



UTILIZING TRADITIONAL KNOWLEDGE FOR DEVELOPMENT IN SRI LANKA: A LEGAL ANALYSIS WITH A SPECIAL EMPHASIS ON INTELLECTUAL PROPERTY LAW

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ABSTRACT

Traditional Knowledge was not originally recognized as a part of the realm of intellectual property rights as its unique attributes did not align with the theoretical underpinning of intellectual property rights. Nevertheless, an emerging trend occurred with Traditional Knowledge becoming susceptible to unauthorized appropriation by third parties without sharing benefits with the knowledge holder, which was commonly referred to as biopiracy. Consequently, developing nations, along with indigenous communities, started advocating for an expansion of the scope of intellectual property law to protect and preserve Traditional Knowledge. Sri Lanka, often renowned for its cultural and biodiversity richness, is a treasure trove of Traditional Knowledge. However, the absence of an adequate legal framework addressing Traditional Knowledge, coupled with a number of failed Legislative attempts such as the Genetic Resources – Access and Benefit Sharing Act of 2000 and 2009 Bill has placed Sri Lanka in a disadvantageous position. Therefore, it is the objective of the researcher to introduce a comprehensive legal framework related to Traditional Knowledge, under IP law, considering the rights of the knowledge holders and the potential for commercialization to achieve the development of the country. This study looks at international standards and Indian laws and policies to gain insights on enhancing the Sri Lankan legal framework. Consequently, the researcher proposes several defensive and positive measures that can be implemented to strengthen the legal framework pertaining to Traditional Knowledge in Sri Lanka. The researcher finds that Sri Lanka could benefit from a sui generis law that takes into account the dual objectives of creating value from Traditional Knowledge and safeguarding the rights of knowledge holders, thereby promoting the country's development.

KEYWORDS: Bio Piracy, Biological Resources, Prior Informed Consent, Sui Generis Law, Traditional Knowledge

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1. INTRODUCTION

This study seeks to explore the challenges associated with Traditional Knowledge in Sri Lanka and analyze the potential reforms required within the current intellectual property framework for the protection and management of Traditional Knowledge, with the aim of harnessing its potential for the country's long-term development objectives while recognizing the interests of the Traditional Knowledge holders.

The advancement of technology resulted in a profound shift from the labor-intensive economic model of the industrial age to a 'knowledge-based economy,' where economic growth is highly driven by knowledge, innovation, and intellectual assets. The success and expansion of science-based technologies such as biotechnologies and advanced pharmaceutical manufacturing methods underscore the power of knowledge in driving economic growth. This massive success further highlights the significant role of the Intellectual Property Rights (IPR) regime in effectively regulating and managing knowledge. Unlike conventional IP rights such as patents, copyrights, and trademarks, Traditional Knowledge (hereinafter referred to as TK) involves a category of knowledge that is inherent to indigenous peoples and local communities and has a long history and cultural traditions. At the present era, this special type of 'knowledge' known as TK has shaped the global knowledge economy, especially through the biotechnological revolution, during which the application of recombinant DNA and DNA sequencing procedures spurred TK's commercial applicability in different areas, especially in the agricultural and pharmaceutical sectors (Dagne, 2012). Nevertheless, at first, Traditional Knowledge was largely disregarded and excluded from the realm of intellectual property, often being viewed as part of the public domain by western nations, which spearheaded the development of international norms.

Scholars often rationalize the exclusion of Traditional Knowledge from intellectual property rights by referring to the narrow utilitarian theory that IPRs are designed to induce innovation and intellectual creativity. (Dagne, 2012) suggests that the absence of

intellectual property rights (IPR) protection leads to inadequate incentives for innovators, which, in turn, diminishes the societal benefits derived from innovation. Thus, the utilitarian standpoint does not coincide with the principles of TK, as Indigenous people and local communities are dedicated to creating, preserving, and passing knowledge as an essential aspect of their survival and group cohesion rather than for any financial gain or incentive for commercialization of inventions.

Therefore, TK and its applications were originally viewed as part of the "commons," referring to resources openly accessible for the collective benefit of humanity, thus positioning them as "global commons" (Dagne, 2012). This provided the leeway for different entities to freely encroach upon and commercialize products developed using TK associated with specific indigenous or local communities in developing countries, without sharing any profits with them. Such widespread misappropriation, misuse, and exploitation of TK beyond its traditional use have resulted in the emergence of a troubling phenomenon known as biopiracy. Hence, developing countries and several indigenous communities started raising concerns emphasizing the need to expand the scope of intellectual property law beyond its narrow focus to address the wider public interest and development-related concerns. Similarly, Sri Lanka, a developing nation, is currently grappling with the challenges posed by the illegal acquisition of bio-resources and the consequential impact on its diverse TK.

