# ANALYSIS OF DEFENSIVE PROTECTIONS FOR TRADITIONAL KNOWLEDGE IN INDIA

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## **1. Introduction**

Looking at the history and development of intellectual property laws and norms at the international level, one notes that they draw from existing national laws. The international dimension provides the framework within which protection can be extended beyond national borders and provides for international cooperation.<sup>2</sup> But for the protection of traditional knowledge no concrete international effort has been solemnize yet and the cases of misuse by third parties are rampant. Many countries have developed some sort of legal protection to protect their traditional assets though not adequate in the absence of transnational protective mechanism. In India traditional knowledge as a valuable asset also needs statutory protection and some efforts have also been made. But when we talk about protection it must be clear what we want to protect? There is lack of an inclusive definition of traditional knowledge. But still some conventional protections as provided to other recognized intellectual property are available for tradition knowledge. These protective measures are generally divided as defensive and positive. Before proceeding towards the aimed analysis, first it is important to discuss the phenomenon.

Discussions on protection of traditional knowledge at international level have been going on for a while at different international fora including WIPO through the Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional knowledge and Folklore since 2000. Proposed protection under the IGC is within the context of intellectual property albeit a sui generis system of protection. To contextualise this discussion, it is important to look at other international regimes especially in the area of intellectual property.

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http://www.wipo.int/edocs/mdocs/tk/en/wipo\_iptk\_ge\_2\_16/wipo\_iptk\_ge\_2\_16\_presentation\_11ouma.pdf

Over the years, IP rights have been formulated as individual, monopolistic rights to protect the innovative, novel and utilitarian ideas of the human mind. TK was thus undervalued: every community has its customary practices, home remedies and cultural expression (folklore). However, the need to protect TK came to the forefront with the adoption of the global Convention on Biological Diversity (CBD) in 1992.<sup>3</sup>

Article 8(j) of the CBD states that every member nation in accordance with its domestic law should move towards the preservation, maintenance and sustainable use of resources important to the TK of the indigenous community. Member nations are urged to promote wider use of TK with the prior approval and involvement of the holder(s) of the knowledge.<sup>4</sup> The fact that industries are using TK without the prior informed consent of the knowledge holders is a concern, as is the lack of benefit-sharing mechanisms.

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the CBD was adopted at the 10th Conference of Parties (COP) to the CBD in Nagoya, Japan, on October 29, 2010. It is the first international instrument particularly relevant to indigenous communities since the adoption of the UN Declaration on the Rights of Indigenous Peoples in 2007. The protocol has 92 signatories and 52 ratifications; it is set to come into force on October 12, 2014, i.e., 90 days after receiving the 50th ratification. The purpose of the protocol is to effectively implement one of three core obligations of the CBD: the access to genetic resources and the sharing of benefits. Obligations have been set out for seeking prior informed consent of indigenous communities for access; provisions have also been made for the sharing of benefits on mutually agreed terms from the use of TK and GRs in accordance with the domestic legislation of the source country. The text of the protocol also contains a review clause, which states those four years after entry into force, the COP is to conduct an evaluation with regard to the effectiveness of the protocol. The COP has decided that the review should be undertaken in the light of developments in other relevant international organisations, including the World Intellectual Property Organization.

<sup>&</sup>lt;sup>3</sup> Vikrant rana, Protection of traditional knowledge in India, (March 16, 2018, 11:12 AM), http://www.mondaq.com/india/x/464940/indigenous+peoples/Protection+Of+Traditional+Knowledge+In+India.

<sup>&</sup>lt;sup>4</sup> Article-8, Convention on Biological Diversity,1992.

The protocol allows for parties to implement other relevant international agreements, provided they are supportive of the objectives of the CBD and the Nagoya Protocol.<sup>5</sup> India signed the protocol on May 11, 2011 and ratified it on October 9, 2012.

## 2. Protected Categories of Traditional Knowledge

TK can be divided into two broad categories.

