>. The BDA with BDR and Guidelines on Access to Biological Resources and Associated Knowledge and Benefit Sharing Regulations 2014, provides for both monetary and non-monetary benefit sharing along with national, state and local biodiversity funds<sup>55</sup> for channelizing benefits for local communities conserving the knowledge of the resources. The NBA can determine the benefit sharing in the following manner:

- Grant of joint ownership of IPRs to the NBA, or where benefit claimers are identified, to such benefit claimers;
- Transfer of technology;
- Location of production, Research and Development (R&D) units in such areas which will facilitate better living standards to the benefit claimers;
- Association of Indian scientists, benefit claimers and the local people with R&D in biological resources and bio-survey and bio-utilization;
- Setting up of venture capital fund for aiding the cause of benefit claimers;

- Payment of monetary compensation and other non-monetary benefits to the benefit claimers as the NBA may deem fit.<sup>56</sup>

As with other provisions of the BDA, this one is also heavily focussed on biological resources. The general approach that seems to have influenced the BDA is that the biological resources and associated traditional knowledge are the nation's property, that is, they are to be controlled and regulated by the government or its agency. Since the Act got administered by MoEFCC, the focus is more on controlling access to the biological material than on preserving and widely using the traditional knowledge in such a way as to bring benefits to the communities including the traditional and folk medicine personnel.

*National Biodiversity Authority (NBA)* The NBA formed under the mandate of the BDA is the main body for granting approval for access to biological resources, for applying for IPRs on any invention based on any research or information on a BR obtained from India and for transferring the results of any such research.<sup>57</sup> It can oppose IPRs in India and any country on claims based on BR obtained in India. It ensures equitable benefit sharing of biological resources accessed in India and advises Central and state governments on matters of biodiversity conservation and benefit sharing. The BDA enables the NBA to provide for fair and equitable benefit sharing on the access to biological resources and associated TK. As of 31 August 2018, the NBA has granted 838 approvals for access, transfer of research, filing of IPRs, etc.<sup>58</sup>

*State Biodiversity Boards (SBB):* SBBs, set up as per BDA, regulate commercial utilization, bio-survey and bio-utilization of biological resources and associated TK by Indian citizens.<sup>59</sup>

*Biodiversity Management Committees:* The BDA provides for constitution of Biodiversity Management Committees (BMCs) by local bodies for promotion and documentation of, among others, knowledge related to biodiversity

in the form of PBRs<sup>60</sup> in consultation with the local people.<sup>61</sup> The purpose of the BMCs is aimed at giving local communities rights in decision making on access to resources in their territorial jurisdiction. As of 5<sup>th</sup> May 2020, there are 25,3040 BMCs.<sup>62</sup>

### **Scheduled Tribes and Other Traditional Forest Dwellers (Recognition of Forest Rights) Act, 2006<sup>63</sup>**

The Act specifically ensures rights to forest dwellers to protect, regenerate or conserve or manage any community forest resource which they have been traditionally protecting and conserving for sustainable use<sup>64</sup>; rights under any traditional or customary law of the concerned tribes of any State<sup>65</sup>; and most importantly right of access to biodiversity and community right to intellectual property and traditional knowledge related to biodiversity and cultural diversity<sup>66</sup>. The right to protect, revive or conserve or manage any community forest resource, which communities have been traditionally protecting and conserving for sustainable use, and this has the potential to enhance conservation has been duly acknowledged. Hence the role of community forests and government owned forests becomes important. FRA is the first legislation in India that involves the village assembly in the exercise of delineation of forest rights.<sup>67</sup> The Act provides protection under Section 2(a) which includes resources within reserved forests, protected forests and protected areas such as Sanctuaries and National Parks to which the community had traditional access, thus marking the indirect protection of TK. It recognises the right of access to biodiversity and community right to intellectual property and traditional knowledge related to biodiversity.<sup>68</sup> However, the absence of any provision elaborating how such protection shall take place is a major drawback of the Act.<sup>69</sup>

The Scheduled Tribes and Other Traditional Forest Dwellers (Recognition of Forest Rights) Act, 2006 (FRA) may be seen as a legislation

aimed at vesting forest rights and occupation of forest land in forest dwelling Scheduled Tribes and other traditional forest dwellers, who have been residing in such forests for generations. It recognises the right of access to biodiversity and community right to intellectual property and traditional knowledge related to biodiversity.<sup>70</sup> It also statutorily empowers holders of forest rights and their *Gram Sabhas* (Village Assemblies) to protect wildlife, forests and biodiversity as well as their habitats. FRA is the first legislation in India that involves the village assembly in the exercise of delineation of forest rights.<sup>71</sup>

### IPR Provisions

From the perspective of potential impact on traditional knowledge protection, the forms of Intellectual Property (IP) that are important are patents, copyrights, trademarks, plant variety protection and Geographical Indications (GIs). The Office of the Controller General of Patents, Designs & Trade Marks<sup>72</sup> (CGPDTM) administers the Patents Act, 1970, the Designs Act, 2000, the Trade Marks Act, 1999 and the Geographical Indications of Goods (Registration and Protection) Act, 1999. It directs and supervises the functioning of: i) The Patent Office (including the Designs Wing), ii) The Patent Information System iii), The Trade Mark Registry and iv), and The Geographical Indications Registry. In 2017, the CGPDTM has issued 'Guidelines for Processing of Patent Applications Relating to Traditional Knowledge and Biological Material' to help patent examiners analyze what constitutes novelty and inventive step in TK related invention.

*The Patents Act, 1970*<sup>73</sup>: The Patents Act has a provision wherein "an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components"<sup>74</sup> is not an invention and, hence, not patentable. The Act defines an invention as a new product or process involving an inventive

step and capable of industrial application".<sup>75</sup> Further, "a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or process for producing such substances" <sup>76</sup> is not an invention and, hence, not patentable. Additionally, sections 3 (b), (c), (d), (f), (h), (i) and (j) are of relevance with respect to the patent applications related to TK and/or biological material. Traditional knowledge of breeding methods is protected from being patented by a provision that excludes "essentially biological processes for production or propagation of plants and animals"<sup>77</sup>. Moreover, applications for patents based on TK, "oral or otherwise, available within any local or indigenous community in India or elsewhere" and/or biological material contravening the provisions of law can be refused<sup>78</sup> in pre-grant opposition<sup>79</sup> and granted patents can be revoked in post-grant opposition.<sup>80,81</sup> This provision enables protection of Traditional Medicinal Knowledge (TMK) anywhere in the world from being granted patents. As per the Patents Rules, 2003, a patent applicant has to disclose the source of the biological resource used in the invention and permission of the competent authority to access the same and, therefore, by extension, of the associated traditional knowledge, if any. Non-disclosure or wrong mention of the source or geographical origin of biological material used for an invention in the complete specification also forms a ground for pre- and post- grant opposition as well as revocation of the patent.<sup>82</sup>

*Patents and the BDA 2002*: If a person applies for a patent for an invention based on biological resources and/or associated TK, permission of the NBA is required to be furnished, though this can be done even after the acceptance of the patent but before the sealing of the patent by the patent authority concerned.<sup>83</sup> This implies that the NBA has a decisive role on matters related to IPRs over TK associated with biological resources. This has major implications for innovations in ISMs

as such innovations generally require access to biological resources. There have been instances of patented innovations in India based on TK and one celebrated case is that of *Jeevani*, a drug developed by the scientists of Tropical Botanical Garden and Research Institute, Thiruvananthapuram based on the traditional knowledge of the Kani community.<sup>84</sup>

*The Geographical Indications of Goods (Registration and Protection) Act 1999*<sup>85</sup>: Geographical Indications (GIs) are signs that identify goods originating in a specific locality, region or territory, and enjoy certain quality, reputation or characteristic adducible to the geographical origin.<sup>86</sup> Under the Geographical Indications of Goods (Registration and Protection) Act, 1999, the scope of 'geographical indication' includes such goods as agricultural goods, natural goods or manufactured goods as originating, or manufactured in the territory of a country, or a region or locality in that territory, where a given quality, reputation or other characteristic of such goods is essentially attributable to its geographical origin.<sup>87</sup> Names that do not denote the name of a country or region or locality can still be considered for registration as long as they relate to a specific geographical area and are used in relation to goods originating from that region. This provides the leeway for extending protection to famous symbols such as 'Alphonso' mangoes and 'Basmati' Rice. The Act facilitates protection of collective rights of the rural and indigenous communities and their TK. By registering an item which is the product of TK as GI, it can be continued to be protected indefinitely by renewing the registration when it expires after a period of ten years<sup>88</sup>. Under the Act, a GI cannot be assigned or transmitted<sup>89</sup> thus ensuring that it does not pass on to the hands of those who are not holders of the knowledge. The Act also prohibits registration of a GI as a trade mark<sup>90</sup>, thereby preventing appropriation of TK in public domain by an individual as a trade mark. The Act has established a registry<sup>91</sup> known as the GI registry, to facilitate registration of

GIs in India. GIs in India have been registered for products ranging from tea and coffee under agricultural category to textiles and carpets under handicrafts category. So far, 323 products have been registered.<sup>92</sup> These include products which are used in ISMs or traditional medicine practices such as *Navara* rice (GI No. 40), and Kamalapur Red Banana (GI No. 115). Some of the registered orange varieties like Coorg Orange (GI No. 27)<sup>93</sup> also claim to have medicinal uses. While the knowledge involved may not get protected under the GI Act, the name receives protection which greatly facilitates access to genuine products by the medical practitioners. In cases of such products the name and the product are closely related and the TK is with reference to the particular product. The use of GIs to secure protection for ISM products and knowledge base may have to be explored further.

*The Trade Marks Act, 1999*: Trademarks are indications of distinctiveness that a trade mark holder may affix on a product for which that mark is registered. Like other trademark legislations, the Indian Act does not protect the knowledge or technology incorporated in a trademarked product and, hence, does not impede the commercialization by a third party of an imitative product, if not protected under the Patents Act, under a different trade mark, or without a trade mark. Two particular categories of trademarks are, however, employed to identify the goods' geographic origin and assist in the protection of TK associated. This includes Certification and Collective marks. Certification marks indicate that the product meets pre-established standards, which can be linked to its place of origin. Collective marks distinguish the goods or services as having a connection with a specific group and can also imply a geographic origin. Trademarks can be used to secure protection for the ISM practices since GI Act does not cover services whereas Trade Marks Act extends to services as well. *Jeevani* referred to above was also registered as trademark<sup>94</sup>.



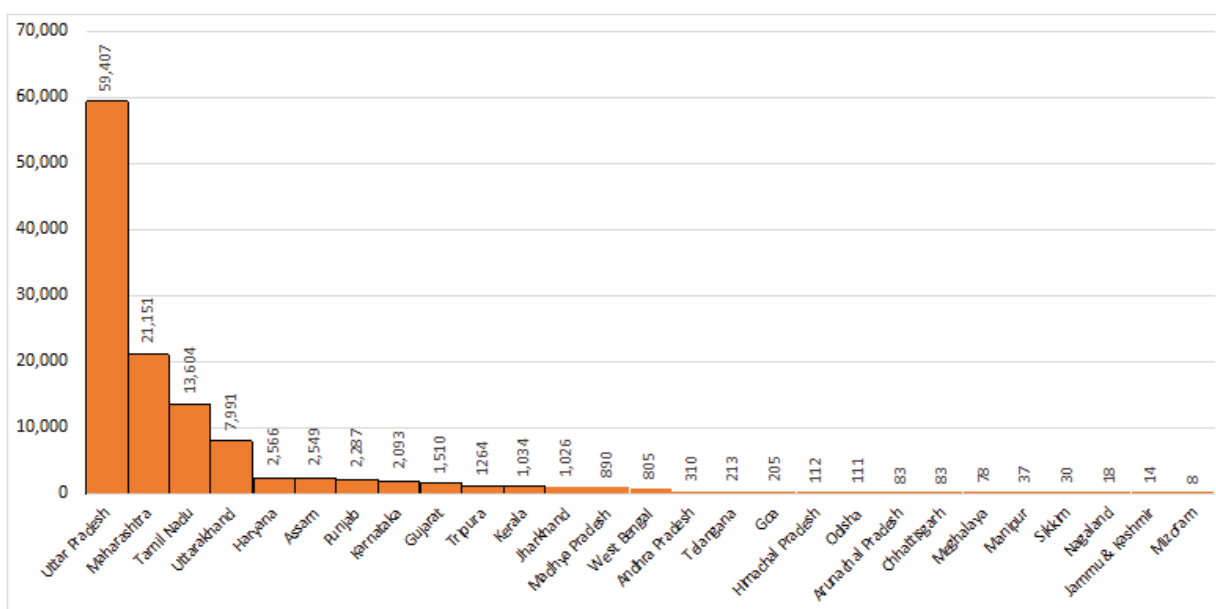
### Registers and Libraries

**Traditional Knowledge Digital Library:** India undertook defensive protection of TK through the development of a digital database in the form of the TKDL in 2001, the earliest and most comprehensive database globally.<sup>95</sup> It is arranged in a patent search friendly format, is accessible in five international languages and is based on an innovative classification system Traditional Knowledge Resource Classification (TKRC). It serves as an important source of information on prior art on the Indian systems of medicine. Internationally, the TKDL is accessible to 12 patent offices<sup>96</sup> but other patent offices can seek access subject to the conditions laid down by the TKDL authority. Till date, in 225 cases the patent applications have either been withdrawn/cancelled/declared dead/terminated or have had claims amended by applicants or rejected by the Examiner(s) on the basis of TKDL submissions.<sup>97</sup> The TKDL is considered a pioneer initiative to prevent misappropriation of the country's traditional medicinal knowledge.

**People's Biodiversity Registers:** The Biological Diversity Rules, 2004 stipulate that “the main function of the BMC is to prepare People's Biodiversity Register (PBR) in consultation with local people. The Register shall contain comprehensive information on availability and knowledge of local biological resources, their medicinal or any other use or any other traditional knowledge associated with them”.<sup>98</sup> As of 5<sup>th</sup> May 2020, 1,19,479 PBRs have been formed.<sup>99</sup> The existence of expansive data with PBRs necessitates safeguards to ensure protection against misappropriation. The state-wise position is presented in the Figure 1.

Considering that India has more than 6 lakh villages (649,481 as per 2011 census), the above figure of slightly more than 1 lakh seems inadequate, even if each village may not have a separate PBR. However, the PBR preparation is still an on-going work. Such registers need to be prepared for each local community. Since the PBRs are to be the main source of TK, including medicinal knowledge, associated with biological resources, this work needs to

**Figure 1: State-wise List of PBRs**



Note: Information for Bihar and Rajasthan not available.

Source: National Biodiversity Authority.

be completed at the early and also to be revised from time to time. Further, the entire work should be digitised. Certain pre-cautions also need to be taken. This should include separating confidential and secret TK from the general PBRs and access to the same be restricted. The general PBRs should be made accessible to the AYUSH industry for carrying out TM research.

### Overviews of Domestic Protection Laws in Select Countries

Countries have accorded varying levels of protection TK. Many countries have provisions focussing on indigenous communities. For example, Philippines has the Indigenous Peoples Rights Act, 1997 extending protection to the “community intellectual property rights” of indigenous peoples, including their traditional medicines and health practices and indigenous knowledge systems and practices. For this study a limited number of countries from which lessons may be drawn has been proposed for further examination.

*Brazil:* Brazil has regulated protection of traditional knowledge through the Law on Access and Benefit Sharing of Genetic Resources and Associated Traditional Knowledge, No. 13.123 dated May 20, 2015.<sup>100</sup> Among the main features of this law, the most important is the ‘benefit sharing agreement’, which provides for one per cent of the total income from sales of a product derived from Brazilian Biodiversity. The focus is more on facilitation of research, innovation and faster access to GRs and TK. Other relevant legislations include Plant Variety Protection Law, No. 9.456, 28 April 1997<sup>101</sup> and Industrial Property Law, No. 9.279, May 14, 1996.<sup>102</sup>

*China:* The Patent Law of the Peoples Republic of China (as amended upto the decision of December 27, 2008,<sup>103</sup> regarding the Revision of the Patent law of the Peoples Republic of China) and the Regulations on the Protection of Varieties of Chinese Traditional Medicine can be described as the main provisions on protection

of TK in China. The Patents Law provides exclusive rights though the scope of protection is limited to traditional medicine. It provides positive protection with the major objective of promotion of innovation. The scope of the Law includes product (a new pharmaceutical composition and preparation thereof, effective ingredient extracted/separated from traditional medicine, effective parts and preparation thereof, new preparation of changing the administration route, etc.), method (preparation method of the products mentioned, new or improved technology of production, etc.) and Use (new indication of medicine, first medical use, the second use of the known medicine, etc.) While the law provides no express access related provisions, conditions on TK protection are based on novelty, inventiveness and utility. The scope of rights extends the rights to prevent third parties not having the right holders’ consent from making, using, offering for sale, selling or importing the patented invention; and bringing litigation when infringement occurs. Regulations on the Protection of Varieties of Chinese Traditional Medicine is limited to protect the production of the protected species and Manufacturing without permission. The rights holders under the Regulations on the Protection of Varieties of Chinese Traditional Medicine are only the manufacturing companies.<sup>104</sup>

*Ecuador:* The Constitution of Ecuador, 2008, recognises the rights of indigenous communities and peoples to “uphold, protect and develop collective knowledge” including their medicine and traditional medical practices.<sup>105</sup> The Intellectual Property Law provides for the establishment of a *sui generis* system for collective IP rights of local communities. The National Biodiversity Policy and Strategy envisages the registration of ancestral knowledge through *sui generis* protection systems.<sup>106</sup>

*Mexico:* While Mexico does not have specific patent laws or laws to protect TK, provisions regarding industrial property are established

in the Law on Industrial Property (LIP), particularly patents in which the link with the use of genetic or biological resources or materials or products derived therefrom are brought out. For example, on biological or genetic materials, Articles 16, 19 and 47 of the LIP are particularly relevant as these are explicitly related to such genetic materials. In Article 16 of the LIP, exceptions to patentability are provided for, some of which are related to genetic resources, biological materials, or biological resources.<sup>107</sup>

*Peru:* Law No 27,811 of July 2002<sup>108</sup>, introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples derived from Biological Resources, is the relevant legislation on protection of TK in Peru. The objectives of the legislation are to protect TK, to promote fair and equitable benefit sharing and to ensure that access and use of TK by outsiders take place with prior informed consent of the holders only. Peru is also the only country in the world that has a commission against biopiracy i.e. the National Commission against Biopiracy (established pursuant to Law No 28216, May 1, 2004)<sup>109</sup>. The law is considering the indigenous peoples as the holders of TK and recognises their collective knowledge. As in India, the Peruvian law provides for a National Fund for Indigenous Development or to benefit directly the TK holders (WIPO). The Peruvian law provides for establishment of traditional knowledge registers to preserve and safeguard TK, almost like our TKDL.

*Costa Rica:* As in India, Costa Rica also extends protection to TK through biodiversity law. Its law No. 7788 of 1998, one of the early laws on the subject, regulates access to TK and provides for equitable distribution of benefits from the exploitation of TK to its holders. An interesting feature of this law is that it defines the concept of 'knowledge' as "a dynamic product generated by society over time and by different mechanisms, and includes that which is produced by traditional means or

generated by scientific practice" (Article 7.6). The Costa Rican law also has provisions extending exclusive rights to TK holders like *sui generis* community IPRs, which includes "the knowledge, practices and innovations of indigenous peoples and local communities related to the use of components of biodiversity and associated knowledge" (Article 82). This right is automatic and does not require any registration as the Article states, "this right exists and is legally recognised by the mere existence of the cultural practice or knowledge related to genetic resources and biochemical; it does not require prior declaration, explicit recognition nor official registration; therefore it can include practices which in the future acquire such status." Thus the Costa Rican law recognises the concept of continuous evolution of TK and this factor is of importance to India, particularly in the context of Traditional Medicinal Knowledge, where TM practitioners are continuously evolving their knowledge systems and practices. The provision is suited to communities innovating and developing on their existing knowledge. The law also has a right to cultural objection which is the right to oppose any access to the resources and associated knowledge, be it for cultural, spiritual, social, economic or other motives (Article 66).<sup>110</sup>

Costa Rica is considered as having a balanced biodiversity and TK protection system. Funds from a fuel tax, car stamp duty and energy fee are channelized to environmental services of providing clean air, fresh water and biodiversity protection.<sup>111</sup> Perhaps, India can also take some cue from this. Biological diversity and environment are affected by certain kind of industrial activities and those engaged in those activities could be made to pay for the same. Clean environment is always good for sustainable biological diversity.