Thus, the present study will assess the legal protection afforded to traditional knowledge in Sri Lanka, in light of the existing intellectual property law framework. Furthermore, recommendations will be proposed, taking into account the findings and references drawn from India and examining their intellectual property measures carried out in relation to TK to promote progress.

Accordingly, this study will commence by delineating the concepts of 'Traditional Knowledge' and 'development.' Subsequently, it will delve into international standards relevant to TK. Next, the

article will engage in a comprehensive analysis of Sri Lanka's legal framework concerning TK, followed by a review of Indian policies and laws aimed at protecting of TK. The study will culminate with an overview of its findings.

2. METHODOLOGY

This study adopts the qualitative research methodology to address the challenges pertaining to TK that has arisen in Sri Lanka, while employing a doctrinal legal study to assess the legal framework related to Traditional Knowledge within the context of intellectual property law in Sri Lanka. It seeks to identify the international standards, Indian laws, and policies pertaining to TK and provides suggestions to improve the legal framework in Sri Lanka. The findings of this study will be utilized to propose a sui generis law for TK in Sri Lanka, with the overarching aim of fostering economic growth while upholding the rights of the knowledge holders. The researcher employs primary sources such as international standards, domestic laws, and case law, while secondary sources, including books, and journal articles, are utilized to provide further insights.

Sri Lanka, a nation characterized by its rich biodiversity and vibrant cultural heritage is in critical need of an adequate legal framework, as it is continuously facing threats of misappropriation of TK by diverse entities. Thus, in its endeavor to suggest a robust legal framework that safeguards the interests of the knowledge holders while facilitating development, this study will engage in a conceptual analysis of the terms 'Traditional Knowledge' and 'Development' as follows.

3. DISCUSSION

Traditional Knowledge

Traditional Knowledge (TK) is a category of living knowledge that is deeply embedded in historical and cultural heritage and passed down through generations among indigenous peoples and local communities. It forms an integral part of the cultural or spiritual identity of the knowledge holders. Van den Daele identifies TK as "embedded knowledge," which extends beyond useful information to encompass

significant social and cultural meanings (Van den Daele, 2004).

As there is no uniform definition, TK is at times defined in a general sense to include the concept of 'Traditional Cultural Expressions' (hereinafter referred to as TCEs) such as dances, poetry, riddles, folk tales, folk songs, instrumental music, and handicrafts. In a strict meaning, TK is distinguished from TCEs and is found to take the form of know-how, customs, beliefs, rituals, practices and innovations (WIPO, 2018). These may take the form of knowledge pertaining to plant breeding techniques, preparation of medicine and food, irrigation methods, social norms, spiritual and religious beliefs, ceremonies and symbols etc. It is present in a wider range of contexts, inter alia scientific, technical, agricultural, medicinal, ecological, and biodiversity-related knowledge (WIPO, 2018).

The significance of TK is particularly emphasized in the management and conservation of biological resources. The Convention on Biological Diversity (CBD), being the first international treaty to formally recognize TK, highlights the vital role of protecting TK in order to preserve biological resources.

It is pertinent to note that the implementation of legal frameworks that protect traditional knowledge can contribute to the conservation of biodiversity, the preservation of cultural traditions, the promotion of intercultural communication, and ultimately help to achieve the development goals of a country.

Development

The term 'development' simply denotes the state of improvement in the standard of living. It can be viewed as a multidimensional concept that transcends beyond the concept of economic growth, incorporating other factors such as social progress and environmental sustainability as well. The parameters of development have often been subject to change and have been defined by scholars from numerous perspectives. Amartya Sen's capabilities approach shifts the focus from traditional economic indicators to a broader aspect of human flourishing, ultimately enhancing individuals' capabilities that drive development (Sunder, 2008). The capabilities

approach has been further elaborated upon by other scholars, such as Nussbaum, and currently serves a significant role in shaping international instruments and frameworks related to development.

Grounded in the notion of human dignity and the inherent worth of every individual, Sen's capability approach acknowledges the intersectionality of capabilities and human rights. Thus, the right to participate in cultural life, enjoyment of progress in the arts and sciences, rights of minority and indigenous people, and preservation of cultural heritage, including TK, remain integral components of rights-based development (Article 27, Universal Declaration of Human Rights, 1948).