**Traditional cultural expressions**: The first category, traditional cultural expressions (TCEs), covers artistic works, musical works, symbols, etc., of indigenous people. The second category is biological resource–related TK, which covers areas like herbal medicine and traditional remedies that have been created through the ability of indigenous communities to identify the medicinal properties of various biological resources within their geographical boundaries. Both categories pose their own unique challenges to the present legal regime.<sup>6</sup>

TCEs can be accommodated, to an extent, within conventional legal regimes such as copyright law, trademark law, and geographical indications law, which protects well-known names that are the result of community efforts. Some well-known examples are Darjeeling tea and champagne. In India, geographical indications law has been used extensively to protect TCEs. Some countries have enacted sui generis laws to protect just TCEs, especially countries with large indigenous populations. For example, the United States enacted the Indian Arts and Craft Arts Act of 1990 for the specific purpose of protecting the arts and crafts of Native Indian tribes.<sup>7</sup>

India, which has assumed the leadership mantle among developing countries in TK negotiations, has yet to pass an equivalent sui generis law to protect TCEs that cannot otherwise be protected under the conventional IP regimes.

**TK associated with biological resources**: The second category (i.e., TK associated with biological resources), is significantly more complicated. The typical targets for protection in

<sup>&</sup>lt;sup>5</sup>Vikrant rana, Protection of traditional knowledge in India, (March 16, 2018, 11:12 AM), http://www.mondaq.com/india/x/464940/indigenous+peoples/Protection+Of+Traditional+Knowledge+In+India. <sup>6</sup> <u>Prashant Reddy & Malathi Lakshmikumaran</u>, Protecting Traditional Knowledge Related to Biological Resources: Is Scientific Research Going to Become More Bureaucratized?, (March 17, 2018, 11:04 AM), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4588132/.

<sup>&</sup>lt;sup>7</sup> <u>Prashant Reddy & Malathi Lakshmikumaran</u>, Protecting Traditional Knowledge Related to Biological Resources: Is Scientific Research Going to Become More Bureaucratized?, (March 17, 2018, 11:04 AM), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4588132/.

this class are herbal remedies or plant-based medicines that have been used by a group of indigenous people for several generations.

An example of such a case in India is that of the *arogyapacha* plant (*Trichopus zeylanicus* subsp. *travancoricus*), whose properties were identified by the Kani tribe located in Kerala, India. According to a World Intellectual Property Organization (WIPO) report,<sup>1</sup> during an expedition in 1987 in which the Kani were guiding government scientists belonging to the Tropical Botanical Garden and Research Institute (TBGRI), the scientists noticed that the Kani were not getting tired despite significant physical exertion and were constantly chewing on some black berries. On inquiring with the Kani, the scientists realized that the berries had properties that relieve fatigue<sup>8</sup> Subsequently, in 1994, the scientists at the TBGRI filed for patents and licensed the same to an Indian pharmaceutical company for U.S. \$50,000 plus 2% royalties on all sales. In 1997 the TBGRI assisted the Kani in setting up a trust to document their TK (they had knowledge of other plants apart from *arogyapacha*) and enter into benefit-sharing agreements. Adult Kanis were in control of the trust. In a couple of years, according to the WIPO report, the Kani reportedly received the first payment of U.S. \$12,500.<sup>9</sup>

Some forms of TK falling under these two categories are protected by legislative and administrative initiatives. Legislative initiatives are included in National Biological Diversity Act 2002, Patents Act (Section-3(p)), Protection of Plant Varieties and Farmers Rights Act, Geographical Indication Act, Scheduled Tribes and Other Traditional Forest Dwellers (Recognition of Forest Rights) Act 2006. And administrative initiative includes TKDL (Traditional Knowledge Digital Library), TKRC (traditional knowledge resource classification) and Community Level Databases-PBRs.

## **3.** Conventional Approaches of Protection

<sup>&</sup>lt;sup>8</sup> S Chaturvedi, The role of scientists and the state in benefit sharing: Comparing institutional support for the San and Kani. In Indigenous peoples, consent and benefit-sharing: Lessons from the San-Hoodia case,(ed. Wynberg R, et al.), pp. 261–270.

<sup>&</sup>lt;sup>9</sup> <u>Prashant Reddy</u> & <u>Malathi Lakshmikumaran</u>, Protecting Traditional Knowledge Related to Biological Resources: Is Scientific Research Going to Become More Bureaucratized?, (March 17, 2018, 11:04 AM), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4588132/.