*South Africa:* National Environmental Management: Biodiversity Act, 2004<sup>112</sup> is the relevant legislation with regard to TK

protection in South Africa. Additionally, the Patent Amendment Act 2005 (Act No.20 of 2005)<sup>113</sup> regulates patent disclosure with regard to TK. Bagley identifies the following four components in the South African framework for TK protection:

- Bio-prospecting and ABS laws and regulations regarding biological resources and associated indigenous traditional knowledge
- Collection, documentation and publication of TK
- IP protection through substantive patent examination and source of origin disclosure requirement
- Sui generis protection through a new bill.<sup>114</sup>
- A new bill has been under discussion since 2013.

*Chile:* Under Law No. 19.039 on Industrial Property (Consolidated Law approved by Decree-Law No. 3).<sup>115</sup> Article 3 states that 'the present Law shall guarantee that the protection afforded by industrial property rights regulated herein shall be granted while safeguarding and respecting biological and genetic heritage, as well as national traditional knowledge. The awarding of industrial property rights that constitute protectable elements, developed on the basis of the material obtained from that heritage or that knowledge shall be subordinated to the acquisition of that material in accordance with the law in force'.<sup>116</sup>

*Thailand:* Among Asian countries, Thailand is one which has a long tradition of Traditional Medicinal Knowledge. It has a vast resource of medicinal plants, according to some about 10,000 plant varieties. Thailand has enacted two legislations that relate to TK in 1999, the first one, the Plant Varieties Protection Act, which, *inter alia*, protects the local knowledge of farmers relating to plant breeding and second, the Protection and Promotion of Thai Traditional Medicine Intelligence Act, which is intended to protect the traditional medicine knowledge and access to TK and biological resources in

herbal medicine. The Plant Varieties law has provisions relating to access and benefit sharing in the case of collection of wild plant varieties for commercial purposes.<sup>117</sup> However, there has been criticism that both laws provide neither a functional system nor an effective enforcement (Meeklam 2015)

## India and WIPO IGC

An analysis of the various proposals before the IGC follows. Position that India can take in the WIPO IGC, in the light of national interest and the national positions of other similarly placed countries, in particular, Article-wise analysis with special focus on contentious issues like public domain, the subject matter and beneficiaries of protection and exceptions and limitations, Protection of undisclosed TK, Ownership and Rights of communities on TK are being explored in this Section.

WIPO's efforts on the intellectual property issues in genetic resources and traditional knowledge began in the late 1990s.<sup>118</sup> Member states of the WIPO, in preparation for the Patent Cooperation Treaty in 2000, brought the issue to the Standing Committee on Patents and gave their first mandate for the organization to take up issues related to TK. WIPO undertook several fact-finding missions throughout 1998 and 1999<sup>119</sup>. Among other things, the fact-finding mission report highlighted the need to reform existing intellectual property laws and to work on creating new legal tools for TK protection.<sup>120</sup>

Member states agreed, as a result of discussions that took place around the Patent Cooperation Treaty, that a permanent forum to discuss issues related to genetic resources (GR), traditional knowledge (TK) and traditional cultural expressions (TCEs) was required.<sup>121</sup> This brought together WIPO's past work on folklore along with the related issues of GR and TK. Thus, the establishment of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional



Knowledge and Folklore (IGC) occurred in September 2000.<sup>122</sup> In 2002, certain TK journals were included in the minimum documentation for applications under WIPO's Patent Cooperation Treaty, and TK classification tools were integrated within the International Patent Classification in 2003. In 2002, the IGC accepted technical standards for the documentation of TK developed at a WIPO meeting in Cochin, India. Subsequently, and formalized in 2009, the IGC worked towards the adoption of an international legal instrument or instruments. Although other forums have held discussions on TK protection, the IGC has been the key international forum in this regard. Various groups of like-minded countries emerged during the process of the IGC negotiations. A general classification of these groups shows that most developing countries (especially those with a high intensity of biodiversity and indigenous communities) strongly advocate the international protection of TK while most developed countries prefer to maintain the status quo. Various groups of like-minded countries include, among others, the Asian Group, the African Group, GRULAC (Latin American and Caribbean Group), Group B (US, JAPAN, New Zealand, EU, and Australia), the Central European and Baltic States, and Central Asian and East European Countries. As can be observed from negotiation texts, developing countries with significant biodiversity resources and traditional knowledge, and those in which a considerable number of local communities reside (especially Brazil, India, Peru and some African countries) are strong *demandeurs* of TK protection<sup>123</sup>. The following statement describes the state of play and the motivating factors of the two groups:

Broadly, during negotiations, two groups of countries have emerged – Group A comprising developing countries like African group, Asian group and GRULAC, where the TK that exists today is largely concentrated, and Group B

comprising of developed countries like EU, Japan, the USA and Canada, which are afraid of losing the free access to GRs, TK and TCE that they have been used to through the colonial period over 200 years. China, which stands apart, has held positions similar to countries like India when discussing scope of protection for TK which is widely/publicly available and has commercial value that is open to misappropriation.<sup>124</sup>

The result of this intense debate has been the development of an important document towards protection of TK, i.e. The '*Protection of Traditional Knowledge: Draft Articles*'.<sup>125</sup>

The Draft Articles, an instrument that WIPO IGC has been deliberating on for more than 13 years, is a highly debated instrument. The contentions relate to details of almost all twelve provisions within it. Most of the provisions are tentative. The nature of the document will significantly change depending on which wording or option is ultimately accepted under each provision. The Draft Articles are divided into three parts: the preamble/introduction, the policy objective, and the substantive and procedural provisions.

The preamble/introduction contains fourteen distinct but interconnected statements on TK protection listing the goals of the Draft Articles. This includes articles on recognising the value of TK, its variation from country to country, the need to promote understanding of, and the promotion of preservation of TK, the role of IP in innovation and economic development of providers and users of TK, the relationship between the Draft Articles and other international agreements, the promotion of access to knowledge and safeguarding of the public domain, the documentation and conservation of TK and the creation of new rules and principles.<sup>126</sup> Most paragraphs are heavily bracketed, which means most members disagree on these.

The key issues that have given rise to tension between the negotiating blocks may generally be grouped into four topics. These include: 1) the definition of TK, especially on whether it should be expanded to include traditional cultural expression or limited to traditional knowledge; 2) the legal nature of the Draft Articles (i.e. whether they should be a binding international instrument or some version of a soft law or guideline); 3) the recurring tension between inserting flexibilities in the instrument and attempting to make it effective and enforceable; and 4) the interaction between TK systems of protection and existing intellectual property laws; that is which should prevail in case of irreconcilable conflict.<sup>127</sup>

The relationship between the Draft Articles and existing international instruments, including IP laws, has been an issue upon which members of the IGC have not agreed. While some members of the IGC, including the European Union, push to make the Draft Articles consistent with existing international IP laws, other members, (mostly developing countries such as Brazil and India) and the African Group, argue that this would unfairly subordinate TK protection systems to existing systems of IP protection.

India has been consistently stressing the importance of protection of TK and associated resources, based on its own domestic legislations. With like-minded parties from Africa, Asia and South America, India has been arguing for a *sui generis* system of protection based on one or more international agreement(s) on the same. India has also expressed that traditional knowledge databases can only ensure defensive protection and not positive protection which is needed in view of the dynamic nature of the TK. The traditional ways of creativity and innovation deserve to be protected like modern scientific innovativeness. It also argued for extension of collective rights to the holders of such knowledge in the way collective ownership is available to producers of goods bearing geographical indications. "As regards

eligibility of protection, India's view was that codified and regulated TK like the traditional systems of healthcare, such as Ayurveda, Siddha and Unani, should be included to be accorded protection as a priority, through legal or other measures."<sup>128</sup>

At the 40<sup>th</sup> Session India reiterated its support for disclosure of origin, and supported the idea of defensive protection, having itself developed the TKDL a database for defensive protection. Since Asian countries like India have many tiers and levels of TK, the tiered approach to protecting TK has been seen as having some benefits, in so far as it identifies which forms can be represented by the national government and which require additional protection. Therefore, as regards the scope of protection, India has agreed that it was important to consider the practicality and the legal implications of the proposed tiers in the tiered approach.

### IGC Draft Articles on TK

The draft text on TK protection before the IGC was of 19 June, 2019. The TGC meeting (41<sup>st</sup> session) which was scheduled to be held from 16 to 20 March 2020 has been postponed on account of COVID-19. The current text is heavily bracketed indicating that there is no consensus on a large number of articles. The general approach of India has been to look into setting minimum standards as in the IPR agreements and leaving details to national authorities.<sup>129</sup>

In fact, in the last session of the IGC (40<sup>th</sup> session held from 17<sup>th</sup> to 21<sup>st</sup> June, 2019, both the draft documents on TK and TCE were considered together. Hence, the observations on the draft text on TK would generally apply to the TCE also and *vice versa*.

#### Preamble

The opening sentence refers of aspirations of "indigenous [peoples] and local communities." India's consistent stand has been that all Indians are indigenous to the country and a separate reference to 'indigenous people' may later pose

certain problems. It would be better for India to retain the unbracketed expression ‘indigenous and local communities’ as that would avoid the issue of separating the population differently for protection of TK.

The other brackets in the Preamble such as ‘intrinsic’ in the context of value in paras. 5 and 6, paras. 9, 10, 13 and 14 about intellectual and artistic freedom, mutual supportiveness of international agreements, need for effective rules regarding enforcement and rights of indigenous peoples may not pose much of a problem for the country and it will be able to go with general consensus.

#### *Article 1 Use of Terms*

The preambular issue of ‘indigenous peoples’ appears in this and subsequent articles also and India should take a consistent stand on the same. The definition of ‘public domain’ restricts it to those not protected by IPR and may make almost all TK public domain as they are not protected by established IPRs. Therefore, India will have to take a nuanced stand on this, so that the protection for TK that the country has been demanding internationally does not become a hollow one.

#### *Article 2 Objectives*

Three different alternative texts exist under this Article. Alternative 2 (The objective of this instrument is to support the appropriate use and effective, balanced and adequate protection of TK within the intellectual property system, in accordance with national law, recognising the rights of [indigenous peoples] and local communities [beneficiaries]) may appear preferable. However, the crucial expressions in this Article that we may insist on are ‘effective, balanced and adequate protection’.

#### *Article 3 Protection Criteria/Eligibility Criteria*

Under this Article there are two alternatives and an alternative article i.e. ‘subject matter of the instrument’. The contentions seem to be about the length of generational transmissions

of TCE and period for prior existence of the TK. Alternative 2 and alternative article limit the period of prior existence to 50 years may affect getting protection for comparatively recent TK and also put the onus on communities to prove the existence of the TK for a period of more than 50 years. Such provisions will create more hurdles and lead to procedural and administrative issues. Hence first alternative may be considered.

#### *Article 4 Beneficiaries same*

There are three alternative texts. The observations made on the Preamble hold here also, though from India’s angle alternatives 1 or 3 are preferable since decisive roles are given to national laws.

#### *Article 5 Scope of Protection*

This is perhaps the most contentious article and also is the most substantial one. Even on the title of the Article itself, so far there has been no consensus. Some prefer to use ‘Scope of Protection’ while some other prefer to use ‘Scope of Safeguarding’. The two expressions emerge out of two views, one preferring protection and another preferring certain safeguards only which may not lead to exclusive rights or real prohibitory provisions.

There are three alternative texts. The first one is talking about safeguarding the economic and moral interests of the beneficiaries concerning their TK. An issue that can come up with such an approach is that of valuation of the TK, which may not be very favourable to traditional or local communities since they have not been commercialising the same and their economic status is most likely to be the bottom half of the economic pyramid.

The third alternative talks about TK which are sacred or secret. In this context the observations made by India in the 40<sup>th</sup> IGC are quite relevant. It is important that to consider the practicality and the legal implications of the scope and approaches to that. When benefit-sharing is proposed only for secret or sacred TK, a

question arises as to how others would come to know or could use a secret TK, given the mere fact that it was secret. As India then stated, if others could use the TK, it might be argued that the TK were no longer secret and that hence there was no case for benefit-sharing. There would be large number of litigation. Putting the onus proof on the rightful heirs of TK instead of on the persons or firms who were using the same without proper authorisation is also not advisable, especially for sacred or secret TK who in most cases would not have any documentary evidence. Even the proposal to 'encourage users to attribute the TK to the beneficiaries' is making the moral right of attribution an optional one, something which goes against principles of IPR as well as ethics. Attribution of authorship or ownership has to be mandatory as in the case of IPRs specially in case of TK.

The draft Article 5(BIS) 'database, complimentary and defensive protection' is also a relevant consideration. For defensive protection, which India has been a leader through its TKDL, this article is specially relevant given India's demand for development of database by all countries.

#### *Article 6 Sanctions, Remedies and Exercise of Rights/Interests*

There are three alternative texts. The first one is proposing a general provision that "Member States shall put in place appropriate, effective, dissuasive, and proportionate legal and/or administrative measures, to address violations of the rights contained in this instrument." The second one provides for "civil and criminal enforcement measures". The third alternative is more like the first one. Sanctions, remedies, etc. have to be decided based on the rights and protection extended to the TK and should be proportionate to that.

#### *Article 7 Disclosure Requirement*

Thus Article is specially relevant as disclosure requirement has been demanded by provider countries like India. Four alternatives have

been provided of which second alternative, providing for mandatory disclosure of origin and revocation of IP on failure to comply with mandatory requirements, is the text that should be supported by India.

#### *Article 8 Administration of Rights or Interests*

Thus, although there are two alternative texts, are more in the nature of national administrative set ups for the TKs which will arise as and when a law is enacted and has to be in accordance with administrative systems and traditions of a country, and better be made quite flexible.

#### *Article 9 Exceptions and Limitations*

This Article is also relevant. They will depend on the provisions regarding scope and kind of protection proposed to be extended to TK. As in the case of most contentious articles, here also there are alternatives. The first one is a very general one and is more in the nature of exceptions and limitations under the Paris Convention and the Berne Convention. The second alternative contains detailed mandatory provisions. Para 1 of this alternative says that if any act is permitted under the IP law, they should not be prohibited by the protection of TK. In second para, it presents a list of activities which should come under exceptions. As stated above, the exception clause will have to be examined in the context of the finally agreed scope of protection and will depend on the same. This will have to be drafted keeping in view cultural advancement without destroying heritage or denying fair and equitable benefits to the holders in case of commercial exploitation.

#### *Article 10 Term of Protection*

The Article leaves the term to the member states.

#### *Article 11 Formalities*

Three proposals are there: one requiring no formalities and the second one requiring the same. The third requires formalities in the interest of transparency, certainty and conservation of TK by national authorities. In the interest of protection of TK the third



alternative is in India's interest.

*Article 12 Transitional Measures*

These are standard provisions, although there are two options proposed in regard to already commercialised TCEs.

*Article 13 Relationship with other International Agreements*

These are also standard provisions.

*Article 14 Non-derogation*

This is standard provision.

*Article 15 National Treatment*

This is standard provision as in the TRIPS Agreement.

*Article 16 Transboundary Cooperation*

There may not have any reservation on this as it is more of a practical and exhortatory nature.

It must be realised that in negotiations, a country has to be flexible, but should try to protect the core interests. Particular language of the treaty will depend on how much consensus emerges and considering the fact that already negotiations have been going on for more than two decades and 40 meetings of the IGC have already taken place without arriving at a final consensus text, the task is quite hard. But India has to push for its national interests and also the policy as proposed in the National Intellectual Property Rights Policy, 2016.

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## Medicinal Plant Genetic Resources in India

**G**enetic resources (GRs) is defined by the Convention on Biological Diversity, 1992 (CBD) as '*genetic material of plant, animal, microbial or other origin containing functional units of heredity that has actual or potential value*'.<sup>1</sup> Global biodiversity hotspots possess some of most abundant reserves of genetic resources. India is one such mega diverse country. India contributes to seven percent of the world's biodiversity. With 17000-18000 flowering species,<sup>2</sup> the degree of endemism in plant species is high in India. About 11,058 species are endemic to Indian region<sup>3</sup>. More nearly 8000 species of medicinal plants distributed in 386 families and 2200 genera of flowering plants are the main source of raw drugs<sup>4</sup> utilised in ISMs .

Protection of medicinal plant genetic resources (MPGR) has become imperative for several reasons. Over the past few years 10-18 percent of total medicinal plant biodiversity (50000 plants) has gained wide recognition in pharmaceutical industries. This has led to an exponential increase in trade of plants, plant parts and value added products. The total domestic demand for raw herbal drugs estimated at 5,12,000 MT for 2014-15, is expected to grow to 6,50,000 MT by 2020. This growth in demand has led to unsustainable collection and cultivation practices from forests, promotion of cultivation of improved varieties of medicinal

plants and cross border movement of LMOs developed with the aid of biotechnology.

In keeping with increasing national and international demand of medicinal plants, the current procurement and supply practices has given rise to challenges of resource depletion. Of the total number of medicinal plants used globally, 21 per cent fall under the endangered category of the International Union for Conservation of Nature (IUCN). UCN updated the Red List in June 2015 and added 44 Indian medicinal plants in the list where eighteen plants are categorised as vulnerable, sixteen as endangered and ten as critically endangered species.<sup>5</sup> Of the ten critically endangered species *Aconitum chasmanthum*, *Chlorophytumborivilianum*, *Gentianakurroo*, *Gymnocladusassamicus*, *Liliumpolypyllum*, *Saussureacostus*, *Tribulusrajasthanensis*, *Valeriana leschenaultia*, *Nardostachysjatamansi* and *Commiphorawightii* , species such as *Chlorophytumborivilianum* are high demand species facing unsustainable collection practices leading to habitat loss. *In situ* and *ex situ* conservation programmes such as gene banks, regulations for unsustainable harvesting are some initiatives in this regard.

Protection of medicinal plant genetic resources is, therefore, to be seen not only from the perspective of IPR protection but also relevant conservation mechanisms towards

sustainable use. GR protection includes regulating access to resources for research, bio-survey and bio-utilization, commercial utilisation, obtaining Intellectual Property Rights (IPRs). Access and benefit sharing (ABS) principles have been designed internationally (through the Convention on Biological Diversity) and nationally to regulate access to genetic resources to ensure sustainable use. It may be noted that GRs themselves, as encountered in nature, are not intellectual property (IP). However, inventions based on or developed using GRs (and associated TK) are eligible for protection through the IP system, either through a patent or, in the case of research and breeding activities that can lead to the creation of new plant varieties. Due to recent technological advances, genetic material can be described with increasing ease and speed through digital sequence information (DSI). Some types of DSI of GRs may also be eligible for copyright protection. Finally, some GRs and some DSI of GRs may be eligible for protection as undisclosed information under certain circumstances. However, the efforts by developing countries have been to obtain the international recognition of an obligation to disclose the origin of genetic/biological resources in IPR claims.

In this Section the following issues relating to medicinal plant genetic resources in India are being explored:

- Adequacy of existing international instruments and policies for medicinal PGR protection
- Adequacy of national governance in protection of medicinal PGRs and any subsequent recommendation for action policy.
- Adequacy of policy linkage from local and state level initiatives to national and international frameworks on medicinal PGR protection and possible conflicts in centre -state jurisdictions over medicinal PGR protection.

- Mechanisms for balancing PGR protection with the needs of the AYUSH sector.
- Impact of modern biotechnology on medicinal PGRs protection.
- Requirement of additional policies for medicinal PGRs protection and conservation.

## International Regimes and Organizations on Medicinal Plant Genetic Resources

The exiting regimes have focussed on various aspects of PGR protection within the realm of property rights. From an environmental and conservationist perspective, protection of medicinal PGRs is addressed by the CBD and the Bonn Guidelines and FAO's ITPGRFA. From an IPR and trade perspective, it is addressed by the IGC on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore of WIPO; and the TRIPS Agreement of the WTO. The international regimes on PGR have also been influenced by domestic policies of states like US and EU.