In addition, the principle of sovereignty over natural resources is an integral part of the right to self-determination, as stated by the UN General Assembly in 1962 (United Nations General Assembly, 1962). Thus, it is of the utmost importance for developing nations to protect their sovereignty over their natural resources and wealth, including protection of Traditional Knowledge.

The protection of TK within the framework of intellectual property law is typically carried out through two main avenues: the defensive approach and the positive approach (Kumar, Das, 2010). The defensive approach aims to prevent unauthorized third parties from obtaining or maintaining intellectual property rights owned by knowledge holders. The positive approach places emphasis on the recognition of the rights inherent to indigenous peoples or local communities in relation to TK. Both of the above approaches serve to ensure the rights of the aforementioned communities are protected. Moreover, the commercialization of TK, which is facilitated by the intellectual property law framework, can lead to improved standards of living for the knowledge holders, which may ultimately benefit the economic growth of the country. In addition, this may further incentivize the preservation of TK among knowledge holders. Hence, establishing a comprehensive legal framework in intellectual property law concerning TK is crucial to facilitating long-term development goals.

International Standards

In the early 1990s, international attention was drawn to the threats posed to biodiversity and the need for the conservation of biological resources. This was further catalyzed by the voices of indigenous communities, scientists, environmentalists, and developing countries. Accordingly, steps were taken to implement CBD, the Nagoya Protocol, and various WIPO mechanisms pertaining to TK, and Genetic resources. Despite the lack of explicit provisions related to TK, and genetic resources, the Trade Related Intellectual Property Rights' (TRIPS) Agreement has recognized the importance of safeguarding TK and TCEs in the 2001 Doha Declaration, under the influence of developing countries (Kumar, Das, 2010).

CBD

The idea of the Convention on Biological Diversity (CBD) was introduced during the Rio Convention, also known as the Earth Summit, in 1992 as an instrument to address challenges posed to biodiversity (Convention on Biological Diversity, 1992). It is the first international legal instrument to explicitly address the need to protect TK as a means of preserving biological resources. CBD can be identified as the first step to shifting genetic resources and their associated TK from the realm of the 'global commons' to one where nations can exercise their sovereign rights.

The core principles of this Convention are rooted in the three main pillars of conservation of biological diversity, sustainable use of its components, and fair and equitable sharing of the benefits arising from the use of genetic resources (Article 1, Convention on Biological Diversity, 1992). It further ensures that the fair and equitable sharing of the benefits should be achieved by appropriate access to genetic resources and by appropriate transfer of relevant technologies (Article 1, Convention on Biological Diversity, 1992).

The Nagoya Protocol on Access and Benefit-Sharing

With the aim of strengthening the third pillar of the CBD, i.e, equitable sharing of benefits under the CBD, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising

from Their Utilization was put into effect in 2010. Unlike its precursor, the Bonn Guidelines, the Nagoya Protocol employs stricter language, featuring terms such as ‘enforced’ rather than ‘encouraged’ as a binding legal mechanism. It regulates better access and the fair and equitable distribution of benefits derived from the use of TK held by indigenous and local communities. In this protocol, Article 5 specifically stipulates the measures related to fair and equitable benefit-sharing that the acceding parties should follow. As per Article 7 of the Nagoya Protocol, accessing TK associated with genetic resources requires prior informed consent or approval, along with the active involvement of indigenous and local communities. This underscores the importance of reaching a mutual agreement between the parties involved. (Article 9, The Nagoya Protocol on Access and Benefit-Sharing, 2010). The provisions outlined in Article 9 require the members to actively promote and foster the participation of users and providers in the conservation and sustainable utilization of genetic resources. Article 12 requires the implementation of mechanisms to inform potential users about the obligations related to TK associated with genetic resources (Article 12, The Nagoya Protocol on Access and Benefit-Sharing, 2010). Additionally, parties are mandated to support the development of community protocols, minimum requirements for mutual agreements, and contractual clauses by indigenous and local communities, with a particular emphasis on women, to ensure equitable benefit sharing arising from the utilization of TK connected with genetic resources.

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

After CBD recognized the sovereign rights of nations over their biological diversity, the TRIPS Agreement was introduced to ensure effective and adequate protection of intellectual property rights (IPRs) for new inventions, technologies, and products developed by individual or corporate bodies. It should be noted that the provisions of the TRIPS Agreement does not provide explicit protection for the TK and innovations of indigenous and local communities within its provisions. Nevertheless, according to Dutfield, it

affords the member states the flexibility to create an unconventional intellectual property protection framework, particularly through Article 1 (Mugabe, 1999).

