

## ***SUI GENERIS* APPROACH TO INTELLECTUAL PROPERTY PROTECTION OF TRADITIONAL MEDICINE KNOWLEDGE (TMK) FOR MSMEs IN MYANMAR**

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### **Abstract**

Traditional medicinal knowledge carries substantial economic and cultural importance. Its economic and cultural value is considerable. Exploitation of medicinal plants and associated knowledge has occurred without sufficient compensation, with instances where researchers or companies have laid claim to it as intellectual property. Consequently, safeguarding traditional knowledge systems appears imperative. Since the existing system of intellectual property protection safeguards such knowledge, nations globally, especially those in the developing phase, should address these perceived inadequacies in existing laws by formulating or implementing additional legislation. Internationally, numerous treaties address traditional medicine, including the Convention on Biological Diversity (CBD) (1992) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (1994). Therefore, various components of a national *sui generis* system, including a law aimed at protecting traditional medicinal knowledge, could be incorporated into national legislation.

**Keywords** - IP, TMK, MSME, TRIPS Agreement

### **Introduction**

Myanmar's traditional medicine knowledge is deeply rooted in its rich cultural and historical heritage. Preserving and improving this knowledge is essential for maintaining cultural identity and promoting a sense of pride and connection within the community. Traditional medicine knowledge often forms the basis for unique products and services. Improving and leveraging this knowledge can unlock economic potential by enabling Micro Small and Medium Enterprises (MSMEs) to develop distinct offerings that cater to both local and global markets.

MSMEs rooted in traditional Medicine knowledge can become sources of employment and income for local communities. By improving and modernizing these enterprises, there is an opportunity to empower local communities economically and enhance their overall well-being.

The research will contribute to the national implementation of the Intellectual Property system, aiming to achieve the highest attainable standard of healthcare for the people by striking a balance between individual patentee rights and public interests. Additionally, it offers valuable insights for national enterprises in MSMEs.

The aim and objective of this paper are to protect the safeguarding of Traditional Medicine Knowledge (TMK) in Myanmar's MSMEs. This includes a comprehensive exploration of legal and policy measures applicable to TMK protection within MSMEs and the development of *sui generis* laws in Myanmar. The possible methods are Patent, Copyright, Industrial Design, and Intellectual Property Rights. Among them, the *sui generis* system would be the most effective for traditional medicine as it could be designed to cover the specific needs of a particular country.

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## Materials & Methods

The paper employs qualitative and analytical legal research methods. The primary data is sourced from international conventions and national legislation, while the secondary data is derived from literary books, articles, online resources, news, cases, and events.

## Findings

Since health is an inherent human right of every individual, knowledge of Traditional Medicine Knowledge should be accessible to everyone. Therefore, training should be provided and distributed. There is no effective, specific law in Myanmar to protect traditional medicine knowledge or apply for a business license. However, even related laws National Drug Law, Small and Medium Enterprises Development Law, the Traditional Medical Council Law, the Patent Law, and the Promotion of Cottage Industries Law, such as in Myanmar have proven inadequate to safeguard their effectiveness. Additionally, Traditional Medicine Knowledge should be fully protected under Intellectual Property Law. Therefore, *sui generis* legislation must be enacted in Myanmar for Traditional Medicine Knowledge.

## Discussion

### Intellectual Property Rights and Traditional Medicine Knowledge

The term “Intellectual Property” (IP) is reserved for types of property that result from creations of the human mind. Intellectual property rights are exclusive rights given to the results generated by the intellectual activities of human beings and they mean intangible rights that which have economic values.<sup>1</sup> Intellectual property rights (IPRs) refer to the legal rights granted to protect one's intellectual creations. This term encompasses copyright, patents, industrial designs, trademarks, and various other forms of intellectual property rights.<sup>2</sup> Ownership refers to the legal right of an individual, group, corporation or government to the possession of a thing. The subject of ownership is made up of two types material and immaterial things. Material ownership is that which is tangible like property, land, a car, a book, etc. Immaterial ownership is that which is intangible like patent, copyright, trademark, etc.<sup>3</sup>

IP is usually divided into two branches, namely industrial property and copyright. industrial property includes patents for inventions, industrial designs (aesthetic creations related to the appearance of industrial products), trademarks, service marks, layout-designs of integrated circuits, commercial names and designations, geographical indications and protection against unfair competition.<sup>4</sup> Copyright relates to literary and artistic creations, such as books, music, paintings and sculptures, films and technology-based works (such as computer programs and electronic databases).<sup>5</sup> These two categories of Intellectual Property tend to give the owner of the property exclusive rights to an invention which has to be novel, involve an inventive step and have industrial applicability.<sup>6</sup>

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<sup>1</sup> Dr Nu Nu Yi, Protection of Traditional Medicine Knowledges in Myanmar Naing Ngan, Jour. Myan. Acad. Arts & Sc.2007 Vol.V.No.7.