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The term 'protection' was initially used very loosely, meaning different things to different people. Only recently has analysis focused on the different facets of protection and a more systematic approach developed to understand what exactly it may mean.<sup>10</sup> In a classic IP context, protection refers to granting exclusionary rights to inventors and creators through IP tools – patents, breeders' rights, copyrights, etc. In the IP realm, protection may also mean compensation, social recognition through moral rights, benefit sharing and maintaining, preserving and controlling access and uses of TK through unfair competition principles. Defensive protection is yet another form of safeguarding rights pertaining to TK and GRs.<sup>11</sup>

Though TK protection initiatives vary considerably in form and substance, there are some common features that stand out. First, most policy and legal instruments (i.e. Peruvian law for TK protection, Costa Rica Law 7788, Panama Law 21) recognize PIC as a critical condition that must be met as a prerequisite for accessing and using TK for any purpose (in general terms). This involves some kind of bilateral approach or negotiation between a user and an indigenous peoples' representative.<sup>12</sup>

Second, almost invariably, TK-related policies and instruments include registers as a tool to support protection measures, whether defensively or to positively help in assigning rights to indigenous peoples. This is the case of existing laws in Costa Rica, Panama, Peru and the Traditional Knowledge Digital Library (TKDL) initiative in India, among others. This is not to say that registers are free from controversy, especially with respect to the fact that they systematize TK under certain pre-established criteria and provide an informational platform that is often alien to indigenous peoples and communities – in content and process. Registers and their role have been strongly contested over time by some indigenous peoples' organizations and nongovernmental organizations (NGOs).

<sup>&</sup>lt;sup>10</sup> Graham Dutfield, <u>Protecting Traditional Knowledge and Folklore: A Review of Progress in Diplomacy and</u> <u>Policy Formulation</u>, UNCTAD-ICTSD, Intellectual Property Rights and Sustainable Development, Issue Paper No. 1. June 2003.

<sup>&</sup>lt;sup>11</sup>Thomas Henninger, Disclosure requirements in patent law and related measures: a comparative overview of existing national and regional legislation on IP and biodiversity. In: Werth, Alexander, Reyes, Susanne (Editors) 2010. Triggering the Synergies between Intellectual Property Rights and Biodiversity. GIZ, Eschborn, Germany. p. 293-226

<sup>&</sup>lt;sup>12</sup> Manuel Ruiz Muller, Protecting Shared Traditional Knowledge Issues, Challenges and Options, ICTSD Programme on Innovation, Technology and Intellectual Property, (March 17, 2018, 12:38 PM), https://www.ictsd.org/sites/default/files/research/2013/11/protecting-shared-traditional-knowledge.pdf.

It is often suggested that classic IP tools – mainly patents, breeders' rights and copyrights - are intrinsically unsuitable to protect indigenous peoples' intellectual efforts and creations. This has been explained above (see Introduction). This assertion, however, must be qualified, given that there may be alternatives in 'soft' IP tools, such as collective marks or geographical indications, or even in the use of unfair competition law principles, which could, under certain circumstances, provide some forms of protection to these efforts and creations. <sup>13</sup>

Finally, and one of the most critical but often overlooked aspects in the development of policies and legal frameworks, are the very general references to 'traditional knowledge' without a precise definition of the concept. This last issue – together with unclear scope - is one potential limitation that could affect the implementation of legal and regulatory frameworks. Do policies and norms refer to TK as an intangible per se, or in its more tangible expression (i.e. a technique, a process, a product)? Do they cover only TK that is publicly accessible or do they mostly refer to TK that is still maintained as confidential by communities or specific community members? Without exception, broad definitions and scope facilitate legal drafting,<sup>14</sup> but often complicate practical implementation, as is currently being experienced in India.<sup>15</sup>

## 4. Defensive Initiative to Protect Traditional Knowledge

Protection of TK is important for communities in all countries and especially developing and least developed countries with their diverse stores of traditional knowledge. Broadly, a twofold approach has been floated for the protection of TK in the present Intellectual Property Rights

<sup>&</sup>lt;sup>13</sup> Graham Dutfield, <u>Protecting Traditional Knowledge and Folklore: A Review of Progress in Diplomacy and</u> <u>Policy Formulation</u>, UNCTAD-ICTSD, Intellectual Property Rights and Sustainable Development, Issue Paper No. 1. June 2003.

<sup>&</sup>lt;sup>14</sup> The TRIPS Agreement does not define an invention in its text, but establishes criteria upon which an invention is measured: novelty, inventiveness and industrial application. These are technical concepts which over time have been described precisely in terms of content and their specific boundaries.