In relation to patentable subject matters, Article 27(3) of the TRIPS agreement excludes plants and animals other than microorganisms from patentability (Article 27(3), The Agreement on Trade-Related Aspects of Intellectual Property Rights, 1994). Accordingly, it obliges countries to recognize patents on microbiological life forms. Nonetheless, it is worth noting that the criteria set forth in the TRIPS agreement related to patentability seem to align with the patent norms observed in the industrialized member states of the WTO. Accordingly, the provision outlined above enables biotechnology companies in industrialized countries to readily secure patent rights on different microbiological life forms for the advancement of pharmaceutical and agricultural industries. This has led to pressure from India, Brazil, and African countries, raising concerns and prompting discussions within the TRIPS Council related to safeguarding TK. This led to a new commitment within the Doha Declaration of 2001, to protect TK while taking fully into account ‘the development dimension’ (Kumar, Das, 2010)

In addition to the aforementioned international instruments, several other mechanisms have been implemented to address the safeguarding of TK at the international level. For instance, the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP) is one such instrument that affirms rights of the indigenous communities to preserve, protect, and develop their cultural heritage, including TK (Article 31, United Nations Declaration on the Rights of Indigenous Peoples, 2007). The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) acknowledges the significance of farmers’ TK in the conservation of plant genetic resources and encourages fair and equitable benefit-sharing. In addition, the Intergovernmental Committee of the WIPO on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore (IGC-GRTKF) has addressed several intellectual property concerns related to TK, GR, and TCEs.

Moreover, in the year 2021, the United Nations officially declared the United Nations Decade on Ecosystem Restoration (2021-2030), recognizing the essential contribution of indigenous peoples and local communities in the effort to restore ecosystems, biodiversity, and associated TK.

Sri Lankan Context

Sri Lanka is known for its diverse ethnic cultures, traditions, values, and a rich biological diversity that includes genetic resources. Although agriculture remains the lowest contributor to Sri Lanka's GDP (7.7%), the country has historical recognition for being self-sufficient in the production of rice (Department of Census and Statistics, 2024). Not only is Sri Lanka globally recognized for its exceptional production of tea, rubber, and coconut, but it also holds the title of being the top global producer and supplier of authentic cinnamon, ranking fourth in terms of cloves production and fifth in nutmeg production (Murigi, 2020). In 2022, Sri Lanka was granted geographical indication certification from the European Union Commission for Ceylon cinnamon, after being recognized for its quality, the long tradition, and the rich history behind its production. The main traditional medical practices in Sri Lanka include Ayurveda, Siddha, Unani, and Deshiya Chikitsa (Weragoda, 1980). Both the Ayurveda and Deshiya Chikitsa practices utilize plant and herbal remedies in disease treatment, with Ayurveda employing approximately 2000 species and Deshiya Chikitsa utilizing about 500 (Weragoda, 1980). In addition, *kem* is a practice used for many purposes, such as healing rituals and agricultural practices. The farmers in Sri Lanka engage in a variety of unique traditional cultivation methods that are unique to the island. Moreover, owing to the wide range of climatic, topographic, and soil conditions present on the island, Sri Lanka is renowned for its dense and diverse array of plants, animals, fungi, and microorganisms, solidifying its reputation as a global biodiversity hotspot.

Nevertheless, throughout the years, TK in Sri Lanka has encountered a multitude of challenges. The unauthorized appropriation of biological resources and

associated TK, commonly referred to as biopiracy, presents a significant challenge in Sri Lanka. The most common plant species affected by illegal trafficking in Sri Lanka at present include Walla patta (*Gyrinops walla*), Kothala Himbutu (*Salacia reticulata*), and Handun (*Santalum album*) (Amarajeewa, 2021).

One of the early cases of biopiracy was recorded in the 1970s, during which a foreign company smuggled out Binara flower (*Excoecaria agallocha*), an endemic plant, to Sri Lanka and sought to obtain patents for the plant, albeit with trivial modifications. One of these patents covered the Maha Binara (*Eittrinerium macranthum*) flower, which is a variant of the Binara flower with drooping stems (Dawoodbhoy, 2019).

In 1985, the Japanese Patent Office approved a patent application, titled "Preventive for Dental Caries" over twelve medicinal plants (Marsoof, Kariyawasam, Talagala, 2022). These products were derived from traditional dental care products that have been in use for generations. Another incident involves a patent license secured by a scientist in New York for the extraction of a plant protein originating from Batu Karawila (*Mormodica chrantia*), which has been scientifically proven to possess therapeutic properties for the treatment of tumors and HIV infections (Marsoof, Kariyawasam, Talagala, 2022).