<sup>2</sup> Section 2 (i) of the Patent Law 2019, (The Pyidaungsu Hluttaw Law No. 7, 2019).

<sup>3</sup> <https://www.toppr.com/guides/legal-aptitude/jurisprudence/kinds-of-ownership/>, Jurisprudence Kinds of Ownership.

<sup>4</sup> WIPO, Understanding Industrial Property, 2<sup>nd</sup> edition, P.O. Box 18 CH-1211 Geneva 20, Switzerland, 2016, p-6.

<sup>5</sup> Ibid.

<sup>6</sup> Dr. Nu Nu Yi, Study on Protection of Traditional Knowledge.

The importance of protecting IP was first recognized in the Paris Convention for the Protection of Industrial Property (1883) (Paris Convention) and the Berne Convention for the Protection of Literary and Artistic Works (1886) (Berne Convention). Both treaties are administered by the World Intellectual Property Organization (WIPO).<sup>1</sup>In Myanmar, Section 37(c) of the Constitution of the Republic of the Union of Myanmar (2008) states that "The Union shall permit citizens' rights of private property, right of inheritance, right of private initiative and patent in accord with the law."<sup>2</sup>And also The Union guarantees the right to ownership, the use of property and the right to private invention and patent in the conducting of business if it is not contrary to the provisions of this Constitution and the existing laws.<sup>3</sup>

Article 1(3) of the Paris Convention provides that industrial property shall be understood in the broadest sense and shall apply not only to industry and commerce proper but likewise to agricultural and extractive industries and to all manufactured or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour.<sup>4</sup> According to one definition knowledge is "Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices".<sup>5</sup>

Traditional knowledge (TK) is accumulated knowledge and understanding of the human place in relation to the universe.<sup>6</sup>It includes a variety of data, such as insights into the utilization of biological and other substances in areas such as agriculture, manufacturing processes, design, literature, music, rituals, artistic techniques, and medical treatment (traditional medicine), among others. Traditional knowledge can also refer to the knowledge passed from generation to generation of their traditional or cultural heritage in indigenous communities. Therefore, Traditional knowledge refers to knowledge or practice for which Indigenous communities act as guardians or custodians. The type of knowledge considered within this scope includes information about the medicinal properties or effects of flora and fauna, as well as hunting or fishing techniques.<sup>7</sup>

Traditional knowledge (TK) systems exist in fields such as medicine, food and agriculture, environmental management and biodiversity conservation, nutrition, and cultural objects to name a few. Some traditional knowledge systems are codified, others are not. Not all traditional knowledge is produced collectively and/or is inter-generational. Accordingly, a broad definition of traditional knowledge may not be limited to codified or systematic forms, or

<sup>1</sup> WIPO, Understanding Industrial Property, 2<sup>nd</sup> edition, P.O. Box 18 CH-1211 Geneva 20, Switzerland, 2016, p-5.

<sup>2</sup> Section 37(c) of the Constitution of the Republic of the Union of Myanmar (2008), The State Peace and Development Council, No. 7/2008.

<sup>3</sup> Section 372, Ibid.

<sup>4</sup> Article 1(3) of the Paris Convention for the Protection of Industrial Property, 1883.

<sup>5</sup> Secretariat of the Convention on Biological Diversity, 1996 Knowledge, Innovations and Practices of indigenous and Local Communities: Implementation of Article 8(j). Document UNEP/CBD/COP/3/19, pp-8-9.

<sup>6</sup> WIPO, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, May 20, 2002, Geneva, Publication WIPO/GRTKF/IC/3/9, p. Annex III (8).