### CBD

MPGR has not been explicitly on the agenda of various CBD meetings. However, CBD contains a large number of obligations for signatory countries that includes *in situ* and *ex situ* conservation and incentives for biological resources that apply to MPGRs. The substantive provisions of the CBD with respect to ABS on PGRs are found in Articles 15, 16 and 19 of the Treaty. These include access to genetic resources, access to and transfer of technology, distribution of benefits arising out of research on biotechnology. In April 2002, (updated in 2010) the CBD adopted the Global Strategy for Plant Conservation which provides a policy environment that is appropriate for addressing the conservation challenges for MAP.<sup>6</sup>

The international regime on ABS constituted of the CBD, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization

(the Nagoya Protocol) also regulates GRs. The implementation of the CBD showed that attaining a fair sharing of benefits resulting from the use of genetic resources and associated traditional knowledge was an elusive objective.<sup>7</sup> The benefits actually obtained were limited or did not materialize at all. One of the reasons for this limited impact was identified and addressed in the negotiation of the Nagoya Protocol. The Protocol introduced three important elements that may contribute to improve the fulfilment of the fair and equitable benefit sharing objectives of the CBD. First, it clarified that the benefit sharing obligations apply to the exploitation of 'derivatives' (as defined in the Protocol) and not only to the genetic resources as such. Second, it introduced specific rules to ensure compliance by user countries including, as mentioned, the identification or establishment of at least one 'checkpoint' to that effect. Third, it introduced the concept of an internationally recognised certificates of compliance.

### WTO TRIPS Agreement 1995

The TRIPS Agreement sets minimum international standards for protection of IP rights. Article 27.3 (b), establishing minimum standards of protection in relation to inventions, indicates that Members may also exclude from patentability plants and animals and essentially biological processes for their production. The provision establishes that Members shall provide for the protection of plant varieties – either by patents or an effective sui generis system or by any combination thereof. Disclosure of Origin is also one of the proposals put forth by developing nations in the WTO. This includes introducing requirement on patent applicants to disclose origin/source of GRs as amendment to Article 29.<sup>8</sup> Disclosure requirements are possibly the most visible form of user measures and are now mainstream in all ABS- and IP-related discussions and in various legal and regulatory frameworks.<sup>9</sup> Both developing and developed countries have adopted and incorporated forms of disclosure

requirements, but implementation is still a challenge.<sup>10</sup>

As regards issues of plants being affected by risks involved with biotechnology, the SPS Agreement of WTO recognises standards set by the International Plant Protection Convention (IPPC). It adopted guidelines for assessing potential risks to plants and plant products to protect plant and crop ecosystems from potential risks arising from introduction of LMOs.

### The WIPO

The WIPO IGC on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore provides a forum for negotiations on issues underlying development of a binding international instrument on PGRs. IP issues related to GRs under discussion in WIPO include prevention of erroneous patents. A number of WIPO Member States have adopted policies aimed at the defensive protection of GRs, which is to prevent erroneous patents being granted over inventions based on or developed using GRs and associated TK that do not fulfil patentability requirements such as novelty, inventiveness or industrial applicability. The defensive protection of GRs can involve the development and implementation of a range of legal and practical mechanisms, such as databases and other information systems on GRs and associated TK to help patent examiners find relevant prior art and avoid the granting of erroneous patents. Proposed new patent disclosure requirements may also address this issue.

While WIPO does not address the regulation of ABS of GRs as such, there are IP issues directly associated with GRs and, in considering these issues, WIPO's work complements the framework provided by the CBD, the Nagoya Protocol. WIPO Member States are considering whether, and to what extent, the IP system may be used to support implementation of obligations related to PIC, MAT and BS, that

are provided for by these ABS systems. One of the options under discussion is to develop a new disclosure requirement that would oblige patent applicants to show the source or origin of GRs, as well as evidence of prior informed consent and a benefit-sharing agreement, if they are required by the provider country. IGC aims at evolving an international instrument legally binding on all members on draft articles.

The draft texts on GR are heavily bracketed<sup>11</sup>, indicating that the IGC Members are as yet not in agreement on a number of issues. The IGC draft text on genetic resources discusses, *inter alia*, defensive databases, a proposed mandatory disclosure requirement and intellectual property clauses calling for mutually agreed terms for access and equitable benefit sharing<sup>12</sup>. It is not yet clear whether disclosure requirements will form part of the treaty text emanating from the IGC. Patent systems like the International Patent Classification System and the Patent Cooperation Treaty, which are administered by the WIPO have seen amendments<sup>13</sup>. The dramatic surge of patent activity for ethnobotanical medicines has led to the introduction of a new series of classification codes within IPC8 under A61K36 which replaced A61K35/78 from the 1st of January 2006<sup>14</sup>. The introduction of A61K36 has been accompanied by the inclusion of 203 sub-group classifiers which describe the family or genus. Additional indexing classifiers are also provided for the parts of plants involved.<sup>15</sup>

India has been a strong supporter of development of databases as a form of prior art to counter erroneous patents. In 2015, India submitted a request to the PCT/MIA to add the Indian TKDL to the PCT minimum documentation (document PCT/MIA/22/8). The following year, the PCT/MIA referred this matter to the PCT Minimum Documentation Task Force with a renewed mandate (paragraph 85 of document PCT/MIA/23/14). At the PCT/MIA in February 2018, India presented a further working document on the inclusion of

the TKDL in the PCT minimum documentation, along with a revised access agreement intending to address concerns that had been raised by some International Authorities during previous discussions of the proposal (document PCT/MIA/25/9). The Indian Patent Office has since shared these documents with the Task Force for consideration as part of its objective to recommend criteria and standards for the review, addition and maintenance of non-patent literature and TK-based prior art under the renewed mandate. As a first step towards achieving this objective, in July 2018, a questionnaire on non-patent literature, TK-based prior art and inclusion of databases in the PCT Minimum Documentation was circulated by the Task Force among the International Searching and Preliminary Examination Authorities.

### **Convention on International Trade in Endangered Species of wild flora and fauna (CITES)**

All CITES Appendix I & Appendix II plant species obtained from the wild is prohibited for export from India. Only cultivated/ artificially propagated plant species listed under Appendix II is allowed for export under cover of CITES export permit and Legal Procurement Certificate (L. P. C.) or certificate of cultivation from the designated authorities.

### **FAO**

FAOs global system includes International Undertaking on Plant Genetic Resources . However, the Treaty focuses more on PGRs for food and less on PGRs for pharmaceutical or other industrial uses. Article 12.3(a) of the Treaty specifies that access to material under the multilateral solely for purposes of “ utilization and conservation for research, breeding and training for food and agriculture”, and excludes “chemical, pharmaceutical and/or other non-food/feed industrial uses.”



### International Union for Conservation of Nature and Natural Resources (IUCN)

IUCN engages with partner organizations in developing National Biodiversity Strategies and Action Plans (NBSAPs), the main vehicle of national implementation of the CBD and other biodiversity related Conventions. IUCN's Red List of Threatened Species, World Database on Protected Areas (WDPA), Green List of Protected Areas, list of key biodiversity areas, Integrated Biodiversity Assessment Tool (IBAT), Global Invasive Species Database, IUCN Red List of Ecosystems are some knowledge products assisting biodiversity assessment. As of April 2019, fewer than 10 per cent of known plant diversity (28,265 species of plant) was assessed on the IUCN Red List<sup>16</sup>. Of these species, over 13,000 (less than 45 percent) species are already considered threatened with extinction in the wild (assessed as Critically Endangered, Endangered or Vulnerable).<sup>17</sup> This means the conservation status of the majority of plant species is unknown, which leads to threatened plants species, and plant conservation in general, being overlooked in national, regional and international conservation planning.

### National Policies and Programmes

#### Conservation Programmes/Policies/Laws

There are no separate policies or regulations for conserving medicinal PGRs in forests. Laws for protecting and conserving medicinal PGRs exist through forest laws and laws regulating access to biodiversity. Threat of habitat destruction is an important concern for medicinal plant protection. The Wild life (Protection) Act 1972 (amended in 2002), through a network of ecologically important protected areas, restricts carrying out any industrial activity inside these protected areas and co-operative management through conservation reserve management committee and community reserve committees. Similarly, the Forest Conservation Act, 1980 (amended in 1988), regulates the de-reservation of forests or use of forest land for non-forest

purposes without the prior approval of Central Government.

Indian Council for Agricultural Research (ICAR) ICAR –National Bank for Plant Genetic Resources (NBPGR) houses the National Genebank (NGB), for *ex situ* conservation of PGRs. National cryobank at NBPGR has responsibility to conserve desiccation sensitive seeds, vegetative tissues, pollen and selected orthodox seed species. Presently 4,30,982 accessions belonging to 1547 species have been conserved at National Gene Bank including 5756 accessions of medicinal plant representing 412 genera and 578 species<sup>18</sup>. ICAR's Directorate of Medicinal and Aromatic Plants Research, under the National Agricultural Technology Project of Plant Biodiversity undertakes collection, evaluation, conservation and documentation of germplasm of medicinal and aromatic plants. Till date, 25 new improved varieties of medicinal plants of 14 species and seven varieties of aromatic plants of six species have been identified and released.<sup>19</sup> Under the Council for Scientific and Industrial Research (CSIR) the Central Institute of Medicinal and Aromatic Plants (CIMAP) for medicinal and aromatic plant research, cultivation and business is engaged in improved varieties & agro-technologies, genetic improvement & breeding efforts, gene banks development and bio-village mission for cultivation and increasing productivity of medicinal and aromatic plants. National Medicinal Plants Board (NMPB) undertakes a wide range of duties for medicinal plants conservation, inventorisation, quantification of medicinal plants for commercial use<sup>20</sup>. Overall, India has adequate regulatory bodies for protection of medicinal PGRS through access control, gene banks, research and development for improved medicinal PGRs.

Several national policies with a focused intervention for medicinal PGR conservation and protection exist. The National Forestry policy (2016 draft)<sup>21</sup> provides for community

participation at the Gram Sabha level for management of forests. The National Wildlife Action Plan 2017-2031 includes some key features such as conservation of threatened species of flora especially local endemics and highly traded species such as medicinal plants and orchids, and use of mobile technology to develop 'Digital Field Guides' for easy identification of various wildlife goods and their derivatives.<sup>22</sup> The National Environment Policy 2006 calls for enhancing and conserving environmental resources which includes biodiversity (section 5.2)<sup>23</sup>, and 'unlocking the value of genetic diversity', encourage cultivation of traditional varieties of crops, traditional water conservation efforts among others. It calls for harmonizing the Patents Act 1970 with the Biological Diversity Act 2002. Impact assessment of implementation of these policies on protection and conservation of medicinal PGRs has not been carried out.

### IPR and ABS Provisions for MPGR

At present there is no exclusive legal framework governing MPGR. However, the legislations related to biodiversity conservation, sustainable use and access and benefit sharing (Biological Diversity Act, 2002) and the protection of farmers' rights and plant varieties (Protection of Plant Varieties and Farmers' Rights Act, 2001) have implications on MPGRs. The collection of forest genetic resources from wild and their transport are regulated by the Indian Forest Act, 1927, Wildlife (Protection) Act, 1972 and various State Forest Acts. The Plant Quarantine (Regulation of import into India) Order, 2003 regulates the entry of germplasm into the country. The Patent Second Amendment Act 2002 and Patent Third Amendment Act 2005, provide for exclusion of plants and animals from the purview of patentability; exclusion of an invention which in effect is traditional knowledge from patentability; mandatory disclosure of the source and geographical origin of the biological material in the specification when used in an invention; and provision for

opposition to grant of patent or revocation of patent in case of non-disclosure or wrongful disclosure of the source of biological material and any associated knowledge. The Scheduled Tribes and Other Traditional Forest Dwellers (Recognition of Forest Rights) Act, 2006, recognises and vests the traditional rights to forest dwelling communities over access to forest goods and occupation in forest lands.

### IPR Protection

IPR protection for medicinal PGR is important particularly when high investment and strategic research are undertaken. IPR for medicinal PGRs emerges in two contexts, i.e. those found in wild and collected for use and those developed through plant breeding systems and used as cultivated MAPs.

Protection of cultivated medicinal PGRs is to some extent ensured through the Plant Varieties and Farmers Rights Act 2001 and Rules 2003. The Act balances rights of breeders with traditional farming communities. It allows the registration of three types of plant varieties i.e. farmers' varieties, extant varieties and new varieties. Although, most of the MAPs in cultivation are farmers' varieties and an instrument is available now to safeguard these varieties from piracy by registration. However, much benefit cannot be achieved in MAPs by the farmers because as per the Rules, all the extant varieties are to be registered within the three years from the date of enforcement of this Act. According to the Act, extant varieties include farmers' varieties also. Under the DUS test guidelines, several varieties of medicinal plant species have been included for registration. This includes *Isabgol*, *Field Mint*, *Periwinkle*, *Brahmi*, *Damask Rose* and *Ashwagandha*<sup>24</sup>. The Act also provides for a national gene fund for promoting PGR conservation activities. For these crop species PPV&FR Authority has developed "Guidelines for the Conduct of Species-Specific Distinctiveness, Uniformity and Stability (DUS)" tests or "Specific Guidelines" for individual crop species. DUS descriptors have

also been developed for species like Eucalyptus, Casuarina, Neem and Pungam as per the guidelines of the Act to mark specific identity to clones and ensure authority over the clones developed.<sup>25</sup> The comparatively low registration of medicinal plants for IPR under the Act shows that awareness generation is required. Besides, much benefit cannot be achieved in MAPs by the farmers because as per the Rules, all the extant varieties are to be registered within the three years from the date of enforcement of this Act. The Act also provides for a national gene fund for promoting PGR conservation activities. The Authority under the Section 39(1) (iii) of PPV&FR Act, 2001 annually confers 35 Awards amounting to Rs. 85 lakh to farmer(s)/ farming communities engaged in conservation of plant genetic resources and which have been used as donor of genes in varieties registerable under the Act. So far 124 farmer(s)/ farming communities have received such Awards.<sup>26</sup>

The Patent Act 1970 prohibits patentability of 'all methods of agriculture and horticulture or processes for the medicinal, surgical or other treatment of human beings'<sup>27</sup>. Plants and animals in whole, or in part including seeds, varieties and species are also excluded from patentability under Act. As per the Patent Rules, 2003, a patent applicant has to disclose the source of the biological resource used in the invention and permission of the competent authority to access the same. Non-disclosure of the source or geographical origin of biological material used for an invention in the complete specification also forms a ground for pre- and post- grant opposition as well as revocation of the patent.<sup>28</sup> Besides, Section 6(i) of the Biological Diversity Act, 2002 requires an applicant to obtain the approval of the National Biodiversity Authority (NBA) before applying for a patent for any invention based on biological resources obtained from India.

Under the Geographical Indications of Goods (Registration and Protection) Act 1999 (GI Act) medicinal plants originating

from particular regions often having distinct medicinal properties are eligible for registration and protection. The Act has established a GI registry<sup>29</sup> to facilitate registration of GIs in India. So far, 562 products have been registered.<sup>30</sup> The number of medicinal plants registered has been negligible, perhaps due lack of awareness among growers and collectors and the legal and financial costs associated with GI registrations.

IPR protection to medicinal PGRs under IPR laws in India have been subsumed under the larger scheme of PGR protection of plant and plant varieties. Also, IPR protection of medicinal PGR is often framed with reference to traditional knowledge of the same.

### ABS Provisions

Conservation and sustainable utilisation of PGRs under the BDA includes regulation of access to genetic resources including medicinal PGRs. Monetary and monetary benefit sharing mechanisms, regulation of transfer of research results based on Indian PGRs and establishment of Designated National Repository (DNRs) are some mechanism to ensure implementation of access regime under the Act. The Biological Diversity Act 2002 and Rules 2004 are the applicable legislations for access and benefit sharing on biological resources. For the effective implementation of the Biological Diversity Act 2002, a three-tier system has been established with NBA at the Centre, SBBs in each state and local level BMCs functioning with municipalities and panchayats. In pursuance of the Nagoya Protocol, the NBA published the ABS guidelines in 2014. The role of these agencies have been related to regulation of benefit sharing in the form of granting of approvals for access to biological resources ( the NBA), the granting of approvals for commercial utilisation, bio-survey and bio utilisation of biological resources (SBB) and preparation, and maintenance and validation of the People's Biodiversity Registers in consultation with the local people<sup>31</sup> (BMC). From 2006 till date, the NBA has been engaged in approvals ranging

from access to bioresources for research to IPRs to third party transfer in 1070 cases<sup>32</sup>. Approvals for access to biological resources for research or commercial purpose included 204 cases. Of late, the role of SBBs in determining terms of access and benefit sharing has been contested and redefining ABS guidelines is underway.

The Protection of Plant Varieties and Farmers Rights Act 2001 also provides two avenues for benefit sharing<sup>33</sup>. The first scheme allows individuals or organizations to submit claims concerning the contribution they have made to the development of a protected variety. The final decision is taken by the Plant Varieties and Farmers Rights Authority established under the Act. The second benefit-sharing avenue allows an individual or organization to file a claim on behalf of a local community or village. The claim relates to the contribution that the village or community has made to the evolution of a variety. A major challenge is that the term “community” has not been defined by the Act. The interpretation of the term has largely been left to the discretion of the Authority. It may be taken to mean a group of farmers having a common interest in production, conservation, or marketing. In addition, they may belong to a particular tribe or community, or be from a specific locality or place, or share some other identifying factors.

## The BDA: Impact on Industry and Research Institutions

The interlinkage of issues of TK protection with the BDA is most manifest in the traditional medicine sector. While the BDA was enacted with the prime objective of protection of biological resources and, in turn, TK associated with them, it has been held to have impacted the key stakeholders associated, i.e. the traditional medicine sector. There have been several instances where an issue of legal interpretation or dispute under or violation of the BDA have come before the judiciary. A body of case law has emerged since the Act began to be

implemented. These case laws highlight the various areas of contention related to access, benefit sharing, and interpretation of law often impacting AYUSH industry and also bring out the narrative on the functioning and possible lacuna in implementation and execution of the BDA. Over time, the cases have also led to attempts to address these lacunae.

From the angle of industry as well as researchers, the BDA is a restrictive law in that it puts considerable restraints on accessing medicinal plants and herbs, the main raw material of the industry and an important ingredient of research and development. In this section, we propose to examine the provisions and impact of implementation of BDA on the Indian traditional medicine industry.

## Interpretation of Provisions and Implementation of Law

**Exemptions:** The BDA exempts certain persons and resources from its purview. This implies exemption from ABS provisions under the law. The interpretation of these provisions for exemptions by the NBA and SBBs have had far reaching consequences in for industry and research organisations. Similar consequences have been faced owing to lack of definition for certain terms mentioned under the BDA.

### *Normally traded commodities (NTC)*

Section 40 states that “*notwithstanding anything contained in this Act, the Central Government may, in consultation with the NBA, by notification in the Official Gazette, declare that the provisions of this Act shall not apply to any items, including biological resources normally traded as commodities*”. Lack of regular update and notification of such items have created space for exploitation and depletion of several threatened species.

When a Notification of 26 October 2009 by MoEF&CC was issued on NTCs under Section 40 of the BDA<sup>34</sup> a PIL filed by Environmental Support Group challenged the notification and submitted to the court that the Environment



Ministry had “shockingly allowed critically endangered and threatened species to be included in a list of 190 plants as those which are “traded as commodities”, thereby allowing their exploitation, making them commodities for global trade and also exempting them from the protection provided under Sections 3 and 7 of the BD Act”. Among other demands, the litigant wanted both Section 40 and the NTC Notification to be struck down. In July 2015 the NBA sought comments on a revised list of NTCs exempt from the provisions of the BDA when traded as commodities. The new list of NTCs was notified by the MoEF&CC on 7 April 2016. The list has 385 plants listed under 22 categories.<sup>35</sup> The NBA explained that “NTCs that are utilised for research and development by certain individuals under section 3 of the Act and for alternate/ commercial uses need to get prior approval from NBA, as the exemption is only for purposes of commodity trade”.<sup>36</sup>

#### “Value added products” (VAP)

VAP is defined under S.2(p) as *products which may contain portions or extracts of plants and animals in unrecognizable and physically inseparable form*. Section 2(c) excludes VAP from the definition of ‘biological resources’. However, there is no clarity on what is to be considered as a VAP. Additionally, there is no clarity on what is considered as “*physically inseparable*”.

NBA and SBBs have, through their decisions, indicated that, VAP obtained from a biological resource is a biological resource under the Act. This interpretation This interpretation is not in harmony with the common understanding in the industry and also by other bodies. For instance, the Coconut Development Board defines coconut oil as VAP, but the NBA disagrees. VAP when declared as a bioresource requires:

- Prior approval from the NBA for a non-Indian entity for access for research and commercialization.

- Prior approval for any entity to file patent applications.
- Prior intimation by Indian entity to SBBs for commercialization.
- Prior approval for any entity to export extracts and oils.

These ambiguities hinder patent applications based on ready-to-use juice, oils and extracts. This misinterpretation also impacts exports of VAP.