Notably, the exploitation of the Kothala Himbutu (*Salacia reticulata*), an endemic plant in Sri Lanka, has become a prominent example of bio-piracy, which caught public attention. A Japanese pharmaceutical company named Morganite Jintan KK and an American company called Shaman Pharmaceuticals Inc. had developed a potent glucose inhibitor named salacinol based upon this plant (Marsoof, Kariyawasam, Talagala, 2022). Nevertheless, the therapeutic efficacy of Kothala Himbutu in diabetes management was already recognized in traditional medicine. As per Dr. Gunawardena, out of the 132 patent applications over this plant, 114 are against the interests of Sri Lanka (Gunawardena, 2017).

In addition, Prof. Wijesundara specifically drew attention to instances where plant trafficking is conducted by misleading the authorities. One such case involved the export of Kekatiya (*Aponogeton*

crispus) with the false claim that they were *Aponogeton ulvaceus*, a plant species originating from Madagascar. However, it was later discovered that the plants in question were not the same species as the ones found in Madagascar. Consequently, the exportation of the Kekatiya plant was prohibited, and appropriate measures were taken (Amarajeewa, 2021).

Another incident involved the landmark case concerning the Neem plant patent, which was revoked following protests initiated by India. The company argued that their neem supply originated from Africa rather than being sourced from Asia or India. But, upon review of the registers of the Forest Department of Sri Lanka, it was later identified that the seeds claimed to have been procured from Kenya were, in fact, sourced from Sri Lanka. Accordingly, the patent was revoked (Amarajeewa, 2021). Thus, it becomes evident that there are specific cases in which biopiracy is carried out by exploiting the prevailing administrative authorities and the existing legal framework.

It is crucial to emphasize that such practices not only contribute to the diminishing of cultural identity and biodiversity but also have economic ramifications due to the potential loss of revenue and economic prospects. Parties that capitalize on TK often do not share the benefits of the inventions related to TK with the knowledge holders. Moreover, it is also worth mentioning that the Central Bank in Sri Lanka values the plant based solely on its timber worth without recognizing any intellectual property value associated with the biodiversity in the country (Amarajeewa, 2021). Hence, it is crucial for Sri Lanka to establish an effective legal framework that not only safeguards and conserves TK but also facilitates its commercialization, taking into consideration the rights of the knowledge holders.

Existing Legal Framework in Sri Lanka

Under Article 27(14) of the Constitution, Sri Lanka recognizes the state obligation to protect, preserve, and improve the environment for the benefit of the community (Article 27(14), Constitution of the Democratic Socialist Republic of Sri Lanka, 1978). Further, the reciprocal duty of every person in Sri

Lanka to protect nature and conserve its riches is highlighted under 28(f) of the Constitution (Article 28, Constitution of the Democratic Socialist Republic of Sri Lanka, 1978). Accordingly, the above two provisions provide a general recognition of the government's responsibility to safeguard the environment. Several pieces of environmental legislation have been implemented, upholding the principles embedded in the above two fundamental laws. Nonetheless, none of the above statutes directly deals with Traditional Knowledge.

Sri Lanka, being a member of the World Trade Organization (WTO), has enacted the Intellectual Property Act No.23 of 2006 in line with the TRIPS Agreement. It is pertinent to note that the IPA is the only legal instrument that provides protection for TK in Sri Lanka. Nevertheless, the scope of protection in IPA is limited to Traditional Cultural Expressions and does not afford legal protection for genetic resources or the associated TK (Hewa Geeganage, 2022).

Copyright Law

Section 5 of the IPA interprets the term “expression of folklore,” while Section 6 recognizes folklore as a protectable work under copyrights. Section 24 of the IPA delineates different forms of exclusive rights granted for folklore expressions, along with their limitations. Furthermore, this provision stipulates that the source of such TCEs must be indicated and that a prescribed fee be levied for the purpose of cultural development. As corresponding provisions for genetic resources and associated Traditional Knowledge are lacking, it poses a significant drawback in the IPA framework.

Patent Law

Patent law, Section 62(3) b excludes plants, animals, and microorganisms that are not genetically altered from patentability. Thus, it is in recognition of domestic law that plants, animals, and microorganisms which are not genetically altered are in the public domain. It should be noted that the Intellectual Property Bill originally stipulated that microorganisms are patentable, although it is not the same case for plants and animals. The Supreme Court in *re Determination of the Intellectual Property Bill*

determined that it is necessary that patentability should only be recognized within transgenic microorganisms and not of all the microorganisms (S.C. Special Determination Nos. 14, 15 16/2003). Accordingly, in order to address its unique needs, Sri Lanka has tailored the provisions of the IPA, deviating from strict adherence to the TRIPS Agreement.