<sup>7</sup> <https://www.business.qld.gov.au/running-business/risk/ip/ip-kit/browse-ip-topics/traditional-knowledge/definitions>, Queensland Government, What is meant by the terms traditional knowledge and Indigenous cultural expression?, Last reviewed: 26 Sep 2020.

knowledge may have originated in a collective way. Even to an external observer, a knowledge system may not be apparent or when a system is not documented, there may well be a traditional system in use by the community concerned. In any event, TK holders may be unwilling to accept that traditional knowledge need to conform to a recognised or documented knowledge system to be potentially eligible for legal protection.<sup>1</sup>

Traditional Cultural Expressions refer to various expressions or combinations, whether tangible or intangible, in which traditional culture and knowledge are conveyed, presented, and demonstrated:

- (i) verbal expressions such as stories, epics, legends, poetry, riddles and other narratives, words, signs, names, and symbols;
- (ii) musical expressions such as songs and instrumental music;
- (iii) expressions by action such as dances, plays, ceremonies, rituals; and,
- (iv) tangible expressions (special creations and productions of art), such as drawings, designs, paintings including body-painting, carvings, sculptures, pottery, ceramic, terracotta, mosaic, woodwork, metal ware, jewellery, lithographic work, weaving work, needlework, attires, glassware, carpets, costumes, handicrafts, musical instruments, and architectural forms, folk heritage written records such as palm-leaf manuscripts, folding manuscripts (parabeik), stone inscriptions, votive tablet scripts, bell-inscriptions, ink writings and mural paintings.<sup>2</sup>

The World Intellectual Property Organization (WIPO) currently uses the term traditional knowledge to refer to tradition-based literary, artistic or scientific works; performances; inventions; scientific discoveries; designs; marks, names and symbols; undisclosed information; and all other tradition-based innovations and creations resulting from intellectual activity in the industrial, scientific, literary or artistic fields.<sup>3</sup>

Another area of uncertainty is the relationship between “traditional knowledge” and “indigenous knowledge.” “Indigenous knowledge” (IK) is either used to describe knowledge held and used by communities, peoples and nations that are indigenous, or to denote knowledge that is itself indigenous, in the sense of specifically originating in a certain region or country: ‘indigenous’ means belonging to, or specific to, a particular place. Whichever sense of ‘indigenous knowledge’(IK) is used, however, the general usage seems to suggest that all indigenous knowledge is traditional knowledge, although it is likely that some traditional knowledge may not have the specific characteristic of being “indigenous”.<sup>4</sup> Indigenous knowledge is one aspect of traditional knowledge.<sup>5</sup>

Traditional Medicine (TM), a manifestation of historical wisdom, has been a longstanding remedy for treating ailments. Since the emergence of humans on Earth, they have consistently turned to their native forms of medicine for healing and wellness. Traditional medicine, as defined by the World Health Organization, is the sum total of the knowledge, skills, and practices

<sup>1</sup> WIPO, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, May 20, 2002, Geneva, Publication WIPO/GRTKF/IC/3/9, Pg.13.

<sup>2</sup> Section 2(z) (bb) of the Copyright Law, (The Pyidaungsu Hluttaw Law No.15, 2019).

WIPO, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, May 20, 2002, Geneva, Publication WIPO/GRTKF/IC/3/9, Pg.11.

<sup>4</sup> Ibid, Pg.10.

<sup>5</sup> Shahid Alikhan, Benefits of Intellectual Property Protection in Developing Countries, WIPO, 2001, p- 84.

based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement, or treatment of physical and mental illness.<sup>1</sup> Traditional medicine is widely and increasingly being used in both developing and developed countries.<sup>2</sup>

### Types of Traditional Medicine Knowledge

Traditional Medicine refers to remedies designed for the physical well-being and longevity of individuals, aligning with any of the four perspectives of traditional medicine, namely Desana naya, Bethistsa naya, Netkhata veda naya, and Vissadara naya.<sup>3</sup> Traditional medicine is sometimes seen as pre-scientific, its practices and treatments are to be replaced by modern, better, more efficient science-based medicine.<sup>4</sup> According to the WHO Global Report on Traditional and Complementary Medicine (2019), various systems of traditional medicine being used around the world include acupuncture, herbal medicines, indigenous traditional medicine, homeopathy, traditional Chinese medicine, naturopathy, chiropractic, osteopathy, ayurvedic and Unani medicine.<sup>5</sup>

Based on the therapies, traditional medicine can be categorized into medication and non-medication. Traditional medication involves the use of herbal medicines, animal parts and minerals. Traditional non-medication involves various techniques, primarily without the use of medication. They include, for example, acupuncture and related techniques, chiropractic, osteopathy, manual therapies, qigong, tai ji, yoga, and other physical, mental, spiritual and mind-body therapies.<sup>6</sup>

Around 40% of pharmaceutical products today draw from nature and traditional knowledge, including landmark drugs like aspirin, artemisinin, and childhood cancer treatments. A closer look at these drugs reveals that the scientists behind them built off traditional knowledge to achieve their breakthrough discoveries.<sup>7</sup> The following are the forms of TK to identify some of the IP implications;

- unfixed TK and fixed TK, to which are related: (a) documented TK and non-documented TK and (b) codified TK and non-codified TK;

<sup>1</sup> <https://www.sciencedirect.com/science/article/abs/pii/B9780128021040000020>, C.-T.Che, Fundamentals, Applications and Strategies 2017, Academic Press, Pg-15-30.