#### “Conventional breeding”

Conventional breeding is exempt under Section 2(f) of the Act, which reads as: “commercial utilization” means *end uses of biological resources for commercial utilization such as drugs, industrial enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours, extracts and genes used for improving crops and livestock through genetic intervention, but does not include conventional breeding or traditional practices in use in any agriculture, horticulture, poultry, dairy farming, animal husbandry or bee keeping*; However, when an application on new plant varieties is filed under the Protection of Plant Varieties and Farmers’ Rights Act (PPVFR Act), the NBA has asked farmers/breeders of such new varieties to pay ABS. This is a major discouragement to file new plant variety application.

#### Indian vs Foreign entities

Access to biological resources by Indians entities are regulated under Section 7<sup>37</sup> through ‘prior intimation’ to SBBs and non-Indian entity under section 3 through ‘prior approval’. A non-Indian entity under Section 3 includes:

- A body corporate, association or organization-
- (i) not incorporated or registered in India; or
  - (ii) incorporated or registered in India under any law for the time being in force which has any non-Indian participation in its share capital or management.



Under such definition most corporate organisations would be defined as ‘non-Indian’ creating little scope for access to Indian enterprises both in manufacturing and research. For example, if a company established and run by Indian nationals includes one foreign person as Director in the Board or one share of the company held by a foreigner, the company will be treated as a foreign company. Publicly listed companies allow purchase of shares by anyone. If the purchaser falls in the categories of foreigners or is even an OCI card holder, the company will have to obtain prior permission for accessing biological resources.

***Jurisdictional and procedural issues:*** These include contention on jurisdiction of several regulatory bodies like the NBA, SBB, NGT.

#### ***Jurisdiction of SBBs and ABS***

Power of SBBs to collect benefit sharing fee: As per Section 7, Indian citizens, body corporate, associations or organisations registered in India are only required to give prior intimation to the concerned SBB for undertaking commercial utilisation or bio survey for commercial utilisation. In practice, various SBBs through State Rules have issued notices to impose ABS under the rationale that Section 7 has to be read with Sections 23 and 24 of the Act, though Section 7 does not explicitly state so. Further, the power of the SBB to collect ABS directly is a jurisdictional overreach as the Act does not grant SBBs such power, including in Sections 23 and Section 24.

With reference to ABS, issues of jurisdiction have been most common. Jurisdiction of the NBA and some SBBs on the ABS issue have been challenged in several cases. The states with maximum number of cases on the issue of ABS are Madhya Pradesh (MP) and Uttarakhand (UK).

The MP SBB’s Notices on Benefit-Sharing led to several entities challenging these notices. Since December 2012 and until March 2013, the MP SBB issued notices under Section 7

of the BD Act<sup>38</sup> to several private companies, including those of pharmaceuticals, coal extracting, liquor, sugar, oil as well as food and industrial processors who according to MP SBB’s interpretation, were (commercially) utilising bioresources. Each of the companies to whom the notice was issued was asked to deposit two percent of their gross sales or gross revenue on financial year basis towards benefit-sharing in the Biodiversity Fund of the state.<sup>39</sup> In another matter the NGT, Bhopal issued notices to Western Coalfields Limited (WCL), Coal India, NBA, MoEF&CC and MP SBB for not sharing benefits from bioresources with local BMCs. In response to these notices, 13 cases starting May 2013 were filed before the Central Zone (CZ) Bench of the NGT at Bhopal. These were filed by several companies (including Dabur) to whom the notices were served.

In March-April 2013, the MP SBB wrote to the NBA asking it to issue uniform guidelines for access and benefit sharing (ABS), which could be used by the SBB as well.<sup>40</sup> Their primary contention was that there are several Indian companies, which use raw material that can be brought under the definition of “bioresources” and thereby ensuring that they pay the SBBs as well as the BMCs for the use of these bioresources. When no clear response was received from the NBA the MP SBB, issued notices to the all companies using “bioresources” to deposit a “benefit sharing” amount for the use of bioresources. The NGT (CZ) then directed the MoEF&CC and NBA to lay down standardised guidelines for ABS. Following internal deliberations between the Environment Ministry, NBA and the SBBs the *Guidelines on Access to Biological Resources and Associated Knowledge and Benefit Sharing Regulations, 2014*. Following the acceptance of these Guidelines, all cases were settled in February 2015.

#### ***Procedural Issues in ABS arrangements***

Multiple approval and benefit sharing agreements: A foreign national or Indian entity

having foreign national or a non-resident Indian has to undergo multiple approval processes and benefit sharing arrangements applicable under several sections ranging from Section 3 to Section 6. Even Indian entities have to provide intimation if it involves commercial utilisation under Section 7 and approvals if it involves (a) transfer of research results to a non-Indian (section 4) or (b) applications for IPR (Section 6) leading to multiple approvals/benefit sharing agreements. Such kind of implementation of the Act and Rules and regulations thereunder act as a tool for double taxation on applicants accessing and using same biological material. The requirement of seeking approvals at multiple stages acts as a deterrent for all entities new and old, having some form of foreign investment.

Other issues include questions on actual access point for considering the ABS obligations. Is it at the time of collection of the biological resource or when subsequently commercial utilization takes place. If industry is accessing it from a *Mandi* are they bound by ABS? If so who are the benefit claimers? Which will be the local community?

## Other Issues

### *Definition of "Benefit Claimers"*

Section 2(a) defines 'benefit claimers' as *the conservers of biological resources, their byproducts, creators and holders of knowledge and information relating to the use of such biological resources, innovations and practices associated with such use and application.*

Many questions remain unanswered in the context of ISMs. Are benefit claimers restricted to local communities only or should a wider interpretation be taken? Are ISM practitioners not conservers and preservers of knowledge associated with biological resources? Are these systems not innovating and practising knowledge associated with India's biological resources? Are not the ASU industry while using biological resources not conservers of their byproducts, creators and holders of

knowledge and information relating to the use of such biological resources, innovations and practices associated with such use and application and, therefore, should they not be 'benefit claimers'? These questions will get unambiguous answer only when the definition gets clarity.

### *Issues in Research and Innovation*

- Requirement of approval of NBA for IPR application under Section 6 : The objectives of the Act have been clearly laid out, i.e. aimed at preventing over exploitation and towards conservation and sustainable use of biological resources. For research, the utilisation of biological resource is an invention and subsequent IPR. Hence the utilization does not contravene the primary objective, i.e. of sustainable use.
- Grant of Foreign Patents contravening Section 6 : Section 6 states that no IPR shall be applied in or outside India without prior approval from NBA . Further, such approval may be obtained after filing of the patent, but before sealing of the same by the patent authority concerned. This provision has procedural flaws since patent applicants have the right to file applications in multiple foreign jurisdictions where the grant of such foreign patents is not governed by the NBA approval in India. Section 6 also provides the applicant an opportunity to obtain NBA approval any time before sealing of the patent (including foreign patent). Accordingly, there may be cases wherein even though a foreign application are filed, they may proceed to grant while application under section 6 (form III) is not filed or is still under process by the NBA. A retrospective approval should be granted by the NBA if necessary

### **Perspective of the AYUSH industry**

According to industry personnel the lack of clarity in the provisions coupled with different interpretations by different SBBs have created uncertainty, confusion and fear of penalty

among the AYUSH industry. The fear among the industry as voiced by Mr Probodh Shah, President of the Gujarat Ayurvedic Aushadh Manufacturers Association (GAAMA) in an interview some time back: “As ayurvedic manufacturers, we are very much dependent on the country’s biological resources, thus protecting the same comes as priority for us as well. However, the act and its provisions in the current form lack clarity, which is impeding our growth and performance. There is a need for better clarification from the government on many provisions enlisted in the biological diversity act. This is essential, so that the industry can work with the government in ensuring their aim and goal of enriching the biological resources through better compliance.”<sup>41</sup>

The access provisions under the BDA may therefore be made simpler in consultation with the ISM industry. Apart from the ABS provisions, the delay in processing applications

for approval is also a major issue. Against 4422 total applications for various approvals, so far only 1485 approvals have been granted and agreements signed. The following Table 1 taken from NBA website gives year-wise and category-wise approvals.

What is obvious is that most of the approvals are for applying for IPRs leading to the conclusion that whether it is biological material or TK, the same has been used for enhancement of current knowledge. That means they have been used more in research and from the angle of advancement of science and technology, the process of approvals should be expedited. The approaches to addressing these issues will be twofold: One, strengthening implementation of the existing legislations in an integrated and coordinated way resolving the conflict situations and, two, addressing some of the specific issues through amendments of provisions, be they in the Act or regulations or guidelines.

**Table1: Status of NBA approvals**

| Year wise status of applications | Form I<br>Access to Bioresources for Research /Commercial Purpose | Form II<br>Transfer of Research Results | Form III<br>Approval for obtaining IPR | Form IV<br>Third Party Transfer | Form B     | Total       |
|----------------------------------|---|---|--|---------------------------------|------------|-------------|
| 2006-2007                        | 4   | 1                                       | 0                                      | 2                               | 0          | 7           |
| 2007-2008                        | 5   | 3                                       | 12                                     | 6                               | 0          | 26          |
| 2008-2009                        | 4   | 4                                       | 21                                     | 6                               | 0          | 35          |
| 2009-2010                        | 2   | 1                                       | 9                                      | 1                               | 0          | 13          |
| 2010-2011                        | 3   | 1                                       | 4                                      | 1                               | 0          | 9           |
| 2011-2012                        | 1   | 2                                       | 6                                      | 0                               | 0          | 9           |
| 2012-2013                        | 1   | 0                                       | 8                                      | 7                               | 0          | 16          |
| 2013-2014                        | 1   | 0                                       | 14                                     | 2                               | 0          | 17          |
| 2014-2015                        | 19  | 0                                       | 22                                     | 1                               | 0          | 42          |
| 2015-2016                        | 31  | 1                                       | 51                                     | 2                               | 7          | 92          |
| 2016-2017                        | 36  | 4                                       | 127                                    | 0                               | 15         | 182         |
| 2017-2018                        | 37  | 2                                       | 245                                    | 1                               | 31         | 316         |
| 2018-2019                        | 61  | 1                                       | 204                                    | 1                               | 17         | 284         |
| 2019-2020                        | 29  | 1                                       | 258                                    | 0                               | 39         | 327         |
| 2020-2021                        | 5   | 0                                       | 103                                    | 0                               | 2          | 110         |
| <b>Total</b>                     | <b>239</b>  | <b>21</b>                               | <b>1084</b>                            | <b>30</b>                       | <b>111</b> | <b>1485</b> |

### Review of BDA and Proposed Changes

Some of the specific issues relating to BDA have been submitted for review with proposed changes.

- **Definition of NTAC:** The NBA should hold stake-holder meetings on definition of NTAC and products to be exempted from the purview of the Act. Approval for NTAC under Section 3 to 6 should also be waived.
- **Definition of VAP:** VAP should be interpreted vis a vis the NTAC list under Section 40 of the Act.
- **Definition of Conventional Breeding:** The NBA should implement a strict interpretation of 'conventional breeding' to exempt farmers developing new varieties through conventional breeding or traditional agricultural practices from the definition of commercial utilization. Further, NBA must come up with the definition of 'conventional breeding' which should include hybrid budding and molecular budding.
- **ABS Procedures:** Timelines should be strictly adhered to by the NBA as delays in approval can be detrimental to the patent applicants. Suitable remedy in case of delay by the NBA should also be provided by the NBA. A single and simplified form/ approval process be developed to cover all intimations/ approvals. Further, benefit sharing agreement under Section 6 should supersede and replace all and any other previous benefit sharing agreements with the related authorities.
- **SBBs' jurisdiction:** The NBA should hold regular meetings with the SBBs to ensure uniform implementation of the Act as per rationally agreed interpretation of the Act.
- **Local Communities:** Greater participation of local communities in benefit sharing arrangements should be assured. For this, strengthening BMCs and greater consultation with local communities by the NBA before decision making on ABS is required. Further, information on use of

the ABS funds collected by the NBA should be provided to the applicants accessing biological resources and charged with ABS fees.

- **Research:** Non-commercial research should be exempted from approval process.
- **Nationality of a body corporate.**

Section 7 maybe rewritten to include PIOs and may be read thus :

No person, who is a citizen of India or OCI card holder or a body corporate, association or organization which is registered in India, shall obtain any biological resource for commercial utilization, or bio-survey and bio-utilization for commercial utilization except after giving prior intimation to the State Biodiversity Board concerned: Provided that the provisions of this section shall not apply to the local people and communities of the area, including growers and cultivators of biodiversity and their cultivated produce, and *vaid*s and *hakims*, who have been practicing indigenous medicine.

Section 24 maybe rewritten thus : Any citizen of India or OCI card holder or a body corporate, organisation or association registered in India intending to undertake any activity referred to in Section 7 shall give prior intimation in such form as may be prescribed by the State Government to the State Biodiversity Board.

### Draft Guidelines on ABS 2019

In order to address some of the concerns of the industry the NBA brought out Draft Guidelines on ABS in 2019. These have been found to have limitations. Based on a discussion with the industry representatives and academics, a set of recommendations have been prepared for modifications to the Guidelines in a tabular format. These are presented in the following Tables 2 and 3:



**Table 2: Comments/suggestions in the Draft Guidelines**

| Clause | Draft Regulation  | Changes and Comments   |
|--------|---|--|
| (2)    | State Biodiversity Boards shall also follow these regulations for benefit sharing while granting approvals in exercise of powers conferred under section 23(b) and section 24(2) for persons and activities regulated under section 7 of the Act.   | <p>Adding State Biodiversity Boards to the scope of ABS.</p> <p>The Powers conferred under the sections mentioned, viz. 23(b) &amp; 24(2) confer only regulatory powers to SBB for controlling commercial utilization of Bio-resources in the geographical area falling under their respective jurisdiction.</p> <p>The Act is silent on S.7 entities paying ABS.</p>  |
| (3)    | In these regulations, the usage of term 'biological resources' may also include associated knowledge, if any.   | <p>Term "Associated Knowledge" has been used instead of Traditional knowledge.</p> <p>This is beyond the scope &amp; spirit of the BD Act as well as CBD.</p> <p>"Associated knowledge" is wider in scope than the term "associated traditional knowledge" or "traditional knowledge" or "knowledge of local people" (S.36(5)).</p>  |
| (4)    | They shall come into force on the date of their publication in the Official Gazette.  | <p>Compliance period of 60-90 days post publication in official gazette is recommended.</p> <p>Must provide regulation for transitional arrangement of 60-90 days. Otherwise neither the NBA nor the Applicants will know what to do.</p>  |
| 1(2)   | <p>The NBA shall, on being satisfied with the application under sub-regulation (1), enter into a benefit sharing agreement with the applicant which shall be deemed as grant of approval for access to biological resource(s) for research referred to in that sub-regulation:</p> <p><i>Provided that in case of biological resources having high conservation and economic value as referred under Annex-I, or associated knowledge are accessed for commercial research, the NBA may impose upfront payment to the applicant, on a case-to-case basis.</i></p> | <p>A list of Bio-resources with high conservation threat, has been annexed as Annexure I.</p> <p>The upfront payment of ABS for utilization of Bio-resources having high conservation threat is currently based on mutually agreed terms (MAT) Reading, "As agreed between the NBA &amp; The applicant"</p> <p>Whereas, in the proposed draft, the same has been amended as "The NBA may impose upfront payment to the applicant, on a case to case basis" - making it a one sided imposition of benefit sharing.</p> <p>This amendment is against the spirit of the Act, i.e. ABS shall be decided based on MAT, mutually agreed terms; and hence the proposed amendment in the clause may be withdrawn.</p> <p>The term "commercial research" is not defined in the Act.</p> |

Table 2 continued...



Table 2 continued...

|          |   |  |
|----------|---|--|
| 2(a)     | <p>Any person who intends to have access to or obtain biological resources for commercial utilization or for bio-survey and bio-utilisation for commercial utilization shall apply to the NBA in Form-I of the Biological Diversity Rules, 2004 or to the State Biodiversity Board (SBB), in such form as prescribed in the respective State Biodiversity Rules, as the case may be.</p>  | <p>The phrase “including Biological resources harvested by JFMC’s/ Forest Dweller/ Tribal Cultivator/ Gram Sabha” omitted in the draft guidelines indicating exemption of the Bio-resources, so obtained.</p> <p>The phrase “For commercial utilization” has been added to the clause.</p> <p>The term ‘obtain’ is not clear. It is not clear whether it includes purchase from the open market.</p>   |
| 2.2.i(a) | <p>Where the applicant intends to access or obtain the biological resources for commercial utilization or for bio-survey and bio-utilization for commercial utilization, the benefit sharing obligations on the applicant shall be in the range of 3.0 to 5.0 per cent of the purchase price of the biological resources.</p> <p>Provided that in the event of the applicant submitting proof of payment of levy fee to the BMC(s) under section 41(3) of the Act, the benefit sharing component payable to the NBA/SBB shall be 25 per cent lower than the benefit sharing amount due.</p> | <ul style="list-style-type: none"> <li>• Current regulation states that Benefit sharing agreement, with the concerned authority, is to be signed only when the manufacturer has not entered into a benefit sharing agreement with JFMC/Forest Dweller/ Tribal Cultivator/ Gram Sabha- Providing alternate options for direct benefit sharing.</li> <li>• This provision has been changed in the draft guidelines indirectly withdrawing the alternate benefit sharing mechanism(s).</li> <li>• The new draft also proposes 25 per cent concession on the applicable ABS amount on the Bio-resources for which, collection fee has been paid to the respective Biodiversity Management Committee.</li> <li>• This encourages persons to avoid paying collection fees or purchase bioresources from local people</li> <li>• The term “trader” has been removed.</li> </ul> |
|          |   | <ul style="list-style-type: none"> <li>• This Clause has been omitted from the draft guidelines. Such an amendment will help the Authority become the single epicenter of power. This is very significant- it goes against the Constitution of India that places subject ‘Forest’ in Concurrent List giving equal powers to State even at local/ panchayat level and Centre.</li> <li>• As one of the objectives of the Act is conservation, such polarization will discourage other forest development and conservation activities performed by these allied bodies.</li> </ul>   |

Table 2 continued...

Table 2 continued...

|                  |   |  |
|------------------|---|--|
| <p>2.2.ii(a)</p> | <p>When the biological resources are accessed for commercial utilization or bio- survey and bio-utilization leading to commercial utilization, the applicant shall have the option to pay the benefit sharing upto 0.5% of the annual gross ex-factory price minus government taxes as given below:-</p> <p>Table: For ABS on Ex-factory price.</p> <p>Provided that in the event of the applicant submitting proof of payment of levy fee to the BMC(s) under section 41(3) of the Act, the benefit sharing component payable to the NBA/SBB shall be 25% lower than the benefit sharing amount due.</p> <p>Provided further that where the applicant is having annual turnover upto rupees one crore, benefit sharing obligation on the applicant shall be rupees five hundred as lumpsum under regulation (2) above.</p> <p>Provided further that there will be no benefit sharing obligation for an applicant under this proviso if he furnishes proof of payment of benefits sharing under regulation 5(2).</p> <p>Provided that in case of biological resource(s) having high conservation/ economic value, as illustrated in the list appended at Annex-I, the benefit sharing component shall be 25% more than the benefit sharing amount due</p> <p><i>Illustrations</i></p> | <ul style="list-style-type: none"> <li>• A new component of Registration fee of Rs.25000/- for three years is reflected in the table provided for ABS on ex-factory price provided in the draft. It is not applicable for organizations having &gt;1 crore annual turnover.</li> <li>• Registration fee concept is not in accordance with the scheme of the Act.</li> <li>• What is the registration for? The BMCs are required to maintain Biodiversity Registers. Neither NBA nor SBB are empowered under the Act to have such Registers. Therefore, there is no need for registration fee.</li> <li>• “Annual turnover” is a loose term since companies may have a majority of the products as non-bioresource based product or as third party marketing.</li> <li>• At Submission of Form 1, already processing fee is being paid. Further, when an organization is entering ABS agreement, and committed to pay the ABS, <u>levying this kind of registration fee is irrelevant.</u></li> <li>• The next para again reaffirms concession of 25% on the ABS amount upon submission of proof of payment of levy fee of BMC(s).</li> </ul> |
| <p>3.</p>        | <p>Collection of fees</p>   |  |
|                  | <p>Collection of fees, if levied by Biodiversity Management Committee (BMC) for accessing or collecting any biological resource for commercial purposes from areas falling within its territorial jurisdiction under sub-section (3) of section 41 of the Act, shall be in addition to the benefit sharing payable to the National Biodiversity Fund or State Biodiversity Fund, as the case may be, under these regulations.</p> <p>Explanation: Applicant having annual turnover of less than rupees one crore shall also be liable to pay charges, if levied by the BMC(s).</p>  | <ul style="list-style-type: none"> <li>• Payment of collection fee is in addition to the purchase price. Therefore, under the principle governing the Act payment of Collection Fee is itself a part of ABS and should be adjusted to the final ABS liability.</li> <li>• Accordingly SBB has to notify what are the bioresources with the BMCs and what are the prices at which they can be purchased etc (under S.24(2) read with State Rules corresponding to Rule 12(13) of Rules of 2004).</li> <li>• Superfluous in light of the Act S.41(3)</li> </ul>  |

Table 2 continued...