<sup>&</sup>lt;sup>15</sup> Just as an example of the potential problems of inexistence of definitions, recently in India, the Supreme Court determined that Novartis would not be awarded a new patent over Gleevec (a cancer treating drug), basically because the "new" "invention" was not deemed significantly different from the original version of the drug. India's Novartis decision, (March 17, 2018, 11:15 AM), <u>http://www.nytimes.com/2013/04/05/opinion/the-supreme-court-in-india-clarifies-law-in-novartisdecision.html</u>? \_r=0.

regime- positive and defensive approaches.<sup>16</sup> This is a negative form of protection that aims to prevent the patenting or third party misuse of TK.

### 4.1. Creation of the Traditional Knowledge Digital Library (TKDL)

India has placed considerable emphasis on defensive patent protection measures because of specific incidents in the 1990s when TK that was well known in India, such as the properties of turmeric, was patented in the United States. Although there was no direct evidence of the patent causing economic harm to Indians, the Indian government appeared to have taken the incident as a slight to national pride. The incident of the turmeric patenting in the United States was accompanied by other cases of basmati- and neem-related patents in both the United States and the EU. The ensuing public outrage in India led to the government of India setting up the TKDL. The TKDL, which has been compiled through the translation and digitization of Indian books on TK, is a confidential database. Patent offices in the United States, EU, and Japan have been granted access to this database by India for the express purpose of weeding out patent applications based on Indian TK.<sup>17</sup>

**The TKDL aims to:** (1) record traditional knowledge in digital form and link it to an internationally accepted patent classification system for ease of searching and information retrieval<sup>18</sup>, (2) make traditional knowledge accessible to the patent office – not only the Indian patent office, but patent offices in other countries in order to prevent the misappropriation of Indian traditional knowledge, as there is no single international framework to regulate and protect the use of traditional knowledge, and (3) reduce Indian traditional knowledge misappropriation, especially by pharmaceutical and biotechnology companies.

<sup>&</sup>lt;sup>16</sup> Vera Shrivastav, Protection of Traditional Knowledge within the Existing Framework of Intellectual Property Rights: Defensive and Positive Approach, (March 20, 2018, 11:33 AM), https://ssrn.com/abstract=2463017 or http://dx.doi.org/10.2139/ssrn.2463017.

<sup>&</sup>lt;sup>17</sup> J.Carr, <u>Agreements that divide: TRIPs v. CBD and proposals for mandatory disclosure of source and origin of genetic resources in patent applications</u>, J Transnational Law Policy. 18, 131(2008).

<sup>&</sup>lt;sup>18</sup> Sageeta Udgaonkar, <u>The Recording of Traditional Knowledge: Will it Prevent "Biopiracy"</u>, Current Science, Vol 82 No.4. (February 2002), (March 20, 2018, 11:33 AM), http://www.ias.ac.in/currsci/feb252002/413.pdf.

Establishing a database in the form of the TKDL was conducted in India for a number of reasons:<sup>19</sup>

A. It has been observed that in the past few years, patents have been wrongly granted to traditional knowledge related inventions that do not fulfil the requirements of novelty and inventive step, particularly due to the existence of relevant prior art. For instance, this has happened in the case of turmeric, Neem, Basmati, etc.

B. The practical obstacle underlying the issue, was that patent examiners could not search relevant traditional knowledge as prior art, because they did not have access to traditional knowledge information in their classified non-patent literature. The primary reason for this non-accessibility is that Indian traditional knowledge exists in local languages such as Sanskrit, Urdu, Arabic, Persian, Tamil, etc., which either was not available or was not understood by patent examiners. TKDL breaks the language and format barrier and makes this information available in English, French, Spanish, German and Japanese in the patent application format, which is easily understandable by patent examiners. TKDL is thus a tool that provides defensive protection to the rich traditional knowledge of India.

C. Opposing a patent granted by a patent office is extremely costly and time consuming, taking, on average, five to seven years and costing between 0.2-0.6 million U.S. dollars. Today Traditional Knowledge Digital Library is capable of protecting (0.226 million) formulation similar to those neem and turmeric. One could only imagine the cost of protecting 0.226 million formulation it will cost 0,2 million US\$ medicinal formulation in the absence of TKDL. Not only the cost that need to spend in order to opposing wrong patent grant but also material damage caused by the block of market access of traditional knowledge because of wrong patent grant.<sup>20</sup>

### Advantages of the TKDL:

1. Prevents grant of patents based on traditional knowledge, especially those associated with medicine and saves huge amounts of money and time needed for contesting the patents.