<sup>2</sup> WHO, EM/RC49/13, Agenda item 12, The WHO Strategy for Traditional Medicine: Review of the Global Situation and Strategy Implementation in the Eastern Mediterranean Region, August 2002.

<sup>3</sup> Section 2 (a) of the Traditional Medical Council Law 2000, (The State Peace and Development Council Law No. 2/2000).

<sup>4</sup> <https://www.who.int/news-room/feature-stories/detail/traditional-medicine-has-a-long-history-of-contributing-to-conventional-medicine-and-continues-to-hold-promise>, WHO, Traditional medicine has a long history of contributing to conventional medicine and continues to hold promise, 10 August 2023.

<sup>5</sup> <https://www.who.int/news-room/feature-stories/detail/traditional-medicine-has-a-long-history-of-contributing-to-conventional-medicine-and-continues-to-hold-promise>, WHO, Traditional medicine has a long history of contributing to conventional medicine and continues to hold promise, 10 August 2023.

<sup>6</sup> WHO, EM/RC49/13, Agenda item 12, The WHO Strategy for Traditional Medicine: Review of the Global Situation and Strategy Implementation in the Eastern Mediterranean Region, August 2002.

<sup>7</sup> <https://www.who.int/news-room/feature-stories/detail/traditional-medicine-has-a-long-history-of-contributing-to-conventional-medicine-and-continues-to-hold-promise>, WHO, Traditional medicine has a long history of contributing to conventional medicine and continues to hold promise, 10 August 2023.

- disclosed TK and non-disclosed TK, to which are related: (a) TK directly controlled by indigenous and local communities and TK on longer in the control of indigenous and local communities and (b) TK held by indigenous and local communities;
- sacred TK and secular TK;
- TK “as such” and TK-based innovations and creations;
- indigenous knowledge and traditional knowledge;
- individual TK and collective TK; and,
- commercialized TK and non-commercialized TK.<sup>1</sup>

Traditional knowledge (TK) can be either codified or non-codified. Codified TK is that which is in some systematic and structured form, in which the knowledge is ordered, organized, classified and categorized in some manner. Codified TK may be imbued with some “authority” or legitimacy.<sup>2</sup>

The Traditional Medicine Team of the World Health Organization (WHO) distinguishes between codified systems of traditional medicine and non-codified traditional medicinal knowledge. Codified systems have been documented in ancient scriptures and are fully in the public domain, while non-codified knowledge, often undisclosed by traditional knowledge holders, is passed on through oral traditions from generation to generation.<sup>3</sup>

### **Rationale for Protection of Traditional Medicine Knowledge**

The rationale for TMK protection is (i) equity, (ii) preservation, (iii) preventing misappropriation, (iv) promoting self-determination, (v) promoting use and development (vi) avoiding bio-piracy. However, as a major portion of traditional medicine is based on medicinal plants and herbs, the prevention of bio-piracy is also a very important goal for the protection of traditional medicine under intellectual property rights. IN this case involving bio-piracy which have attracted international attention are the so-called “Turmeric and “Neem” Cases.<sup>4</sup>

Turmeric is a tropical herb grown in east India. Turmeric powder is widely used in India as a medicine, a food ingredient and a dye to name a few of its uses. For instance, it is used as a blood purifier, in treating the common cold, and as an anti-parasitic for many skin infections. It is also used as an essential ingredient in cooking many Indian dishes. In 1995, the United States awarded patent on turmeric to University of Mississippi medical center for wound healing property. The claimed subject matter was the use of "turmeric powder and its administration", both oral as well as topical, for wound healing. An exclusive right has been granted to sell and distribute.<sup>5</sup>

<sup>1</sup> WIPO/ GRTKF/IC/17/INF/9, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, November 5, 2010.

<sup>2</sup> WIPO/ GRTKF/IC/17/INF/9, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, November 5, 2010.