Table 2 continued...

|                 |   |   |
|-----------------|---|---|
| 4               | <p>Any person who intends to transfer results of research relating to biological resources occurring in or obtained from India, to person referred to under sub-section (2) of section 3 of the Act for monetary consideration or otherwise, shall— (i) Apply to the NBA in Form II of the Biological Diversity Rules, 2004 for transfer of the results of research relating to biological resources occurring in or obtained from India for any purpose;</p> <p>(ii) provide evidence of approval of NBA for access to the biological resource and/or associated knowledge involved in the research:</p> <p>Provided that the requirement of evidence under this clause shall not apply to an applicant who is a citizen of India or a body corporate, association or organization which is registered in India and not having any non-Indian participation in its share capital or management;</p> <p>(iii) provide complete information on potential commercial value within the knowledge of the applicant, of the results of research.</p> | <p>No Change.</p> <p>If there is no monetary consideration, then how does the Applicant pay the percentage required in sub-regn 2 below?</p>  |
| 5(1)            | <p>The NBA shall, on being satisfied with the application under sub-regulation (a), enter into a benefit sharing agreement with the applicant which shall be deemed as grant of approval for obtaining IPR.</p>   | <p>There cannot be a benefit sharing agreement if the IPR is not commercialized.</p>  |
| 6               | <p>Procedure for transfer of accessed biological resource and/or associated knowledge to third party for research/ commercial utilization and mode of benefit sharing thereof</p>   | <ul style="list-style-type: none"> <li>• Mode of benefit sharing added to the title.</li> </ul>   |
| 6(1)<br>6(1)(a) | <p>Procedure for transfer</p> <p>Any person who intends to transfer the biological resources and/or associated knowledge which has been granted access under regulation 1 to a third party for research or for commercial utilization, shall apply to NBA in Form IV of the Rules.</p> <p>Provided that application in Form-IV will be applicable only in the event of complete transfer of biological resources along with the results of research thereof, if any, no longer required by the applicant.</p>   | <ul style="list-style-type: none"> <li>• The clause directs person(s) intending to transfer the Biological resource, to apply to NBA in Form IV.</li> <li>• The draft guidelines further explain that application in Form IV will be applicable only in the event of complete transfer of Bioresources along with results of research.</li> <li>• The proviso is complicated and beyond the scope of Rule 19</li> </ul> |

Table 2 continued...

|          |  |  |
|----------|--|--|
| 8        | <p>Deposition of novel microbial strain(s) in the repositories outside India.-</p> <p>Any Indian researcher/scientist who intends to deposit the novel microbial strain(s) discovered from India in the repositories outside India for publication in the journals as per the international obligations, shall provide prior intimation to the NBA in Form 'B' annexed to these regulations.</p>   | <p>The draft guidelines contain a new clause on deposition of microbial strains in repositories outside India.</p> <p>Form B to be filed by the applicant for the purpose.</p> <ul style="list-style-type: none"> <li>• The term "prior intimation" lacks clarity.</li> <li>• It is not clear whether there is a requirement to sign MAT Agreement, or if the Applicant can deposit a novel microbial strain(s) in the repositories outside India just after filing Form 'B' or has to wait for an approval.</li> </ul>  |
| 9(b)     | <p>Determination of benefit sharing shall be based on considerations such as commercial utilization of the biological resource, stages of research and development, potential market for the outcome of research, amount of investment already made for research and development, nature of technology applied, time-lines and milestones from initiation of research to development of the product and risks involved in commercialization of the product.</p> <p>Provided that special consideration may be given to cases where technologies/ innovations/products are developed for controlling epidemics/diseases; for mitigating environmental pollution affecting human/ animal/ plant health.</p> <p>In such cases, the benefit sharing obligation on the applicant may be 'minimal', as decided by the NBA, on a case-to-case basis.</p> <p>Provided further that in the event of contributing to non-monetary benefits as mutually agreed, the monetary benefit sharing obligation under these regulations shall be as reduced as determined by the NBA, as the case may be.</p> | <p>No change</p> <ul style="list-style-type: none"> <li>• Minimal benefit sharing shall be applicable where technologies are developed for controlling epidemics/ diseases; for mitigating environmental pollution affecting human/ animal/ plant health- <i>Because the same would amount to non-monetary benefit sharing</i></li> </ul> <p>The term "minimal" is not defined.</p> <p>Since this is service to society, it should be free; and it is non-monetary benefit to society</p> <p>It's not clear if the R&amp;D done by Indian/ non-Indian AYUSH companies for treatment of diseases are exempt or subject to minimal ABS</p> |
| 10(1)(b) | <p>95% of the accrued benefits shall go to concerned BMC(s) and/ or benefit claimers:</p>  |  |

Table 2 continued...

Table 2 continued...

|          |   |   |
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|          | <p>Provided that where the biological resource or knowledge is sourced from an individual or group of individuals or organizations, the amount received under this clause shall directly go to such individual or group of individuals or organizations, in accordance with the terms of any agreement and in such manner as may be deemed fit:</p> <p>Provided further that where benefit claimers are not identified, such funds shall be used to support conservation and sustainable use of biological resources and to promote livelihoods of the local people from where the biological resources are accessed.</p> | <p>No change.</p> <p>The NBA and SBB MUST have a criteria to identify benefit claimers (Please see Chandra Bhan case where NGT ordered setting up of BMCs in every state). This criteria must be notified through Government Notification.</p> <p>This transparency MUST be made a prerequisite for all ABS payments under this new draft.</p>  |
| 10(1)(c) | <p>The interest earned on the benefit sharing amount deposited in the national/state biodiversity fund will remain with the NBA/SBB, as the case may be, and shall be utilized in a manner as decided by the competent authorities in the NBA/SBBs.</p>   | <ul style="list-style-type: none"> <li>The interest earned on benefit sharing amount to be deposited to Biodiversity fund- The same amount can be utilized for rewarding and encouraging active conservationists.</li> </ul> <p>This provision encourages NBA /SBB (if applicable) to hold money and not disburse it for conservation / equitable sharing of benefits to gain more money through accumulated interests which amounts to unjust enrichment.</p> <p>Writ Petitions filed by AYUSH industry state that SBB cannot levy ABS and cannot deposit in SB Fund since SB Fund can only accept grants and loans from NBA &amp; State Government or Application fees as notified by the State Government.</p> |
| 10(2)(a) | <p>The sharing of accrued benefits shall be as under. –</p> <p>The SBB may retain a share, not exceeding 5% of the benefits accrued towards their administrative charges and the remaining share shall be passed on to the BMC concerned or to benefit claimers, where identified:</p> <p>Provided that where any individual or group of individuals or organizations cannot be identified, such funds shall be used to support conservation and sustainable use of biological resources and to promote livelihoods of the local people from where the biological resources are accessed.</p>                             | <p>Industry maintains that SBB cannot collect ABS.</p> <p>No change.</p>  |



Table 2 continued...

|       |  |   |
|-------|--|---|
| 11    | Processing of applications received by NBA/SBB(s).   | <ul style="list-style-type: none"> <li>SBB's have been added to the title in the draft guidelines whereas the current guidelines only direct about processing of applications received by NBA.</li> <li>This also suggests that the makers of the Act were clear that such applications will be processed by NBA only</li> </ul> <p>Industry maintains that SBBs cannot process applications for ABS.</p> |
| 11(2) | Incomplete applications devoid of any relevant information specifically sought, including ambiguous replies, incomplete disclosure, absence of proof, etc., shall be returned to the applicants.   | <p>No change.</p> <p>Multiple formats are required for the same set of bioresource in a single application leading to waste of time in granting approvals.</p>  |
| 11(5) | <p>While processing the application for access to any biological resource (including plants and/ or animals and/or their parts or genetic material or derivatives), the NBA/ SBB(s) may consider the following factors, namely:</p> <p>Whether the biological resource is:</p> <p>(a)cultivated or domesticated or wild;</p> <p>(b)rare or endemic or endangered or threatened species;</p> <p>(c)accessed directly through the primary collectors living in natural habitat or obtained through intermediaries like traders;</p> <p>(d)developed or maintained under ex-situ conditions;</p> <p>(e)of high value/ importance to livelihoods of local communities;</p> <p>(f)restricted under the Act or any other law for time being in force;</p> <p>(g)exempted under section 40 of the Act;</p> <p>(h)included in crops listed under Annex I to the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), to which India is a contracting party;</p> <p>(i)Included in the Appendices of the Convention on International Trade on Endangered Species(CITES).</p> | <ul style="list-style-type: none"> <li>SBB has been added to the clause. Indicating that the SBB shall also process ABS applications.</li> <li>Other clauses are same.</li> </ul> <p>It is not clear as to what will happen if the Bioresource is cultivated or domesticated. Clarification is needed if there will be ABS imposed on cultivated Bio-resources.</p>                                       |

Table 2 continued...

Table 2 continued...

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| <p>12(d)</p> | <p>accessing biological resources for conventional breeding or traditional practices in use in any agriculture, horticulture, poultry, dairy farming, animal husbandry or beekeeping, in India;</p> <p>Explanatory note: <i>The conventional breeding and traditional practices for the purposes of these regulations shall be developing more genetic variability or improvement of animal and plant species by facilitating meiotic combination of genes expressing themselves in the subsequent generations that are practiced in agriculture, aquaculture, horticulture, sericulture, poultry, dairy farming, animal husbandry or bee keeping and animal husbandry, etc., by the growers/cultivators/farmers/individuals based on their traditional knowledge passed on to them from their previous generations. However, when practiced for scaling up with a commercial intent will not be considered as conventional breeding and traditional practices.</i></p> | <p>The explanatory note added about conventional breeding is technically incorrect. The information provided is also inadequate.</p> <p>This change will have a direct negative impact on agriculture. More than 90 per cent of the existing crop varieties are bred using conventional breeding methods as defined and recognized by ICAR. But, NBA does not agree to the understanding of the most credible Agriculture Authority of the country.</p> <p>Levying any kind of fees/benefit sharing on the seed companies will result in directly proportional increase in the price of high yielding varieties, commonly used by farmers. This will not only result in overburdening the farmers of the country but also in proportionate raise in essential commodities.</p> <p>Further, this assumption/explanation is against PPFVRA &amp; ECA.</p> <p>This provision might hamper the growth of AYUSH industry in view of the fact that definition of VAP is not clear nor are the Products of NTAC regarding their exemption from the Act is clear.</p> <p>Industry suggests that NBA &amp;SBBs should not work in isolation and also consider bigger interests of the nation and its nationals.</p> |
| <p>12(g)</p> | <p>items listed below are exempted under section 40 of the Act as normally traded as commodities.</p> <ol style="list-style-type: none"> <li>1. Timber/bamboo/cane and products derived out of these through forestry / plantations, etc., except species such as sandal, red sanders, agar wood and rose wood.</li> <li>2. Finfish, shellfish and products derived out of these.</li> <li>3. Poultry, livestock and products derived out of these.</li> <li>4. Items/products derived from cultivated biological resources (agriculture, horticulture, apiculture) except those notified under the Geographical Indication Act, 1999.</li> <li>5. Items/products derived from cultivated medicinal plants/trees.</li> </ol>  | <ul style="list-style-type: none"> <li>• As per current guidelines, the clause exempts the NTACs from the scope of ABS. But, in the draft guidelines, by adding conditional points to the clause, almost all NTAC's are targeted to be brought under the scope of ABS.</li> <li>• The draft guideline states that only a selected range of end uses for the NTAC will be exempted. This will bring all other commercial application under the ambit of the ABS, i.e., even powdering or boiling a NTAC.</li> <li>• Industry submits strong objection to this change.</li> </ul> <p>It is not clear if this provision is in addition to the notified NTAC list or a replacement of the NTAC list.</p>   |

Table 2 continued...

Table 2 continued...

|       |   |   |
|-------|---|---|
|       | <p><b>Explanatory note:</b></p> <p>1. The above regulation is to facilitate trade of items including biological resources which are normally traded as commodities. However, if any of these items is intended to be used for research, bio-survey and bio-utilization for research and for obtaining IPR, the relevant provisions of the aforesaid Act shall apply.</p> <p>2. The above exemption shall not apply to the folk varieties, land races and wild relatives of cultivated species (biological resources).</p> <p>3. NBA/SBBs may restrict or prohibit access or collection of any biological resource or a product derived from it based on a reasoned order by the competent authority. In other words, it may not be treated as NTAC for a particular period.</p> |   |
| 12(h) | <p>in the event of accessing biological resources such as pests, insects, pathogens, microorganisms, plants or animals for testing/trial on any invention (for example a new seed variety) and product (for example a pesticide) for statutory regulatory requirements. However, this exemption will not be applicable if such biological resource is a part of their invention or claim or ingredients in their product.</p>   | <ul style="list-style-type: none"> <li>• <b>New Clause.</b> Exempting accessing hazardous BR's provided the same is not used for any invention or claim or ingredient.</li> <li>• It is not clear if the animals used for clinical trials are also exempt.</li> </ul> |

Source: Views expressed by participants at Industry Consultation on Biological Diversity Act 2002, organised by RIS/FITM, 5 September 2019.

**Table 3 Suggestions on changes in the Biological Diversity Act 2002**

| Section No. | Existing Provision   | Suggested amendment   |
|-------------|--|---|
| 2 (p)       | <p>“Value added products” means products which may contain portions or extracts of plants and animals in unrecognizable and physically inseparable form.</p> | <p>“Value added products” means value added to the genetic resources and resultant products may contain portions or components of plants and animals in unrecognizable and physically inseparable form, such as oils, botanical powders, oleoresins, extracts, phytochemicals and formulations.</p> |

Table 3 continued...

Table 3 continued...

|        |  |  |
|--------|--|--|
| 7      | No person, who is a citizen of India or a body corporate, association or organization which is registered in India, shall obtain any biological resource for commercial utilization, or bio-survey and bio-utilization for commercial utilization except after giving prior intimation to the State Biodiversity Board concerned: Provided that the provisions of this section shall not apply to the local people and communities of the area, including growers and cultivators of biodiversity, and <i>vaid</i> s and hakims, who have been practicing indigenous medicine. | No person, who is a citizen of India or OCI card holder or a body corporate, association or organization which is registered in India, shall obtain any biological resource for commercial utilization, or bio-survey and bio-utilization for commercial utilization except after giving prior intimation to the State Biodiversity Board concerned: Provided that the provisions of this section shall not apply to the local people and communities of the area, including growers and cultivators of biodiversity and their cultivated produce, and <i>vaid</i> s and hakims, who have been practicing indigenous medicine. |
| 24 (1) | Any citizen of India or a body corporate, organization or association registered in India intending to undertake any activity referred to in section 7 shall give prior intimation in such form as may be prescribed by the State Government to the State Biodiversity Board.  | Any citizen of India or OCI card holder or a body corporate, organization or association registered in India intending to undertake any activity referred to in section 7 shall give prior intimation in such form as may be prescribed by the State Government to the State Biodiversity Board.   |

Source: Views expressed by participants at Industry Consultation on Biological Diversity Act 2002, organised by RIS/FITM, 5 September 2019.

There are other issues also that the industry is facing with reference to the implementation of the Act. The background of the BDA law is bio-piracy, commonly by foreign nationals or foreign corporates. That way, one can see it as a law to prevent exploitation of local people by foreign nationals and foreign corporates as well as to prevent foreign nationals and foreign nationals from exploiting biological resources without authorisation. This is done in the interest of conservation of biological diversity. This has to be done in such a way that the nationals get easy access to their biological material for legitimate purposes and exploitation in a sustainable way. But when interpretations of the law by certain SBBs include honey, milk, butter, cow-dung, etc., which are essential raw materials in AYUSH, as either extracts or VAPs, it becomes detrimental to the Traditional Medicine Knowledge and Industry. One way out is to bring out a very

elaborate list of products and extracts, including all such products, which are exempted from the ABS regime.

Industries also have difficulties to indicate the source or origin of a product when they are purchasing the same from *Mandis*. There has to be an easy mechanism to regulate the same so that the industry is not forced to face hurdles.

An area where clarifications are required is about cultivated plants. Sustainable biodiversity means encouraging cultivation of many species which are either in large demand as the medicinal plants required by the AYUSH industry or which are endangered. However, the claim over all biological resources occurring in the country whether cultivated or in the wild leads to an expanded definition of the biological resources for which ABS has to be paid. This is likely to discourage cultivation and may not be conducive to the BR and TK associated with

them. They like coconut, orange, etc. should be clearly excluded from the purview of the BDA. Similarly products like coconut oil or orange juice should not be considered as a BR.

Another area is the requirement of research and development. Prior intimation for R&D being insisted by many SBBs and also requiring them to await the approval, is clearly discouraging research. Academic studies should be totally exempt and, if and when the study results lead to a commercial exploitation or IPR, the Act itself provides for obtaining prior permission at that stage.

Further, academic collaborations will have to be viewed more positively. Instances of R&D getting adversely affected are presented in a report published in 2018.<sup>42</sup> One such case is that of not granting approval for sending a specimen of an insect to the foreign collaborator and identification and return. When the country has to undertake large number of such studies specimen collections whether of plant or animal or insect will be required. Therefore, the way of dealing with academic research and collaboration between institutions have to be looked upon sympathetically.

Industries have been objecting to the criminal liability clauses in the BDA. This is a matter that needs a re-examination keeping in view the objectives of the BDA.

Besides, the issues the industry has with BDA, there are also certain steps required for promotion of Traditional Medicine sector. One such is the accreditation of traditional knowledge practitioners<sup>43</sup> ( traditional healers outside the established systems). They are a veritable mine of local traditional medicine knowledge and practice. At the same time, leaving them totally unregulated may bring bad name to the AYUSH industry and service. Therefore, the Ministry of AYUSH may consider establishing a simple, easy to operate register for all traditional healers across the country. It will serve as a database on the practitioners and reach out to them with awareness and other

programmes. It will also boost their self respect and will deter bogus and fake claimants and practitioners out of a fear of being monitored.