Nevertheless, it is pertinent to note that the recognition of plants, animals, and microorganisms in their original form as part of the public domain may open the door for entities, which engage in biopiracy to take advantage of boundless possibilities, underscoring the necessity for restrictions. Hence, laws must be introduced mandating the requirement of consent from the knowledge holder for the usage of plants, animals, and microorganisms associated with TK for patents.

Geographic Indications

Moreover, the enactment of the Intellectual Property (Amendment) Act 2022 (Act No. 7 of 2022) aims to safeguard geographical indications upon registration. In the realm of intellectual property, it pertains to products or services that originate from a territory or a specific region or locality within that territory, where the quality, reputation, and characteristics of the goods are essentially attributed to the geographical origin. The use of Geographical Indications (GIs) can indirectly safeguard TK by preventing the misuse of goods derived from TK associated with a specific region or the false association of goods with a particular geographical area (WIPO, 2014). Moreover, when integrated with effective branding strategies, GIs have the potential to not only alleviate the decline of TK but also enhance export performance and ultimately contribute to the long-term development objectives of the country. In addition, under trademark law, the collective marks and certification marks may provide indirect protection by helping establish the authenticity and quality of the goods associated with TK and prevent misuse.

Draft Laws and National Policies

Moreover, even though Sri Lanka has ratified the CBD, there is no existing legal framework in place to specifically deal with access to genetic resources and

associated TK. In 2000, efforts were made to introduce a draft law titled, the Genetic Resources – Access and Benefit Sharing Act of 2000, which did not progress to become a part of the national law (Marsoof, Kariyawasam, Talagala, 2022). Moreover, in 2009, a draft legal framework for the Protection and Management of Traditional Knowledge was introduced by the Intellectual Property Office of Sri Lanka which was not incorporated into Sri Lankan legal framework. This proposal provided for registration of traditional knowledge and proposed the establishment of a TK registry. The proposal further recognized knowledge holders' rights and their limitations and proposed the protection for 50 years from the date of registration or death of the holder. In cases where a group of knowledge holders are involved, the term of protection lasts until the death of the last surviving knowledge holder. Moreover, the proposal provided for licensing of TK. Nevertheless, the above proposed legislative attempt was not successfully implemented. Furthermore, several weaknesses could be identified in relation to the 2009 Bill.

One of the major drawbacks appears to be the lack of involvement of the indigenous community in the decision-making process. Furthermore, the traditional knowledge fund suggested under Section 26 requires further revision to effectively benefit the knowledge holder. Accordingly, it is imperative that the control and freedom in maintaining the funds are entrusted to the knowledge holders themselves. Although, the minimum royalty and license fee can be prescribed by the Government, it is necessary that the governmental intervention remains minimal. In addition, Section 17(1) empowers DG to disclose information regarding knowledge holder and the benefits of TK to third parties subject to a prescribed fee. Nevertheless, in order to ensure the confidentiality of TK, it is necessary that such information should be disclosed subject to the prior consent of the original knowledge holder. Furthermore, Section 17(2) under the proposal provides the DG and any other state officer access to register of TK in the discharge of their duties. Nevertheless, the proposal seems to lack any accountability mechanism to ensure lawful access of

TK by State Officers. The draft law further requires clarity in relation to the procedure of obtaining prior informed consent, especially when multiple knowledge holders exist. In addition, the draft law does not seem to have strong protection against misappropriation by foreign entities. Accordingly, it is imperative that these deficiencies be rectified in any future legislative endeavors.

In 2020, National Policy and Strategies on Traditional Knowledge and Practices Related to Biodiversity was introduced. This included proposals for amendments to be made to intellectual property laws to combat the unauthorized use of TK and bad faith practices in knowledge sharing. Nevertheless, no significant progress has been made in implementing these proposals (National Policy and Strategies on Traditional Knowledge and Practices related to Biodiversity, 2020). Furthermore, in the same year, a National Policy on Access to Biological Material and Benefit Sharing was introduced to provide a mechanism related to access of biological resources and associated TK and to encourage fair and equitable sharing of benefits derived from biological resources and associated TK, with due consideration for intellectual property rights issues (National Policy on Access to Biological Material and Benefit Sharing, 2020).