<sup>&</sup>lt;sup>19</sup> TKDL: F&Q, (March 19, 2018, 7:33 AM), http://www.tkdl.res.in/tkdl/Langdefault/common/Faq.asp ?GL=Eng#q3.

<sup>&</sup>lt;sup>20</sup>Protecting Traditional Knowledge from Biopiracy, (March 19, 2018, 8:08 PM), http://www.wipo.int/meetings/en/2011/wipo\_tkdl\_del\_11/pdf/tkdl\_gupta.pdf.

2. Documents the scattered information on the Indian systems of medicine, particularly in a lingua franca, which is easily understood by patent examiners.

3. Integrates widely dispersed and distributed references on the traditional knowledge system in a retrievable and accessible form and acts as a bond between the traditional and modern knowledge systems.<sup>21</sup>

## Enactment of Section 3(p) of Patent Act

In addition to the TKDL, the Patents (Amendment) Act, 2002 also introduced into Indian patent law Section 3(p), which prohibits the patenting of traditional knowledge. Specifically, the provision bars the patenting of "traditional knowledge" or the "aggregation or duplication of known properties of traditionally known component or components." The provision reads as follows:

### Section 3: What are not inventions

(*p*) 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>22</sup>

This provision was more a result of politics because the existing bar in Indian law against inventions that are not novel or inventive would have in any case prohibited the patenting of TK. Accordingly, there was thus no need for a specific provision to prohibit the patenting of TK. However, after the outrage in India against the patenting of basmati, neem, and turmeric in the United States, the enactment of Section 3(p) became a political device aimed at reassuring Indians that TK would not be patented in India.

In 2013 the Controller General of Patents, Designs & Trademarks released a set of "Guidelines for Processing of Patent Applications Relating to Traditional Knowledge and Biological Material."<sup>23</sup> These guidelines substantially raise the bar to patentability for inventions related to TK. The research community and patent lawyers have expressed concerns that these

<sup>&</sup>lt;sup>21</sup> Shukla & B Dipak, <u>Synergy of Intellectual Property and Traditional Knowledge: Holy Grail for Protection and</u> <u>Sustainable Future</u>, 1The Open Conference Proceedings Journal.150,156(2010), available also at, http://www.benthamscience.com/open/toprocj/articles/V001/150TOPROCJ.pdf

<sup>&</sup>lt;sup>22</sup> Section-3(p), The Patents Act,1970.

<sup>&</sup>lt;sup>23</sup> Guidelines for Processing of Patent Applications Relating to Traditional Knowledge and Biological Material, (March 18, 2018, 9:13 PM), http://www.ipindia.nic.in/.

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guidelines are unreasonable and are prohibiting the patenting of genuine inventions. For example, Guiding Principle 1 states, "If the subject-matter as claimed relates to extracts/alkaloids and/or isolation of active ingredients of plants, which are naturally/inherently present in plants, such claims cannot be considered as novel and/or inventive when use of such plants is pre-known as part of teachings of Traditional Knowledge." This is an extremely high barrier to patentability. Identifying, isolating, and purifying an active compound from a plant known to demonstrate certain properties can take significant amounts of time, skill, and investment. Such innovation deserves to be rewarded with a patent. The five other guiding principles mentioned by the Indian Patent Office similarly raise the bar to patentability by presuming certain combinations or uses from TK to be barred by Section 3(p) or are presumed to be obvious.

Over the last couple of years, the TKDL, which is administered by the Council for Scientific & Industrial Research, has actively started filing pre-grant oppositions to patent applications on the grounds of Section 3(p). With the passing of time, as more patent applications are dismissed and appealed, the law on patenting related to TK will slowly evolve to provide applicants with a better understanding of the boundaries of patenting TK-related inventions.

### 4.2. Mandatory Disclosure of Geographical Origin of Biological Material

A second limb of defensive protection demanded by developing countries like India is for a mandatory disclosure, in the specification of the patent application, of the origin of biological material that was used in the invention being claimed in the patent application. The intention behind this demand is to give more teeth to an international enforcement regime under the CBD, which seeks to regulate the international transfer of genetic material.<sup>24</sup> A working example of this demand is as follows: If Company A files a patent application in Country B on the basis of research conducted on biological resources sourced from India, it would have to disclose in its patent application filed in Country B that the material has been sourced from India, failing which it could be revoked.