## Protection of Medicinal PGRs in Select Countries

### Conservation Programmes

China's conservation programmes of medicinal PGRs: The Chinese government launched the overall plan of Chinese medicinal materials protection and development (2015–2020) in 2015. China had established 2729 nature reserves in approximately 1590 counties in mainland China by the end of 2014, including 428 national, 858 provincial and 1443 municipal nature reserves and covering approximately 14.8 per cent of its total landmass.<sup>44</sup> In Brazil, the National Center for Genetic Resources and Biotechnology – Cenargen, in collaboration with other research centers of Embrapa (Brazilian Agricultural Research Corporation), and several universities, has a program to establish germplasm banks for medicinal and aromatic species.<sup>45</sup> Programmes/projects/activities on in situ conservation of Wild Crop Relatives and Wild Plants for Food and Agriculture have so far been poor in Bangladesh.<sup>46</sup> The Department of Agriculture undertakes research work on plant genetic resource (PGR) management and production technology aspects and collected herb and spice plants of about 1,500 species from five areas in different parts of Thailand. 20 promising herbs have been identified for R&D efforts and presented a road map for the promotion of MAP species in Thailand (2014-19) which includes the promotion of MAP products for use in national drug industry and export, standardisation of Thai products using Thai GAP and conservation of MAP genetic resources.<sup>47</sup>

### IPRs

Countries have adopted a wide range of practices and legal mechanisms under the flexibilities provided under Article 27.3 (b) of the TRIPS Agreement – regarding the specific subject of the patentability of plants. A number



of countries have adopted statutory provisions excluding plants from patent protection, e.g., Andean countries (includes Peru) (Subsection (c) of Article 20 of Decision 486 of 2000).<sup>48</sup> A number of countries have excluded plant varieties from patent protection under statutory provisions, including China. The China Patent Office (SIPO) has issued guidelines that state transgenic plants obtained through biological methods like DNA recombination technology engineering belong to the category of “plant variety”. Thus, in accordance with the provisions of Article 25.1 (4), no patent right is to be granted over them. Aiming to protect Chinese genetic resources, amendments to Article 5 and Article 26 of Chinese Patent Law regulate the use of genetic resources in a patent: Under the amended Article 5, if the acquisition or use of genetic resources violates relevant laws and regulations of China, then no patent will be granted for any invention that relies upon such genetic resources. Amended Article 26 further requires that, for an invention that relies on such genetic resources, an applicant must disclose in the patent application the direct and the original source of such genetic resources, and if the applicant cannot identify these, he or she must specify reasons for the failure to do so. Failure to comply with such disclosure requirements could result in the denial or invalidation of a patent.<sup>49</sup>

Some countries exclude essentially biological processes for the production of plants from the purview of IPRs. This includes countries like Brazil which does not consider it an invention. In South Africa the Patents Act (57/1978) states that a patent will not be granted for any variety of plant though new plant varieties are protected exclusively under the Plant Breeders’ Rights Act (15/1976).<sup>50</sup> However, genetically modified plants could be subject matter under the Patents Act as they are not strictly classed as new varieties of plants. In Bangladesh, plant varieties qualify to be protected by patents under the Patents and Designs Act, 1911.<sup>51</sup>

### **Biosafety**

The Brazilian Biosafety Law (Lei No. 11.105) (24<sup>th</sup> March 2005) regulates use of genetic engineering techniques in, among others, environmental release and discharge of GMOs.<sup>52</sup> The law is administered by the national technical biosafety committee (CTNBio). South African Executive Council for Genetically Modified Organisms was set up in 1997 under the Genetically Modified Organisms Act (1997) as the responsible agency for authorising imports and release of GMOs.<sup>53</sup> In China agricultural GMOs are regulated by the ‘Implementation Regulations on Safety Assessment of Agricultural GMOs, Implementation Regulations on Safety of Import of Agricultural GMOs and the Implementation Regulations on Labelling of Agricultural GMOs’.<sup>54</sup> Peru’s national biosafety law (Law No. 27104) (1999) regulates prevention of risks derived from the use of biotechnology.<sup>55</sup> The law covers issues related to living modified organisms (LMOs) for the safe handling, transfer and use of LMOs<sup>56</sup>. In Thailand, the National Science and Technology Development Agency (NSTDA) and the Ministry of Science, Technology and Environment established the biosafety guidelines drafting committee in 1990<sup>57,58</sup>. Biosafety in Bangladesh is governed by the Biosafety Rules of Bangladesh, promulgated under the Environment Conservation Act (1995) and published in the National Gazette in 2012<sup>59</sup>. These rules codify the regulatory structures and processes contained in the Biosafety Guidelines of Bangladesh (2008)<sup>60</sup>.

### **ABS**

In South Africa the Biodiversity Act No. 10 of 2004, along with other regulations and the National Biodiversity Strategy and Action Plan regulate ABS implementation in the country<sup>61</sup>. Brazil’s Provisional Act 2.186-16 enacts Articles 1, 8j, 10c, 15, 16.3 and 16.4 of the CBD by regulating: (i) access to components of genetic heritage existing within the national territory, on the continental shelf and in the exclusive economic zone, for the purposes of

scientific research, technological development or bioprospecting; access to and transfer of technology for the conservation and sustainable use of biological diversity (Art.1). “Access” is not the same as “collection”. The three categories of access activity covered by the Provisional Act are scientific research, technological development and bioprospecting.<sup>62</sup> In Peru, ABS requirements and procedures on ABS are outlined through two main instruments: : Supreme Decree 003-2009- MINAM on the Regulation on Access to Genetic Resources (2009) , Law 28216 on the Protection of Access to Biological Diversity and Collective Knowledge (2004) , Supreme Decree 035-2011-PCM on the Regulation of Plant Breeders’ Rights (2011) and Supreme Decree 018-2015- MINAGRI on the Regulation for Forestry Management (2015)<sup>63</sup>. China currently lacks a policy system for regulating ABS for its genetic resources. China currently lacks a policy for regulating ABS for its genetic resources though it has strict regulations concerning the collection of plant genetic resources both for nationals and foreigners. For the import of germplasm, Material Transfer Agreements (MTAs) are used. Access regulations are spelt out clearly.

## WIPO IGC Draft Text on Intellectual Property and Genetic Resources

At the IGC 40<sup>th</sup> Session , the issue of GRs was discussed through the Consolidated Document Relating to Intellectual Property and Genetic Resources.<sup>64</sup>The IGC meeting (41<sup>st</sup> session) which was scheduled to be held from 16 to 20 March 2020 has been postponed on account of COVID-19. The current text is heavily bracketed indicating that there is no consensus on a large number of articles. The general approach of India has been to look into setting minimum standards as in the IPR agreements and leaving details to national authorities.

### Preamble

The Preamble is almost entirely bracketed. India’s stand should be to ensure agreement

on sovereign rights over genetic resources and the ‘rights of local communities’ as mentioned. Further, role of intellectual property as against only patent system, providing certainty of rights for legitimate users and providers of genetic resources is important for India and which it should insist on. Also, ‘disclosure of origin’, ‘compliance with national laws’, and easily searchable ‘prior art’ on TK on GRs to prevent erroneous patents are other key words that should be in India’s interest in the draft text.

### Article 1: Definitions

The IP approach to protection of GRs is consistent in the definitions and India may support these .

### Article 2: Objective

The objective of the instrument is being stated as protection of GRs through mutual supportiveness, transparency and access to appropriate information. The brackets offer both IP and patents, and India may insist on the use of the term IP.

### Article 3: Subject matter of instrument

The draft offers two alternatives, first a broad based protection and second focussed on patent protection. India may opt for the first alternative .

### Article 4: Disclosure requirement

The draft provides two alternatives on compliance to ABS and PIC (4.1) , the second exempting applicants from ABS . Hence India should opt for the first alternative. The draft also places no obligation of IP office from verifying contents of disclosure. This should be opposed by India.

### Article 5: Exceptions and Limitations

The draft provides many exceptions to disclosure including human genetic resources, derivatives, TK in public domain and those necessary to protect human, animal or plant life or health. This gives a broad based exemption and India should oppose these provisions.

*Article 6: Sanctions and remedies*

While it is India's interest that the draft calls for place appropriate, effective and proportionate legal and administrative measures to address non-compliance with the disclosure requirement of Article 4, and shall include pre and post grant measures, the revocation of IP in case of failure to comply, as mentioned in 6.3, India should support the first alternative which mandates revocation as against the second alternative which states that failure to comply would not affect the validity of the patent.

II: Alternatives to Articles 2-6 with no new disclosure requirement

This is focussed on patent applications as against the entire gamut of IP applications. These alternatives provide a more lenient approach with no obligation for disclosure requirement. Hence these may be avoided in the interest of protection of India's genetic resources and associated TK.

*Article 7: Due Diligence*

At the outset the draft access to genetic resources subject to national legislation on ABS and other regulatory requirements. It calls for databases to be built in each country (though not mandatorily). It also calls for such databases to be accessible to potential patent licensees to confirm lawful chain of title of protected genetic resources upon which a patent is based. While it is important and in India's interest, the draft is limited to patent applications. India may argue for a more broad-based 'IP application' to the draft Article.

*Article 8: Prevention of the Erroneous Grant of Patents and Voluntary Codes of Conduct*

This draft is essentially for national/domestic legislations and regulations ensure effective mechanisms in place to counter erroneous patents. India already has established databases, legal and administrative measures and should support other member states to comply with this draft Article.

*Article 9 : preventive Measures for Protection*

This Article is important as it prevents GRs existing in nature from being a subject matter of IP/patents.

*Article 10: Relationship with International Agreements*

This is a standard provision

*Article 11: International Cooperation*

This is also a standard provision for practical considerations and may be supported

*Article 12 : Transboundary Cooperation*

This is also a standard provision and may be supported

*Article 13: Technical assistance, Cooperation and Capacity Building*

Given the countries and stakeholders involved in the GRs, these recommendatory provisions on awareness generation are welcome, at least during the initial years of the Instrument.

It must be realised that in negotiations, a country has to be flexible, but should try to protect the core interests. Particular language of the treaty will depend on how much consensus emerges and considering the fact that already negotiations have been going on for more than two decades and 40 meetings of the IGC have already taken place without arriving at a final consensus text, the task is quite hard. But India has to push for its national interests and also the policy as proposed in the National Intellectual Property Rights Policy, 2016.

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## Traditional Cultural Expressions of India

In this Part issues pertaining to protection of TCEs are being examined. Many of the issues and documents have similarities to those studied under Part I Traditional Knowledge.

### Introduction

TCEs are closely associated with TK and, in a way, form part of it in a manner in which they cannot be separated. The deliberations that formed the foundation of WIPO IGC admitted that the TK, folklore and GR are closely knitted together, and each cannot be addressed effectively in absence of the others<sup>1</sup>. For example, many cultural rituals are associated with certain traditional medicine practices. They also have social, cultural and economic values. The indigenous communities consider them as essential part of their culture and lifestyle. India's tribal and non-tribal communities are extremely rich source of cultural expressions and folklore, contributing to India's cultural identity in the form of crafts, languages, rituals, health practices, customs, handicrafts, textiles, songs, hymns, religious practices, art, architectural designs, recipes, etc.

Most Traditional Medicines form part of the Traditional Knowledge. However, many a time they also form part of the cultural heritage of people. For example, 'Yoga' is closely associated with Indian culture, so is the case with Ayurveda. One cannot think of

Chinese culture devoid of Traditional Chinese Medicine. Limiting them to the ambit of TK only, therefore, may not be advisable. It may be necessary to consider what aspects of such medicine systems would be required to be included within the scope of the TCE.

### Key Issues pertaining to TCE

The unique nature of TCE has given rise to challenges in protection of the same. This pertains to issues of agreed definition of TCE, adequacy of existing legal provisions, existence of such expressions across national regional boundaries and emerging challenge created by technology itself.

The TCE definition has been a topic of debate. Even after years of discussion, there is a lack of consensus, and the gap, as analyzed by the WIPO, refuses to narrow. The WIPO Gap Analyses identifies this as one of the most fundamental challenges in context of protection of TCEs.<sup>2</sup> According to the analysis there is no commonly acceptable definition as it differs from country to country, region to region or from one international instrument to another. The conflict is over the narrowness or broadness of the definition for TCEs. The problem arises because the stakeholders, the indigenous communities often do not agree with them.<sup>3</sup> Also, the developing countries and the developed countries have failed to reach a

consensus since both view TCEs from different perspectives.

There is an ongoing debate that the exclusive rights given by IP laws are not sufficient to protect forms, expressions and representation of traditional culture, which have collective and, in some instances, individual features. Often the features of TCEs do not fit into the definition of various IP forms, thus raising doubts about the adequacy of IP laws to safeguard TCEs.

Some indigenous communities do not consider IP measures to be sufficient or appropriate for protecting TCEs. There is an absence of consideration of local customary laws, which have governed these age-old trans-generational heritages for aeons. India provides for Prior Informed Consent (PIC) for genetic resources, however, no such provision is available for the TCEs.

Same TCEs may appear concurrently in more than one country because of geographical proximity and cultural exchanges which gives rise to trans-boundary issues among neighbouring countries. With internet and easy access, these trans-boundary issues go beyond borders and are thus bound to bring up new challenges to protect TCEs in the context of IP laws.

Further, technological improvement has ushered in an era of digitalization, allowing for easy storage and preservation of TCEs and their protection from monopolistic exploitation<sup>4</sup> However, digitalization has also given scope for duplication and transmission of copies of various forms of TCEs, thus creating an environment where it is easy to exploit cultural heritage of the indigenous people with or without their approval.

There exists a constant conflict between the ideology of freedom of expression and public domain on the one hand and problem of free riding, privacy concerns and adequate representation of the knowledge holder on

the other hand. New licensing models such as Creative Commons and internet protocols sensitive to the cultural issues are being offered by many service providers. On the other side, there is a glaring reality that most of the TCE holders do not have access to technologies like internet.

## **Internationals Conventions, Treaties and Fora on TCEs**

Although the demand for protection of the TCEs was first made in 1960s' (Bannerman, 2015), it was developing countries who took initiative to get legal protection for TCEs. The Bangui Agreement of 2 March 1977, through which the African Intellectual Property Organization (OAPI) was established, declared cultural expressions such as folklore as the cultural heritage of the nation.

## **Berne Convention for the Protection of Literary and Artistic Works, 1886**

The Berne Convention was amended in 1967 in the Stockholm Conference to introduce Article 15.4<sup>5</sup> in response to the demand of protection for folklore by many countries, including India. The article states that "unpublished works where the identity of the author is unknown, but where there is every ground to presume that he is a national of a country of the Union" thus creating a legal framework to provide copyright protection to unpublished traditional knowledge, where eligible.

## **WIPO**

WIPO may be described as the most important international organisation with respect to protection of TCE. Along with the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, its collaboration with other international organisations like UNESCO have played a crucial role in according protection to TCEs.

### **The WIPO Performances and Phonograms Treaty (WPPT), 1996**

This Treaty deals with the rights of performers and producers of phonograms. Article 2 of the treaty provides for protection of performances of “expressions of folklore”. India has yet not acceded to the treaty.

### **WIPO’s Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), 2000**

WIPO- IGC was established in 2000. This was to discuss IP-related issues pertaining to TK, TCEs and GR and to reach a consensus on the international norms which can be adopted by all Member-States and also, act as a forum for cases of alleged misappropriation. The scope of the IGC negotiations includes definition of TCEs, deciding on the beneficiaries, term of protection to be granted and limitation of the rights. The IGC has, over the time, been updating Model Provisions; actively engaging indigenous people in the discussion process to design multilateral treaty to safeguard TCEs, as recommended by UNDRIP; working on the preparation of a *sui generis* model law; and examining existing regulatory framework and customary laws. By 2010 the expression “traditional cultural expressions” (TCEs) was coined to replace “expression of folklore”, and IGC started undertaking text-based negotiations to reach consensus on an international legal instrument for effective protection of TCEs.<sup>6</sup> WIPO-IGC has undertaken some important studies in the context of TCEs and folklore. In 2001, WIPO circulated a ‘*Questionnaire on National Experiences with the Legal Protection of Expressions of Folklore*’ to elicit legal and practical information from Member-States on their experience in implementation of Model Provisions<sup>7</sup>. In 2003, WIPO published ‘*Minding Culture: Case Studies on Intellectual Property and Traditional Cultural Expressions*’ by Terri Janke; providing information based on case studies where the existing IP laws were used to protect

TCEs and folklore.<sup>8</sup> A 2003 background paper titled ‘*Consolidated Analyses of the Legal protection of Traditional Cultural Expressions/Expressions of Folklore*’ provides a detailed analysis of the issues that arise in context of IP protection of TCEs and folklore.<sup>9</sup> IGC has identified ten key issues on protection of TCEs and folklore based on which it prepared a “Gap Analysis” report, identifying gaps existing at the international level with respect to the protection of TCEs. It also carried out a ‘Consolidated Analysis’, a review of the available IP and *sue-generis* systems or laws for protection framework for TCEs.<sup>10</sup> In 2010, *Intellectual Property & the Safeguard of Traditional Culture* was published, which analysed legal questions pertaining to protection of TCEs and folklore while giving examples of good practices<sup>11</sup>. A practical guide was published in 2013 on *Intellectual Property and Folk, Arts and Cultural Festivals* with the objective of providing effective IP management for owners of cultural expressions.<sup>12</sup> In 2013, WIPO also published *Intellectual Property, Traditional Knowledge and Traditional Cultural Expressions/Folklore: A Guide for Countries in Transition*, a guide on how to put legal framework in place.<sup>13</sup> During 34<sup>th</sup> IGC in 2017, *Practical Guide to Intellectual Property for Indigenous Peoples and Local Communities* was published, explaining and giving examples how IP can be a strong tool for empowerment of indigenous communities.<sup>14</sup>

In March 2017, during the 33<sup>rd</sup> session, the IGC renewed deliberations on the draft text to safeguard TCEs after a gap of three years. India has been an active participant in the IGC, voicing the need for a legally binding flexible instrument for protection of the TCEs. The 34<sup>th</sup> IGC developed the next draft for legal instrument to protect TCEs. It focused on the core issues of policy, subject matter, beneficiaries, scope of protection, exceptions and definition of misappropriation.<sup>15</sup> The session also identified issues to be resolved in the next session.<sup>16</sup> But, despite the 2009 start towards drafting of binding legal provisions on protection of TCEs, the gap among the countries, civil society and

the stakeholders has not narrowed much as there remains contention over issues such as definition of TCEs and folklore, scope of the rights and remedies available to those whose rights have been infringed.

India has been championing the cause of TCE owners and holders by demanding IP protection for them to ensure that their economic and moral rights are not violated. In 2001, India's permanent mission to UNO on behalf of Asian group and China submitted a position paper supporting IGC work, acknowledging inter-relationships among TK, TCE and GR. In context of TCEs, the paper suggested conducting national level consultations on legal systems; creation of national focal points to protect TCEs; exploration of exiting Intellectual Property Rights (IPRs) such as copyright, design right, trademarks, Geographical Indications (GIs) of goods and so on by the WIPO to protect intangible property rights; explore new laws for those which cannot be protected under existing ones; and study of exploitation of intangible cultural expressions in light of new technological environment.<sup>17</sup>

### **WIPO- UNESCO Joint Initiatives**

- **Tunis Model Law on Copyright for Developing Countries, 1976**

The Tunis Model Law enacted jointly by the WIPO and UNESCO, clearly states that the works of folklore are subject matters of copyright laws. According to the model law, Member-States are required to set up a competent authority to represent the author of the protected subject matter to protect his economic and moral rights.<sup>18</sup> India is one of the first countries to set-up a competent authority in communication with the WIPO.<sup>19</sup> However, the Tunis Model has been criticized for leading to national legislations, which are not coherent.<sup>20</sup>

- **UNESCO- WIPO Model Provisions for National Laws on the Protection of Expressions of Folklore against Illicit Exploitation and Other Prejudicial Actions, 1982**

Model Provisions adopted by the WIPO and UNESCO in 1982 were an attempt to provide Member-States with a 'model law' that they could adopt to safeguard the TCEs and folklore. The provisions include definition of subject matter, role and duty of the competent authority, and exceptions, etc. An attempt was made to transform these model provisions into a binding international treaty; however, it was not successful as many countries raised issues such as clash between national definition and the scope of international treaty and conflict arising out of trans-boundary spread of the TCEs, which could not be resolved under the model laws.

- **UNESCO/WIPO World Forum on Protection of Folklore, 1997**

This forum<sup>21</sup> viewed existing copyright law provisions to be inadequate for protection of folklore. It recommended a plan of action for conducting regional consultations for paving a way for a *sui generis* law.

- **United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP), 2007**

The declaration, although not legally binding, was adopted in light of the dynamic nature of the international legal provisions and their impacts on TK and right of indigenous people attached to it. Article 11<sup>22</sup> of the declaration states that the indigenous people have the "right to maintain, protect and develop the past, present and future manifestations of their cultures" and can ask for provisions of redress and restitution to protect their property when taken without a PIC.

Article 31(1)<sup>23</sup> explicitly states the right of indigenous people to "maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions." The declaration also advocates for inclusion of the indigenous people in the policy-making process, initiated by the state.



### **Beijing Treaty on Audiovisual Performances<sup>24</sup>, 2012**

Beijing Treaty was adopted, keeping in tandem with the digital era, to deal with IP rights of performers in the audiovisual performances. The provisions of this treaty compliment with WPPT. Article 2<sup>25</sup> of the treaty, while defining performers, includes in its ambit actors and performers of the TCEs. Both WPPT and Beijing Treaty provide the same level of economic and moral rights to the performer of expression of folklore as the other performers.<sup>26</sup> India has not yet acceded to the treaty.

### **Indian Legal Provisions**

India does not have in place a separate legislation for protection of TCEs. The existing laws governing TCEs directly or indirectly are listed below.

### **Constitution of India**

Article 21 of the Constitution of India provides for the Right to life and personal liberty. A liberal interpretation of the article can provide protection to TCE owners. The Constitution of India in Article 29 (1)<sup>27</sup> identifies protection of cultural rights of minorities as a Fundamental Right. However, only the communities falling within the ambit of minorities protected under the section can safeguard their rights, thus leaving out of the scope the protection of smaller communities relatively more vulnerable to the threat of exploitation than the prominent communities. Article 51A (f)<sup>28</sup> puts the onus of preservation, respecting and safeguarding the rich heritage of the Indian culture on every citizen of India as their fundamental duty. The TCEs and folklore constitute heritage as well as culture.