The aforementioned legal policies do not possess the power to compel adherence. Hence, the absence of binding legal statutes concerning biological resources, and the associated Traditional Knowledge can be identified as a notable deficiency within the legal system.

Indian Legal Framework and Other Initiatives

India is a country with a rich diversity of species and is considered one of the countries with the largest megadiversity in the world. India has been at the forefront of the global movement to introduce international instruments related to TK. It should be noted that India has followed a defensive approach, seeking to guard against unauthorized intellectual property rights obtained by third parties over Traditional Knowledge, rather than pursuing a positive approach (Kumar, Das, 2010).

Patent Law:

India has not recognized the patentability of TK within the Patents Act, 1970. Especially Section 3(p) of the Patents Act 1970 excludes any TK or an aggregation or duplication of known properties of traditionally known component(s) (Section 3(p), Patents Act, 1970). Nevertheless, under Section 10(4)(D)(ii) of the Patents Act 1970, lawmakers have ensured that patent applicants disclose the sources of TK and the origin of the invention in question in case TK is involved (Section 10(4)(D)(ii), Patents Act, 1970).

Moreover, the Patents (Amendment) Act, 2005, was later enacted with the special aim of protecting and preserving the rights of indigenous communities. These amendments were introduced alongside the Prior Informed Consent (PIC) and benefit-sharing requirements of the Biological Diversity Act, 2002, to effectively address the challenges posed by biopiracy at a domestic level (Jose, 2021). The 2005 amendments have outlined several bases for refusing a patent application or canceling a patent. These bases include failure to disclose or misrepresentation of the geographical origin of biological resources associated with the patent and anticipation of the patent having regard to the knowledge of the indigenous community (Jose, 2021).

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

As mentioned earlier, GIs can be utilized for obtaining indirect protection over TKs. The Indian Geographical Indications of Goods (Registration and Protection) Act provides legal protection over TK, which is associated with particular geographic areas and prevents misuse of GIs related to specific goods involving TKs. Further, it prevents the false attribution of traditional practices followed during the manufacturing of goods belonging to a certain area.

The Biological Diversity Act 2002 (BDA)

India has introduced the BDA to addresses access to genetic resources and associated knowledge by foreign individuals, companies, or institutions, and to ensure equitable sharing of benefits from the use of these knowledge and resources by the country and the

people. It necessitates the permission of an authority named the National Biodiversity Authority, whenever a person has applied for a patent involving biological resources and/or associated TK (Section, 19, Section 21, The Biological Diversity Act, 2002).

Moreover, another key highlight would be the Traditional Knowledge Digital Library (TKDL), initiated by the Indian government, which contains a digital database of Traditional Knowledge associated with medicinal and other plants. The database is classified according to the Traditional Knowledge Resources Classification (TKRC) system, which is linked to the International Patent Classification (IPC) system, which helps prevent the approval of patents that are already in the public domain (WIPO, 2011). Moreover, village-wise Community Biodiversity Registers (CBRs) are established in all states for documenting all knowledge, innovations, and practices (Kumar, Das, 2010).

Moreover, India has taken several measures to ensure access by users with prior consent and just and equitable benefit sharing among the users and the knowledge holder, parallel to Article 8(j) of the CBD. Accordingly, India has introduced a model of benefit sharing, referred to as the TBGRI Model or Pushpangadan Model, that was first applied to a patent of herbal formulation named 'Jeevani' obtained with a mutual agreement with the Kani Tribe in India. Pursuant to the model, the Kani tribe was granted a 50% share of the royalty and license fee. The majority of the Kani tribe agreed to establish a trust, which was fully owned and managed by the tribe themselves.

4. RECOMMENDATIONS:

When assessing the required legal reforms to safeguard TK in Sri Lanka, it is crucial to focus on two elements of protection: defensive protection and positive protection. Defensive protection involves the prevention of the unauthorized acquisition or maintenance of IP rights by third parties outside the community of knowledge holders.

Hence, in order to adopt a defensive stance, it is essential to make several amendments to the existing patent law in Sri Lanka. Similar to the Indian Patent

Law, Sri Lanka should introduce amendments to the existing provisions of patent Chapter in the IPA to require disclosure of the geographical origin and the community from whom the knowledge was obtained. Furthermore, grounds for cancellation or revocation of the patent should include the non-disclosure of origin or misrepresentation of origin of the biological resources relevant to the Patent. The Director General of the Intellectual Property Office should be granted explicit authority to revoke or cancel a patent in such instances.