This demand by India and other developing countries has led to quite a stir in the international community, with several countries like the United States that are yet to ratify the CBD and do not recognize national sovereignty of countries over biological material. The United States

<sup>&</sup>lt;sup>24</sup> J.Carr, <u>Agreements that divide: TRIPs v. CBD and proposals for mandatory disclosure of source and origin of genetic resources in patent applications</u>, J Transnational Law Policy. 18, 131(2008).

argues that patent law and its associated treaties like TRIPs should not be used to implement issues pertaining to the CBD and is unlikely to accede to such a demand.<sup>25</sup> India has already enacted amendments requiring disclosure of geographical origin of biological material in patent applications.

## Enactment of Biological Diversity Act, 2002: The Nationalization Of Biological Resources In India

In 2002, about 8 years after India became a signatory to the CBD, the Indian Parliament enacted the Biological Diversity Act, 2002 (BD Act), implementing as national law the provisions of the CBD. A key focus of this legislation as outlined in the "aims and objectives" of the legislation was to ensure the "fair and equitable sharing of the benefits arising out of the use of biological resources".<sup>26</sup>

In a manner of speaking, the legislation nationalizes India's biological resources because the legislation in effect proclaims the sovereignty of the Indian state over all biological resources located within its territory. In doing so, India has reversed the fundamental principle of how natural resources were considered to be the common heritage of all mankind, without recognition of international boundaries. The reversal appears to have been fueled by a presumption that India had more to lose than gain under a legal regime that allows for the free trade of biological resources.<sup>27</sup> This presumption, however, may not be entirely true, as India has benefited considerably through the free trade of biological resources. India's Green Revolution, in the 1960s, which ensured food security, was fueled by Norman Borlaug's hybrid variety of wheat, which was of foreign origin. Similarly, other food crops that are staples of the Indian diet, such as potato, tomato, and peas, are not of Indian origin.

<sup>27</sup> KD Prathapan & DP Rajan, <u>Biodiversity access and benefit sharing: Weaving a rope of sand</u>, 100 Curr Sci. 290,293(2011).

<sup>&</sup>lt;sup>25</sup> G.Laurie, Should there be an obligation of disclosure of origin of genetic resources in patent applications?— Learning lessons from developing countries, (March 18, 2018, 5:25 AM), http://www.law.ed.ac.uk/ahrc/scripted/vol2-2/laurie.asp.

<sup>&</sup>lt;sup>26</sup> S N Gopalakrishnan, <u>Protection of traditional knowledge: The need for a sui generis law in India</u>, 5 J World Intell Prop. 725,742 (2002).

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Subsequent to the enactment of the BD Act, foreigners now need permission from the National Biodiversity Authority (NBA) before accessing any biological resources located within India for the purpose of "research" or "commercial utilization" or "bio-survey" or "bio-utilization." On the other hand, Indians can access any biological resources located within India after a mere intimation to the State Biodiversity Board. However, the result of any research by Indians on such biological material cannot be transferred to foreigners without prior approval of the NBA.

The fact that Indians are allowed to access such biological resources without any preconditions presupposes that Indians are going to be fair and just in their dealing with their fellow Indians who may own valuable TK pertaining to biological resources. This crucial distinction in the permission required by Indians and foreigners betrays the protectionist, nationalist intent of the Indian legislation.

The legislation also prohibits any person, whether Indian or foreign, from applying for any IP rights "for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of the NBA before making such application." While granting approval for the filing of such IP rights, the NBA has been given the power to "impose benefit sharing fee or royalty or both or impose conditions including the sharing of financial benefits arising out of the commercial utilization of such rights." These conditions may be imposed regardless of whether or not there is TK associated with such biological resources.