### **The Copyright Act, 1957**

The Copyright Act, 1957 does not anywhere directly mention about the protection of TCEs. However, the interpretation of definitions of artistic work, dramatic work, engravings, Indian work, literary work, musical work,

performance, and performers as defined in the Act would include works which fall within the ambit of TCEs. Various sections of the Copyright Act such as Section 31A<sup>29</sup> on compulsory licence provides for copyright of unpublished or published work and of unknown authors, Section 38 recognizes performer's rights, Section 57<sup>30</sup> provides for author's special rights also called *moral rights* as per which the author has a right to claim authorship, restrain or claim damages in case of distortion, mutation, modification or any such act which is prejudicial to his honour or reputation, can be interpreted to extend safeguards to the interests of TCE owner.

### **The Geographical Indications of Goods (Registration and Protection) Act, 1999**

To comply with Article 22<sup>31</sup> of Agreement on Trade Related aspects of Intellectual Property Rights (TRIPS), India enacted the Geographical Indications of Goods (Registration and Protection) Act in 1999. Unlike other IPRs, the GI is a community right; as a result traditional communities often rely on GIs to safeguard certain of their rights associated with their goods which have some quality or reputation or other characteristics linked to the geographical area in which they are produced. Products like Chanderi saree, Pochampalli ikat or Madhubani painting represent cultural expressions of the communities who are engaged in their manufacturing. The Indian Act specifically provides for extending Geographical Indications Goods protection to handicrafts and handlooms which are inherent part of Indian culture, apart from food items like Bengali rasgulla. The authorized GI mark on the good helps create a brand image for the traditional good which embodies age-old culture.

### **The Trade Marks Act, 1999**

A Trade Mark (TM) is a mark capable of distinguishing the goods and services of one person from others. TM also enables the consumer to identify the source of the goods

or the services. Registered trademarks of traditional goods and services can be protected Under Section 29 of the TM Act against any infringement and for non-registered goods and services; the common law provision of passing off is available. Collective marks can be used to create a brand image for traditional goods and service such as paintings, handlooms, weaves, etc. Certification Marks can be used to protect traditional goods, which have cultural significance.

### Effectiveness of IP laws in safeguarding TCEs

While India has a rich heritage of TCEs, but, unlike Australia, Panama and Philippines, which have *sui generis* laws, India relies on other laws to protect the same. However, at IGC, India has always championed the cause of *sui generis* laws for protection of TCEs.<sup>32</sup>

The existing Copyright Act may be useful in protecting contemporary TCEs. However, the pre-existing TCE works, which at present form part of the public domain as per the copyright law, are open for use by anyone giving rise to a conflict of interest between the rightful owners and the users. Further, TCEs fit uncomfortably into the copyright protection scheme because of their conflicting characteristics such as their nature and centuries old ownership by the community. 'Originality' and 'individuality' are two principles of copyright laws which do not conform to TCE works (Fiscor, 1996). The Act emphasizes on 'authorship', which is primarily missing in case of traditional communities. So also, protection provided under copyright is for a limited time span. TCEs by the very nature of existence have been there for centuries and cannot be allowed to lapse into public domain, after a limited period, unlike the case with copyright.

Many TCE owners rely most on the GI Act to protect products of their labour, particularly in case of handlooms and handicrafts. Traditional handicrafts, unlike paintings and music,

have evolved due to human necessity. They also carry cultural heritage in the form of regional and traditional motifs.<sup>33</sup> According to the WIPO-IGC, as traditional handicrafts represent cultural and traditional values of the indigenous society, they need to be protected. The Indian traditional handicrafts are protected under the GI Act, 1999. Sixty-one per cent of the GIs registered in India during the period up to March 2018, were handicrafts.<sup>34</sup> The GI Act helps in securing community rights for a collective heritage. The protection, however, has not led to any innovation from the members of these communities,<sup>35</sup> and has no provision for individual rights. New designs based on traditional cultural expressions may get protected under the Copyright Act and the Design Act, as the case may be.

According to some experts, GI is a law against unfair trade practices protecting interest of consumers, rather than economic interest of traditional handicraft artisans against counterfeit (Correa, 2001). Similar is the case with Trade Marks, which also give rise to conflict between monopoly and collective rights of TCEs. GI and TM laws are more helpful in protecting interests and concerns of the owner of TCEs against counterfeits, but not against misappropriation and unauthorised use.

### Online Libraries and Digitalisation

TCEs and folklore have anchored themselves into the digital realm *via* digitalization, online libraries and depositories. These digitalisation efforts have been made to preserve languages; to promote open access and make information accessible online; for preserving and augmenting cross cultural exchanges; for creation of databases by indigenous communities for preserving their knowledge and to fight bio piracy by outsiders<sup>36</sup>. Although the initiatives to create online libraries and digitalized databases of TCEs have witnessed a rise, yet it lacks the attention and the emphasis given to other TK databases, such as the Traditional Knowledge

Digital Library (TKDL), in government policies and initiatives.

### **Civil Society-led initiatives on folklore and TCE**

Civil societies and NGOs have made some commendable contributions towards digitization efforts for protection of TCEs in India. Some of them are mentioned briefly in the following paragraphs.

### **Indian National Trust for Art and Cultural Heritage (INTACH)**

INTACH, a non-governmental organization, set up in 1984, spearheads awareness and protection of tangible and intangible heritage of India with the aim of developing policies and regulations, and making legal interventions to protect India's heritage when necessary.<sup>37</sup> Having a stakeholder-driven structure where local volunteers directly interact with the people and communities owning the TCEs, the Intangible Cultural Heritage department at the INTACH documents and initiates programmes to safeguard cultural expressions.<sup>38</sup>

### **National Folklore Support Centre (NFSC)**

National Folklore Support Centre (NFSC) has been involved in documentation and creation of archives of tangible and intangible TCEs with the help of the communities. An important initiative of NFSC is the creation of fellowships to fill gaps in the study and research available for folklore and TCEs.

### **American Institute for Indian Studies in India (AIISI)**

Archives and Research Centre for Ethnomusicology at American Institute for Indian Studies in India (AIISI) has made efforts to safeguard the rights of performers by limiting the rights of the depositors of field recording and by contacting the performers of the deposited recordings to explain their rights.<sup>39</sup>

## **Government initiatives and policies to protect TCE and interests of TCE holders**

### **National Mission on Cultural Mapping of India**

The government of India has launched a *National Mission on Cultural Mapping of India*, which aims to convert cultural canvas of India into an objective cultural-map designing mechanism to fulfil aspirations of the whole artist community of the nation and in preserving rich cultural heritage of India in the form of a repository of artists and art forms.<sup>40</sup> It would open direct channels of communication between the government and the artists.

### **National Mission for Manuscripts (NMM)**

NMM, established in 2003 by the Ministry of Tourism and Culture, documents, preserves and digitalizes the vast wealth of manuscripts of India. These manuscripts have a wide range of themes, textures, aesthetics, scripts, languages, calligraphies, illuminations and illustrations<sup>41</sup>. In 2008, NMM had submitted a legal and policy framework for promoting equitable access to documentary heritage to the UNESCO. Manuscript Resource Centres have documented 31,23,000 manuscripts, and a total of 1,85,88,390 pages could be digitalized by the end of 2014.<sup>42</sup>

### **Draft National Cultural Heritage Conservation Policy**

The Draft National Cultural Heritage Conservation Policy is based on the UNESCO philosophy for protection of cultural heritage. The policy although emphasizes on creating digital databases, but has not addressed IPR related problems.

### **Indira Gandhi National Centre for Arts (IGNCA)**

A major initiative of the government in protecting TCEs has been the establishment of the Indira Gandhi National Centre for Arts

(IGNCA). This Centre, under the UNESCO Programme on Cultural Industries and Copyright Policies and Partnership, came out with a Report on Cultural Mapping of India. It is a handbook containing data on viable cultural industries needing protection. One of the recommendations emphasises importance of IP protection for community-based designs, patterns, meanings and shapes to preserve originality of the product and for ensuring recognition and compensation for TCE owners.<sup>43</sup> Another initiative by the IGNCA is to digitally document expressions of traditional culture and folklore such as manuscripts, books, audio, video, art, etc. It includes projects like the National Databank on India Art and Culture; Kalasampada, a digital library resource for Indian cultural heritage project; and Cultural Informatics established with the UNDP assistance. The documented material for which copyright is available can be accessed on internet, and those with no protection can also be accessed on the intranet of the project.

## Overview of Laws/Practices of Brazil, China, Ecuador, Mexico, Peru, South Africa and Thailand

### Brazil

In Brazil protection of TCEs falls within the ambit of the copyright laws. Although, the Act does not mention TCEs or folklore anywhere, it was amended to comply with Article 15.4 of the Berne Convention to recognize the rights of unknown authors and artists. The subject matter of the TCEs was covered under the Article 5 of Law No. 9.610 of February 19, 1998 on Copyright and Neighbouring Rights<sup>44</sup>.

### China

China does not have in place a separate law to protect TCEs. It relies on the Copyright Law to protect TCEs and derivative works. During the 34<sup>th</sup> IGC session, China informed that provisional regulations on copyright protection of folk literary and artistic work

have been drafted, and would be implemented soon. However, the Intangible Cultural heritage Law, 2011, accords administrative protection of intangible heritagewhich includes ‘all traditional cultural expressions regarded as part of cultural heritage carried forward by generations of different ethnicities, as well as physical objects and places related to such expressions’.<sup>45</sup> In addition, the Regulations on Protection of Traditional Arts and Crafts was adopted for the purpose of protecting traditional fine arts and crafts. IPR protection includes Copyright , Trademark laws among others. Copyright protection to CE in China include works such as folk literature, folk music, traditional operas, and other forms of folk art, characters, calligraphy, dance, quyi performances, etc.<sup>46</sup> They include ICH items listed in Categories 1 and 2 in the Convention for the Safeguarding of Intangible Cultural Heritage. The cases of Guo Xian’s paper-cutting artworks and Zhao Menglin’s Beijing opera facial masks are typical cases for successful protection.<sup>47</sup> Under the Trademark Law, a trademark is composed of specific symbols, colors, letters, graphics or 3D signs. Under the relevant provisions of China’s current trademark law, ICH items will not be denied a trademark simply because they originated a long time ago; moreover, a registered trademark can be renewed multiple times to extend the protection period. Using China’s current trademark law to protect ICH has a great advantage, and all ICH items can be placed under the protection of the Trademark Law by applying for a trademark. A good case in point is the Tongliang Dragon Dance in Chongqing. Time-honored trademarks using this mode of protection include Guizhou Maotai liquor, Zhang Xiaoquan scissors, Yunnan white drugs, Ansai waist drums, and Suzhou embroidery.

### Ecuador

In Ecuador, TCEs are governed by the Intellectual Property Law (Consolidation No. 2006-13) law.<sup>48</sup> Article 7 covers subject matter



and clearly defines expressions of folklore. The scope of protection covered in Article 9 states that economic and moral rights apply to creations and adaptations of expression on folklore.

### Mexico

The TCEs are protected under the Federal Law on Copyright in Mexico. Article 116 protects performer rights of anyone, who performs an expression of folklore, and Article 157 protects literary, artistic works, which are a manifestation of the original work forming part of the Mexican culture and heritage, including the ones where the author is not known. Article 158 and Article 160 clearly demarcate the scope of protection to include and protect cultural expressions, which have eternalized themselves in the roots of Mexico, against any prejudice. The Act also provides for public access to TCEs.<sup>49</sup>

### Peru

In Peru, the Copyright Law (Legislative Decree No. 822 of April 23, 1996)<sup>50</sup> protects TCEs. Sections 2, 5, and 6 provide protection to both original and derivative works of TCEs and Section 57 sets the scope of protection. After the expiration of the term of protection, these works fall into public domain.

### South Africa

The South African legislature amended the Copyright Act, 1978, Performers' Protection Amendment Act, 2002, and Trade Marks Act, 1993 in 2013<sup>51</sup> to ensure that effective provisions are in place to protect indigenous knowledge (IK). These amendments have provided for recognition and protection to performances of traditional works; establishment of National Council for indigenous people under the copyright law provisions; creation of National Database for recording indigenous knowledge and works; recognition of indigenous terms and expressions as Trade Marks; and creation of National Trust and Fund for indigenous knowledge.<sup>52</sup>

South Africa in 2015 tabled a Traditional Knowledge Bill, which provides for a *sui generis* intellectual property approach for protection of different aspects of TK. In the bill, definition of TCEs includes language, music or different forms of expressions, which have become inherent part of the traditional and the indigenous community. The Intellectual Property Policy of the Republic of South Africa Phase I (2018) recognizes the creation of a system for protection for traditional knowledge which will guard against misappropriation and exploitation as a key reform.

### Thailand

The TCEs in Thailand are protected by IPR laws. However, according to the Department of Intellectual Property, a *sui generis* law bill to protect TCE's can be tabled.<sup>53</sup>

## India and Its TCEs

Certain issues come to the fore when we look into the status of TCE protection in the country. Firstly, there is no *sui generis* law to protect TCEs and folk lore. Dependence on existing IPR legislations, particularly on the Copyright Act, 1957 is not sufficient for two reasons. One, Copyrights are extended to original works with identifiable authors, which is not the case with TCEs. Two, copyrights have fixed term which may not be appropriate in the case of TCEs, since the year of creation is not known. The concept of TCE protection, like that of TK protection, include the elements of prior informed consent and fair and equitable benefit sharing which are more suited to such collective intellectual creations which have been in existence for long.

A second aspect issue is with the absence of a proper database on TCEs of the country, like the TKDL. A similar database may be built up over the time. Along with such a database, there is also need for a compilation of all the customary laws relating to the subject in view of the large number of traditional communities in the country. Apart from the traditional



communities, there are many local communities who have TCEs of their own which are also government by certain customs. We need to compile a list of all of them

### IGC Draft Text on TCE

The draft text on TCE protection before the IGC is of 19 June, 2019 (Appendix I). The TGC meeting (41<sup>st</sup> session) which was scheduled to be held from 16 to 20 March 2020 has been postponed on account of COVID-19. The current text is heavily bracketed indicating that there is no consensus on a large number of articles. The general approach of India has been to look into setting minimum standards as in the IPR agreements and leaving details to national authorities.<sup>54</sup>

In fact, in the last session of the IGC (40<sup>th</sup> session held from 17<sup>th</sup> to 21<sup>st</sup> June, 2019, both the draft documents on TK and TCE were considered together. Hence, the observations on the draft text on TK would generally apply to the TCE also and *vice versa*.

#### Preamble

The opening sentence refers of aspirations of “indigenous [peoples] and local communities.” India’s consistent stand has been that all Indians are indigenous to the country and a separate reference to ‘indigenous people’ may later pose certain problems. It would be better for India to retain the unbracketed expression ‘indigenous and local communities’ as that would avoid the issue of separating the population differently for protection of TCE.

The other brackets in the Preamble such as ‘intrinsic’ in the context of value in paras. 5 and 6, paras 9, 10, 13 and 14 about intellectual and artistic freedom, mutual supportiveness of international agreements, need for effective rules regarding enforcement and rights of indigenous peoples may not pose much of a problem for the country and it will be able to go with general consensus.

#### Article 1 Use of Terms

The preambular issue of ‘indigenous peoples’ appears in this and subsequent articles also and India should take a consistent stand on the same.

The definition of ‘public domain’ restricts it to those not protected by IPR and may make almost all TCEs public domain as they are not protected by established IPRs, except some original expressions which would be covered by the Copyright law. Therefore, India will have to take a nuanced stand on this, so that the protection for TCEs and folklore that the country has been demanding internationally does not become a hollow one.

#### Article 2 Objectives

Three different alternative texts exist under this Article. Alternative 2 (The objective of this instrument is to support the appropriate use and effective, balanced and adequate protection of traditional cultural expressions within the intellectual property system, in accordance with national law, recognising the rights of [indigenous peoples] and local communities [beneficiaries]) may appear preferable. However, the crucial expressions in this Article that we may insist on are ‘effective, balanced and adequate protection’.

#### Article 3 Protection Criteria/Eligibility Criteria

Under this Article there are two options. The contentions seem to be about the length of generational transmissions of TCE and period for prior existence of the TCE. Limiting the period of prior existence to 50 years may affect getting protection for comparatively recent TCEs and also put the onus on communities to prove the existence of the TCE for a period of more than 50 years. Such provisions will create more hurdles and lead to procedural and administrative issues.

#### *Article 4 Beneficiaries*

There are three alternative texts. The observations made on the Preamble hold here also, though from India's angle alternatives 1 or 3 are preferable since decisive roles are given to national laws.

#### *Article 4 Scope of Protection*

This is perhaps the most contentious article and also is the most substantial one. Even on the title of the Article itself, so far there has been no consensus. Some prefer to use 'Scope of Protection' while some other prefer to use 'Scope of Safeguarding'. The two expressions emerge out of two views, one preferring protection and another preferring certain safeguards only which may not lead to exclusive rights or real prohibitory provisions.

There are three alternative texts. The first one is talking about safeguarding the economic and moral interests of the beneficiaries concerning their TCEs. An issue that can come up with such an approach is that of valuation of the TCEs, which may not be very favourable to traditional or local communities since they have not been commercialising the same and their economic status is most likely to be the bottom half of the economic pyramid.

The third alternative talks about TCEs which are sacred or secret. In this context the observations made by India in the 40<sup>th</sup> IGC are quite relevant. It is important that to consider the practicality and the legal implications of the scope and approaches to that. When benefit-sharing is proposed only for secret or sacred TCEs, a question arises as to how others would come to know or could use a secret TCE, given the mere fact that it was secret. As India then stated, if others could use the TCEs, it might be argued that the TCEs were no longer secret and that hence there was no case for benefit-sharing. There would be large number of litigation. Since TCEs are about 'expressions' there would be no benefit-sharing at all on the ground that they would have already been expressed and

hence not 'secret'. Putting the onus proof on the rightful heirs of TCEs instead of on the persons or firms who were using the same without proper authorisation is also not advisable, especially for sacred or secret TCEs who in most cases would not have any documentary evidence. Even the proposal to 'encourage users to attribute the TCEs to the beneficiaries' is making the moral right of attribution an optional one, something which goes against principles of IPR as well as ethics. Attribution of authorship or ownership has to be mandatory as in the case of IPRs. This is particularly so in the case of TCEs.

#### *Article 6 Administration of Rights or Interests*

This, although there are two alternative texts, is more in the nature of national administrative set ups for the TCEs which will arise as and when a law is enacted and has to be in accordance with administrative systems and traditions of a country, and better be made quite flexible.

#### *Article 7 Exceptions and Limitations*

This is also, like Article 5, very important. They will depend on the provisions regarding scope and kind of protection proposed to be extended to TCEs. As in the case of most contentious articles, here also there are three alternatives. The first one is a very general one and is more in the nature of exceptions and limitations under the Paris Convention and the Berne Convention. The second alternative contains detailed mandatory provisions. Para 1 of this alternative says that if any act is permitted under the IP law, they should not be prohibited by the protection of TCEs. In second para, it presents a list of activities which should come under exceptions. Similar provisions are also proposed under alternative 3. As stated above, the exception clause will have to be examined in the context of the finally agreed scope of protection and will depend on the same. This will have to be drafted keeping in view cultural advancement without destroying heritage or denying fair and equitable benefits to the holders in case of commercial exploitation.

#### *Article 8 Term of Protection*

Here also three options have been proposed. But all three leave the term to the member states, though in the first two it is to be as long as the TCEs remain as such.

#### *Article 9 Formalities*

Two contrasting proposals are there: one requiring no formalities and the second one requiring the same. As already observed above, subjecting TCE protection to formalities is a cumbersome process and also may lead to denying benefits to the traditional communities, not to speak of the practicality of the same as in the case of copyrights.

#### *Article 10 Sanctions, Remedies and Exercise of Rights/Interests*

There are three alternative texts. The first one is proposing a general provision that “Member States shall put in place appropriate, effective, dissuasive, and proportionate legal and/or administrative measures, to address violations of the rights contained in this instrument.” The second one provides for “civil and criminal enforcement measures”. The third alternative is more like the first one. Sanctions, remedies, etc. have to be decided based on the rights and protection extended to the TCEs and should be proportionate to that.

#### *Article 11 Transitional Measures*

These are standard provisions, although there are two options proposed in regard to already commercialised TCEs.

#### *Article 12 Relationship with other International Agreements*

These are also standard provisions.

#### *Article 13 National Treatment*

This is standard provision as in the TRIPS Agreement.