There are several laws in Sri Lanka that impose criminal liability on parties engaged in biopiracy. However, it is suggested that the willful non-disclosure of the source and geographical origin of biological resources used in the invention or misrepresentation should be recognized as intellectual property-related offenses under Chapter XXXVIII of the IPA (Intellectual Property Act, No. 36 of 2003).

Furthermore, measures need to be taken to establish a searchable database of traditional medicine in Sri Lanka, akin to India, that is interconnected with international patent search databases. This will gather evidence of prior art in Sri Lanka and effectively prevent the approval of patent applications that involve bioresources and associated TK belonging to Sri Lanka on an international level. Moreover, it should strike a balance, where they serve as evidence of prior art globally while also maintaining the confidentiality of the knowledge belonging to indigenous populations and other communities.

The positive approach entails recognizing the intellectual property rights of knowledge holders and enabling them to acquire, assert, and use TK and TCEs, as well as to control their uses and to benefit from commercial exploitation. Some jurisdictions have introduced sui generis law specifically recognizing the intellectual property rights of the indigenous people and the local community, while other jurisdictions try to utilize the existing IP legal framework to protect TK and TCEs.

Moreover, the strategies delineated in the National Policy and Strategies on Traditional Knowledge and Practices Related to Biodiversity 2020 included

acknowledgement of the intellectual property rights of Traditional Knowledge holders. Hence, it is suggested that Sri Lanka implement a sui generis law that specifically aims at recognizing the rights related to biological resources and associated TK in conjunction with the existing IPA.

Accordingly, sui generis law should be introduced, which grants rights to knowledge holders upon registration. Moreover, the registry must ensure that the intricate details of TK remain confidential, even when conducting searches for prior art. The legal framework must clearly outline the subject matter eligible for protection, the duration of protection, and the criteria for eligibility for protection. Furthermore, the nature of the rights granted to the knowledge holder and the limitations on the said rights should also be provided. To ensure the fair resolution of any conflicts that may arise between the users and knowledge holders, and knowledge holders themselves, it is crucial to establish a separate dispute resolution mechanism. Alternatively, the Director General of the NIPO can be empowered with the appropriate authority to determine such matters. Moreover, stronger provisions should be introduced to protect the traditional knowledge from being misappropriated by foreign entities.

In addition, provisions related to the commercialization of TK should be included in the sui generis law. In relation to commercialization of TK, it is imperative to give due consideration to two aspects as per the CBD, especially concerning access: obtaining prior informed consent for the access of bioresources and TK and ensuring a just and equitable sharing of benefits between the knowledge holder and the user (Article 15(4), Article 15(5), Convention on Biological Diversity, 1992).

Moreover, at present, the National Policy on Access to Biological Material and Fair and Equitable Benefit Sharing (NPABM&FEBS) ensures that the material transfer agreement (MTA) is entered into with prior informed consent (PIC) for access and with mutually agreed terms (MAT) (Clause 6(iii), National Policy on Access to Biological Material and Fair and Equitable Benefit Sharing, 2020). In accordance with the above

policy, the recognition of knowledge holders' rights is ensured through contractual terms. Nevertheless, it is necessary to recognize the rights of the knowledge holders, going beyond contractual provisions, with the capacity to impose civil as well as criminal liability in instances of willful infringement.

It is pertinent to note that the draft laws titled, Genetic Resources – Access and Benefit Sharing Act 2000 and the Legal Framework for the Protection of Traditional Knowledge in Sri Lanka 2009 have included some of the above recommendations regarding defensive and positive protection within their proposal. However, these draft legislations failed to materialize and have been subject to numerous criticisms. Hence, provisions of the previous draft laws could be integrated into the sui generis law, provided that they are revised as per the contemporary needs of the country.

5. CONCLUSION

With its abundant cultural and biological diversity, Sri Lanka stands as a country of immense TK. Nevertheless, TK in Sri Lanka remains vulnerable due to the absence of a legal framework that directly addresses the challenges concerning TK. While the Intellectual Property Act (IPA) partially safeguards Traditional Cultural Expressions, it does not afford protection for genetic resources and the associated TK. It is pertinent to note that Sri Lanka has witnessed multiple failed initiatives to regulate biological resources and TK. Moreover, the national policies enacted have not provided a satisfactory resolution either. Hence, it is imperative for Sri Lanka to implement a comprehensive legal framework that maximizes the economic potential of TK, while also upholding the rights of its holders. In light of the foregoing, the researcher concludes that Sri Lanka, in its pursuit of rights-based development, should introduce a sui generis law that encompasses both the recognition of rights and provisions related to commercialization.

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