Given the framework imposed by the BD Act, it would not be an exaggeration to say that the Indian legislation in effect "nationalizes" biological resources and knowledge related to those biological resources, including TK held by indigenous people, because it is only bureaucrats sitting in the NBA who can decide the terms and conditions of benefit sharing. There is a gratuitous provision in the legislation that requires the NBA to ensure that "equitable benefit sharing" takes place on "mutually agreed terms and conditions between the person applying for such approval, local bodies concerned and the benefit claimers." But how can benefit claimers enter into a mutually beneficial deal when it is the NBA and not the benefit claimers who have the final say on how the resources are accessed.<sup>28</sup>

<sup>&</sup>lt;sup>28</sup> <u>Prashant Reddy</u> and <u>Malathi Lakshmikumaran</u>, Protecting Traditional Knowledge Related to Biological Resources: Is Scientific Research Going to Become More Bureaucratized?, (March 20, 2018, 10:03 AM),https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4588132/

Perhaps the most troubling aspect of the BD Act is that it does not provide for any statutory guidance on the issue of "equitable benefit sharing." This is a complicated issue. Take, for example, the Kani tribe. What percentage of the royalties would be deemed fair and equitable for the Kani's TK pertaining to the *arogyapacha* plant? How could the Kani have reached a "mutually" beneficial deal when they did not have the power to walk out of a deal that was not in their interests? The fact that a country like India, which has been one of the most vocal supporters of the Nagoya Protocol and the CBD, has found it difficult to notify ABS guidelines 2 decades after signing the CBD is perhaps an indication that the CBD and Nagoya Protocol need to be revisited. Given the Indian experience so far, the international community needs to question whether the IP rights framework is the best way to protect TK.

## **5.** Conclusion

There is a widespread belief that TK (in its intangible form) can, in fact, be controlled and subjected to effective use restrictions. Information is one of the most complicated goods to control and protect, especially once it becomes shared and spreads among social structures. Traditional knowledge is mostly shared, dispersed and disseminated among communities and indigenous peoples. This is not to say that there may be very valuable TK that is still maintained and kept confidential within community structures – but, for this category of TK, other alternatives should be kept open.

As in the case of GRs, TK is almost invariably shared – to some extent or degree. This is not the exception but, rather, the rule. As a result, the complete "Protection of TK" should be understood in a broad sense (i.e. exclusive rights, control, compensation, maintenance of TK, etc.), more like a strategic goal, than as an IP-exclusive type of right. Depending on the emphasis placed on each element of protection, a specific tool or mechanism might be applied, including in the case where TK is shared.

TK was the accumulated knowledge which was the result of intellectual activity and insight in a traditional context and included the know-how, skills, innovations, practices and learning that formed part of traditional wisdom embodied in the traditional lifestyle systems. It could contain the codified knowledge systems past between communities or people or other groups of persons identifying traditional culture between generations. Such was the case with the traditional medicine system, Ayurveda, of India. Such knowledge could also remain uncodified as was

the case with folk medicine practiced by many communities. The knowledge could include any field of technology.<sup>29</sup> And for such vast empire of traditional knowledge only defensive means are not sufficient to effectively protect.

Over the last few years, countries have not been able to agree on the aim of the international instrument for protection of traditional knowledge. So far at the IGC there are three alternatives as to the purpose of the international instrument. Alternative 1 states that the instrument seeks to prevent misappropriation, misuse and unauthorised use of TK, control of use of TK beyond the traditional and customary context, fair and equitable benefit sharing, and encouragement of tradition based innovation. Alternative 2 seeks to prevent misuse/unlawful appropriation of protected traditional knowledge and encourage tradition-based creation/innovation. Alternative 3 seeks to have an instrument that contributes to protection of innovation and to the transfer and dissemination of knowledge to the mutual benefit of holders and users of protected TK in a manner conducive to the social and economic welfare and to balance the rights and obligations. It seeks to recognise the value of a vibrant public domain and to protect and preserve the public domain.<sup>30</sup>

Indian efforts to protect traditional knowledge through legislative and administrative means are good towards building a road towards the destination of protection to a vast and diverse treasure. Indian experiences for misappropriation of TK are not new but a unified law on the issue is still awaited as all the positive and defensive protections are scattered in different statutes.

<sup>&</sup>lt;sup>29</sup> WIPO Intergovernmental Committee On Intellectual Property And Genetic Resources, Traditional Knowledge And Folklore,(March 20, 2018, 7:03 AM), http://www.wipo.int/tk/en/tk/.

<sup>&</sup>lt;sup>30</sup> WHY AND HOW TO PROTECT TRADITIONAL KNOWLEDGE AT THE INTERNATIONAL LEVEL, (March 16, 2018, 11:12 AM),

http://www.wipo.int/edocs/mdocs/tk/en/wipo\_iptk\_ge\_2\_16/wipo\_iptk\_ge\_2\_16\_presentation\_11ouma.pdf.