#### *Article 14 Transboundary Cooperation*

There may not have any reservation on this as it is more of a practical and exhortatory nature.

#### *Article 15 Capacity Building and Awareness Raising*

Given the countries and stakeholders involved in the TCEs, these recommendatory provisions on awareness generation are welcome, at least during the initial years of the Instrument.

It must be realised that in negotiations, a country has to be flexible, but should try to protect the core interests. Particular language of the treaty will depend on how much consensus emerges and considering the fact that already negotiations have been going on for more than two decades and 40 meetings of the IGC have already taken place without arriving at a final consensus text, the task is quite hard. But India has to push for its national interests and also the policy as proposed in the National Intellectual Property Rights Policy, 2016.

## **Conclusion**

WIPO has performed better compared to other international organisations in taking steps for moving towards international instruments for protection of TK, TCE and plant genetic resources in that it has adopted three treaties relating to substantive norms in the area of copyright, two on procedural aspects relating to the registration of trademarks and one on procedural aspects regarding applications for patent protection; a convention on geographical indications was also revised.<sup>55</sup> However, only one of these instruments answered to concerns voiced by developing countries. Other initiatives by governments or civil society to develop new instruments under the auspices of WIPO such as on broadcasting, copyright exceptions for libraries, industrial designs and, notably, genetic resources, TK and Traditional Cultural Expressions (TCEs), have failed so far. Further negotiations are expected at the WIPO to explore any possibility of a legally binding instrument for IPR protection, though the heavily bracketed draft articles are indication of the serious differences that may impact the fulfilment of this objective.

IGC represents a platform where India can intervene as the draft articles being designed by the WIPO-IGC have a direct bearing on the Indian TK, GRs and TCE. India should use WIPO-IGC as a platform to achieve its objective of stronger legal regime, be it IPR laws or *sui generis* laws, to demand for PIC and access to benefit-sharing provision, emphasise on a holistic definition of TK and TCE; bring attention to customary laws; and *via* IGC can attempt to resolve trans-boundary issues, which may arise by using mechanisms like dispute resolution. The WIPO-IGC has often been criticized for maintaining a *status quo* which tips the balance of power in favour of the developed countries by maintaining minimum IP standards. Here, India can be the voice of developing countries.

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31. Article 22 - Protection of Geographical Indications  
1. Geographical indications are, for the purposes of this Agreement, indications which 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.
2. In respect of geographical indications, Members shall provide the legal means for interested parties to prevent:
- (a) the use of any means in the designation or presentation of a good that indicates or suggests that the good in question originates in a geographical area other than the true place of origin in a manner which misleads the public as to the geographical origin of the good;
- (b) any use which constitutes an act of unfair competition within the meaning of Article 10bis of the Paris Convention (1967).
3. A Member shall, ex officio if its legislation so permits or at the request of an interested party, refuse or invalidate the registration of a trademark which contains or consists of a geographical indication with respect to goods not originating in the territory indicated, if use of the indication in the trademark for such goods in that Member is of such a nature as to mislead the public as to the true place of origin.
4. The protection under paragraphs 1, 2 and 3 shall be applicable against a geographical indication which, although literally true as to the territory, region or locality in which the goods originate, falsely represents to the public that the goods originate in another territory.
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# Recommendations

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India's rich heritage of traditional medicinal knowledge, whether they are in the documented and systematised Ayurveda, Yoga, Siddha, Unani and Sowa Rigpa, or in the mostly oral folk and tribal medicine field, and also its grand cultural heritage, and the cases of misappropriation of the knowledge and cultural expressions through unauthorised access have led to India taking a stand internationally for the protection of Traditional Knowledge and Traditional Cultural Expressions and Folklore in various fora such as CBD, UNESCO and WIPO. These have borne much fruit in that most of the countries are now conscious of the need for international agreements for protecting TK and TCE. India is in the forefront in the discussions in the WIPO on three draft legal instruments on protection of TK, TCE and GR. India also took lead in the negotiations that led to the Nagoya Protocol which contain obligations on recipient countries as well on Genetic Resources. Domestically, India has enacted many legislations relating to the protection, particularly the BDA. It also established a comprehensive TKDL to prevent grant of wrong patents based on India's TK. During the last two decades, many practical difficulties have cropped up in the implementation of the BDA particularly for the AYUSH industry, a depository of Traditional Medicine Knowledge and a prominent user of biological material. The National IPR Policy, 2016, took note of the changed circumstances and suggested an examination of the issues. Accordingly, in the light of the preceding analysis, the following recommendations are proposed:

## Traditional Knowledge

- While India does not have a separate legislation for protection of TK, GR and TCEs, it has a number of legislations which provide defensive protection like the Patents Act and positive protection like the BDA. These legislations fulfil India's obligations under various international treaties and conventions on the subject, including the Nagoya Protocol. Therefore, there may not be any need for drafting a new *sui generis* legislation, at least for TK and GR.
- The TKDL is sufficient to protect India's interests on TK in the digital world. However, the scope of the same needs to be expanded to cover knowledge outside the AYUSH systems. It should specifically document oral and folk knowledge available with communities all across the country.
- Since the TKDL databases are primarily traditional medicine knowledge, it would be appropriate if the administrative control of the same is with the Ministry of AYUSH.
- The TKDL should also be made more easily accessible to researchers, particularly in the field of AYUSH, in the interest of R&D and promotion of AYUSH.
- This would also facilitate the TKDL to advise the patent offices on patentability of new inventions based on TK but with sufficient innovativeness and also done with proper PIC and ABS mechanisms.
- Adequate precautions should be taken while documenting oral knowledge. These would include prior informed consent

- of the knowledge holders and controlled access to the knowledge as agreed to be the knowledge givers.
- There is need for clear demarcation of access to biological materials and access to traditional knowledge. While the former may continue to be governed by the existing provisions of BDA, the latter should have specific provisions.
  - AYUSH industry and practitioners should be considered as depositories of Traditional Medicine Knowledge documented in the authorised texts and may not be required to have any benefit sharing on use of such knowledge by themselves. It is suggested that all the AYUSH classical drugs prescribed in the texts/pharmacopoeia may be exempted from ABS (limited to finished products only). This may be discussed and debated and before taking appropriate action.
  - Proprietary drugs/ Patented drugs, cosmetics products, scientifically validated herbal drugs, functional food, botanicals value added products herbal extracts, phyto medicines and other health care products including products related to wellness remain under ABS.
  - Raw materials used by the preparations of classical drugs should be charged with levy as mentioned in the BD Act/ Rule.
  - Others who access such knowledge may continue to have to follow PIC and ABS provisions, but the benefit share should go to a fund for the promotion of the AYUSH sector.
  - Laws/Policy on ABS, TK associated with GR with tribal communities of India (mostly still in the oral tradition) shall be worked out and prepare a separate database on this for the protection of TK, TCEFS and genetic resources a view to prevent unsustainable collection of bio resources.
  - Systematic documentation of TK associated with Biodiversity, sector wise/subsector wise, is highly essential to establish ownership right of an individual or family or community. It is also essential to codify the information/knowledge from the knowledge holders/providers (from the oral tradition)- primary data as well as secondary data after obtaining the prior informed consent (PIC). Based on this, different PICs according to the sector and subsector be developed. A possible codification format is presented in the Table 4.

**Table 4: Codification of TK associated with Biodiversity**

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| PART I -Primary Data   | SUB SECTOR -3, TRADITIONAL KNOWLEDGE RELATED TO ANIMAL HUSBANDRY   |
| <ol style="list-style-type: none"> <li>1. Art and Culture</li> <li>2. Agriculture</li> <li>3. Animal Husbandry</li> <li>4. Architecture</li> <li>5. Biodiversity Conservation and utilization</li> <li>6. Eco-Friendly practices</li> <li>7. Fisheries</li> <li>8. Forest and Wild life Management</li> <li>9. Health Care</li> <li>10. Medicinal plants and Food Plants</li> <li>11. Rural Technology</li> <li>12. Miscellaneous</li> </ol> | <ul style="list-style-type: none"> <li>• Selection of appropriate breeds</li> <li>• Feed and fodder</li> <li>• Breeding and delivering</li> <li>• Pre natal and post natal care</li> <li>• Enhancement of milk production</li> <li>• Animal health care and disease management</li> <li>• Plants used in veterinary medicine</li> <li>• Use of milk, other animal products</li> <li>• Taboos and benefits in rearing and keeping animals.</li> </ul> |

Table 4 continued...

Table 4 continued...

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| <p>SUB SECTOR -1, TRADITIONAL KNOWLEDGE RELATED TO ART AND CULTURE</p> <ul style="list-style-type: none"> <li>• Songs</li> <li>• Dances</li> <li>• Drama</li> <li>• Murals and Paintings</li> <li>• Dyes and natural colours</li> <li>• Music and Musical instruments</li> <li>• Martial arts.</li> <li>• Ornaments and costumes</li> <li>• Customs and benefits</li> <li>• Tribal customs and beliefs</li> <li>• Taboos and religious practises</li> </ul> <p>SUB SECTOR -2, TRADITIONAL KNOWLEDGE RELATED TO AGRICULTURE</p> <ul style="list-style-type: none"> <li>• Common agricultural practises including selection of seeds, selection of sites. Propagation and seeds before sowing etc.</li> <li>• Propagation of multiplication</li> <li>• Prevention of soil erosion</li> <li>• Desalination/ reclamation of soil etc.</li> <li>• Timing for sowing seeds, weeding application of manure, harvesting etc.</li> <li>• Pest control</li> <li>• Irrigation</li> <li>• Inter cropping</li> <li>• Water harvesting/ watershed management/ maintaining ecological balance</li> <li>• Combating unexpected and sudden change in climate</li> <li>• Enhancing soil fertility</li> <li>• Breeding and hybridization</li> <li>• Harvesting</li> <li>• Post harvesting technology</li> <li>• Storage of Harvests</li> <li>• Processing harvested goods.</li> <li>• Religious, ritual and spiritual practises concerning agriculture.</li> <li>• Fish harvesting</li> <li>• Fish processing and preservation</li> <li>• Fish poisoning plants</li> <li>• Vernacular name, credibility and other properties</li> <li>• Medicinal properties.</li> </ul> | <p>SUB SECTOR -4, TRADITIONAL KNOWLEDGE RELATED TO ARCHITECTURE</p> <ul style="list-style-type: none"> <li>• Dwelling places</li> <li>• Places of worship</li> <li>• Places of public assembly, commercial establishment etc.</li> <li>• Traditional construction techniques including masonry, carpentry, varnishing etc.</li> <li>• Tribal Knowledge</li> </ul> <p>SUB SECTOR -5, TRADITIONAL KNOWLEDGE RELATED TO BIODIVERSITY CONSERVATION UTILIZATION</p> <ul style="list-style-type: none"> <li>• Collection of non-wood</li> <li>• Forest produce</li> <li>• Non-destructive and renewable extraction technique</li> <li>• Timing and periodicity of extraction</li> <li>• Conservation and utilization of rare, endangered and threatened species of plants.</li> <li>• Conservation of frequently extracted species.</li> </ul> <p>SUB SECTOR -6, TRADITIONAL KNOWLEDGE RELATED TO ECOFRIENDLY PRACTICES</p> <ul style="list-style-type: none"> <li>• Topography and terrain</li> <li>• Self-protection and safe guarding against wild animals and reptiles.</li> <li>• Prediction of sudden climatic changes and natural calamities.</li> <li>• Ethnic food and natural drinks</li> <li>• Allergic and poisonous plants.</li> </ul> <p>SUB SECTOR -7, TRADITIONAL KNOWLEDGE RELATED TO FISHERIES.</p> <ul style="list-style-type: none"> <li>• Seasonal availability and migration of fish in the sea and river waters</li> <li>• Weather forecasting and fishing</li> <li>• Manufacture of fishing boat.</li> <li>• Breeding and egg laying hatching etc.</li> <li>• Pisciculture.</li> <li>• Poisons toxic and edible fish</li> </ul> |
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Table 4 continued...

Table 4 continued...

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| <p>SUB SECTOR -8, TRADITIONAL KNOWLEDGE RELATED TO FOREST AND WILD LIFE MANAGEMNT</p> <ul style="list-style-type: none"> <li>• Flora, fauna of the forest</li> <li>• wild edible and toxic plants</li> <li>• Mushrooms</li> <li>• Plants yielding dyes and pigments</li> <li>• Plants yielding useful gums and resins</li> <li>• Aromatic plants</li> <li>• Plants having insecticidal properties</li> <li>• Concentration, migration and movement of wild animals</li> </ul> <p>SUB SECTOR -9, TRADITIONAL KNOWLEDGE RELATED TO HEALTH CARE</p> <ul style="list-style-type: none"> <li>• Health and hygiene</li> <li>• Prevention of diagnosis</li> <li>• Method of diagnosis</li> <li>• Disease Management</li> <li>• Custom, rituals and religious practices</li> <li>• Healing techniques</li> <li>• Pre natal and post natal care</li> <li>• Animal products</li> <li>• Metals and minerals</li> </ul> <p>SUB SECTOR -10, TRADITIONAL KNOWLEDGE RELATED TO MEDICINAL AND FOOD PLANTS</p> <ul style="list-style-type: none"> <li>• Medicinal plants</li> <li>• Wild edible plants</li> <li>• Food plants</li> <li>• Single drug remedies</li> <li>• Compound drugs</li> <li>• Selection and collection of drugs, processing preparation, storage and administration of food and medicine</li> </ul> | <p>SUB SECTOR -11, TRADITIONAL KNOWLEDGE RELATED TO RURAL TECHNOLOGY</p> <ul style="list-style-type: none"> <li>• Traditional crafts such as treatment of coconut husk, preparation of fibre, coir and coir products</li> <li>• Bamboos, reeds and their products</li> <li>• Hand loom cotton cloth, dyeing and printing of textiles using natural colours</li> <li>• Medicated cloth</li> <li>• Tanning of leather</li> <li>• Potteries and clay products</li> </ul> <p>SUB SECTOR -12, TRADITIONAL KNOWLEDGE RELATED TO MISCELLANEOUS</p> <ul style="list-style-type: none"> <li>• Any other relevant information based on above mentioned sectors or other areas.</li> </ul> |
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## Recommendations for MPGRs

1. Overall, given the criticality of conservation and protection of medicinal PGRs a separate legislation regulating the same would be highly recommended. There is no legal framework for MPGRs. Strategies, plans and programmes though legislations like BDA and National Biodiversity Action Plan serves

as the framework for biodiversity related matters, including medicinal PGR, at present. In view of the special nature of the medicinal PGRs , such as, their location in forest areas that are remote and inaccessible, traditional knowledge available with the forest dwelling tribes, the growing demand for resources and threat of extinction (Most of the medicinal

- plant species in India are found in forest areas. But there is no special act to protect rare species except the Forest (Conservation) Act, 1980 and Wild Life (Protection) Act, 1972. Schedule VI of the Wild Life (Protection) Act, 1972 covers only five species.), a special legislation is needed for medicinal PGRs.
2. Documentation of medicinal PGRs is of prime importance. The genetic diversity of many MPGR is yet to be known.
  3. Advances in biotechnology offer new methods for conservation of rare and endangered medicinal plants. Institutions like ICAR and CIMAP may be harnessed to develop gene banks of entire range of medicinal PGRs in India.
  4. Cultivation of medicinal PGRs is also a critical step to lower dependence on forest resources thereby reducing threat of extinction of species.
  5. Illegal trade practices involving threatened species requires strict monitoring in light of growing international demand for medicinal plants from India.
  6. With reference to medicinal plants cultivation, there is inadequate data or estimates of the number of farmers' varieties in existence, or on the current state of use of farmers' varieties.
  7. Protection of Plant Varieties and Farmers' Rights Authority has acknowledged that very few farmers are actually aware of the right to registration of plant varieties. The Authority in collaboration with National Agricultural Research System (NARS) and Krishi Vigyan Kendras (KVKs) and Non-Governmental organizations (NGOs), has made efforts and this has borne fruit to a great extent. However, large scale awareness programmes are required to encourage propagation and conservation of medicinal plant varieties.
  8. It takes much longer for a farmer to register a variety than it does for a private sector entity. A likely reason for this is the informal nature of the breeding and conservation processes that characterise farmers' varieties. Various technical details such as difficulty in determining parental lines, lack of comparative data with other varieties, lack of varietal characterisation, and failure to obtain the appropriate endorsement of applications have often proved to impede the process of registration of farmers' varieties.
  9. The absence of a clear definition of the term "community" under the PPVRA Act 2001, coupled with the informal nature of many farmers' groups and organisations in the country, may create confusion with respect to the ownership of varieties, thus leading to substantial difficulties in identifying beneficiaries. Hence a review of the Act specifying the term is important to allocate clear ownership to intended beneficiaries.
  10. Review of BDA and Proposed Changes:
    - Definition of NTAC: The NBA should hold stake-holder meetings on definition of NTAC and products to be exempted from the purview of the Act. Approval for NTAC under Section 3 to 6 should also be waived.
    - Definition of VAP: VAP should be interpreted *vis-a-vis* the NTAC list under Section 40 of the Act.
    - Definition of Conventional Breeding: The NBA should implement a strict interpretation of 'conventional breeding' to exempt farmers developing new varieties through conventional breeding or traditional agricultural practices from the definition of commercial utilisation. Further, NBA must come up with the definition of 'conventional breeding'



which should include hybrid budding and molecular budding.

- **ABS Procedures:** Timelines should be strictly adhered to by the NBA as delays in approval can be detrimental to the patent applicants. Suitable remedy in case of delay by the NBA should also be provided by the NBA. A single and simplified form/ approval process be developed to cover all intimations/ approvals. Further, benefit sharing agreement under Section 6 should supersede and replace all and any other previous benefit sharing agreements with the related authorities.
- **SBBs' jurisdiction:** The NBA should hold regular meetings with the SBBs to ensure uniform implementation of the Act as per rationally agreed interpretation of the Act.
- **Local Communities:** Greater participation of local communities in benefit sharing arrangements should be assured. For this, strengthening BMCs and greater consultation with local communities by the NBA before decision making on ABS is required. Further, information on use of the ABS funds collected by the NBA should be provided to the applicants accessing biological resources and charged with ABS fees.
- **Research:** Non-commercial research should be exempted from approval process.
- **Nationality of a body corporate:**  
Section 7 may be rewritten to include PIOs and may read thus:  
  
No person, who is a citizen of India or OCI card holder or a body corporate, association or organization which is registered in India, shall obtain any biological

resource for commercial utilisation, or bio-survey and bio-utilisation for commercial utilization except after giving prior intimation to the State Biodiversity Board concerned: Provided that the provisions of this section shall not apply to the local people and communities of the area, including growers and cultivators of biodiversity and their cultivated produce, and *vaid*s and *hakims*, who have been practicing indigenous medicine.

Section 24 may be rewritten thus: Any citizen of India or OCI card holder or a body corporate, organization or association registered in India intending to undertake any activity referred to in Section 7 shall give prior intimation in such form as may be prescribed by the State Government to the State Biodiversity Board.

11. In order to address some of the concerns of the industry the National Biological Diversity Board brought out Draft Guidelines on ABS in 2019 a set of recommendations have been prepared for modifications to the Guidelines in a tabular format. These are presented in the following Tables 2 and 3 of the Report.
12. Confusion over jurisdictional overreach has created further challenges for the industry. While the BD Act states that appeals against the violation of the law (especially the access provisions) lie before the NGT, the High Courts have not abdicated power to oversee matters under their writ jurisdiction. The litigations on TK and biological resources have taken place at different levels from courts of judicial magistrates, other district level courts to the apex court and high courts, as well as before

different benches of the National Green Tribunal (NGT). The venues of conflict have been spread across India. This needs to be resolved to bring clarity to all stakeholders concerned.

### Recommendations of TCE

1. The governance of TCE is based on liberal interpretation of different laws, since no law addresses TCE specifically. India needs *sui generis* laws like the ones that exist in Australia, Panama and Philippines for the protection of TCEs.
2. The existing IPR regime of India protects TCEs through GI and TM. However, it has been noted that GI and TM laws are more helpful in protecting interests and concerns of the owner of TCEs against counterfeits, but not against misappropriation and unauthorized use. Laws that can prevent misappropriation of TCEs, (even on digital platforms) needs to be framed.
3. Indian Penal Code 1860 (IPC), which punishes offences, including those committed in cyberspace (such as defamation, cheating, criminal intimation and obscenity) should be extended for the protection of TCEs on cyber space.
4. Like TKDL, India should start building a comprehensive database on TCEs over the time.



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