<sup>3</sup> WIPO/ GRTKF/IC/17/INF/9, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, November 5, 2010.

<sup>4</sup> Dr Nu Nu Yi, Protection of Traditional Medicine Knowledges in Myanmar Naing Ngan, Jour. Myan. Acad. Arts & Sc. 2007 Vol. V.No.7.

<sup>5</sup> <https://www.mondaq.com/india/patent/586384/traditional-knowledge-and-patent-issues-an-overview-of-turmeric-basmati-neem-cases>, Saipriya Balasubramanian, India: Traditional Knowledge And Patent Issues: An Overview Of Turmeric, Basmati, Neem Cases, 18 April 2017.

The Indian Council for Scientific and Industrial Research (CSIR) had objected to the patent granted and provided documented evidences of the prior art to USPTO. Though it was a well-known fact that the use of turmeric was known in every household since ages in India, it was a herculean task to find published information on the use of turmeric powder through oral as well as topical route for wound healing. Due to extensive researches, 32 references were located in different languages namely Sanskrit, Urdu and Hindi. Therefore, the USPTO revoked the patent, stating that the claims made in the patent were obvious and anticipated, and agreeing that the use of turmeric was an old art of healing wounds. Therefore, the TK that belonged to India was safeguarded in Turmeric case.<sup>1</sup>

The neem tree (*Azadirachta indica*) originates from the Indian subcontinent and now grows in the dry regions of more than 50 tropical countries around the world. The neem tree has multiple uses. It is mentioned in Indian texts written over 2000 years ago and has been used for centuries by local communities in agriculture as an insect and pest repellent, in human and veterinary medicine, toiletries and cosmetics. It is also venerated in the culture, religions and literature of the region. The neem tree, is known in Sanskrit as “*sarva-roga nivarini*”. It is also seen as a prominent resource in the country.<sup>2</sup>

The patent for Neem was first filed by W.R. Grace and the Department of Agriculture, USA in European Patent Office. The said patent was deemed to be a method of controlling fungi on plants comprising of contacting the fungi with a Neem oil formulation. A legal opposition was filed by India against the grant of the patent. The legal opposition to this patent was lodged by the New Delhi-based Research Foundation for Science, Technology and Ecology (RFSTE), in cooperation with the International Federation of Organic Agriculture Movements (IFOAM) and Magda Aelvoet, former green Member of the European Parliament (MEP).<sup>3</sup>

Since the grant of the patent, Dr. Shiva, one of the activists in India, along with the International Federation of Organic Agriculture Movement and the Green Party in European Parliament, had been opposing it. Later, in 2000, the European Patent Office revoked the patent but the victory was short-lived as the revocation was followed by an appeal. The European Patent Office in Munich in 2005 dismissed an appeal against revoking a patent granted by it for the preparation of a fungicide derived from the seeds of the neem tree. Because it was neither a novel idea nor was it invented. It is the major victory that the appeal has been dismissed.<sup>4</sup>

### Concept on Ownership and Knowledge

There are three concepts of ownership of knowledge. One concept is that all the knowledge existing in the world is in the public domain. Another concept is that knowledge exists in the private domain and is protected by customary law and intellectual property rights laws. A third concept holds that there are three domains of knowledge: individual, community and public. It may, hence, be (“individual knowledge”), (“distributed knowledge”) or (“common knowledge”).<sup>5</sup>

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<sup>1</sup> Ibid.

<sup>2</sup> <https://www.mondaq.com/india/patent/1286020/the-neem-patent-case>, Tarun Khurana, India: The Neem Patent Case, 23 February 2023.

<sup>3</sup> <https://www.mondaq.com/india/patent/1286020/the-neem-patent-case>, Tarun Khurana, India: The Neem Patent Case, 23 February 2023.

<sup>4</sup> Ibid.

<sup>5</sup> Dr Nu Nu Yi, Protection of Traditional Medicine Knowledges in Myanmar Naing Ngan, Jour. Myan. Acad. Arts & Sc. 2007 Vol. V.No.7.

In view of the high prices generally charged for patented medicines, traditional medicine is of vital importance in the developing world. The WHO whose Traditional Medicine Strategy incorporates four objectives, policy, safety, efficacy and quality, access and national use, encourages and supports member states to integrate traditional and alternative medicine into the national health care system and to ensure their national use.<sup>1</sup>

Demands for traditional medicine from the public and the growing economic importance of traditional medicine have led to increased interest on the part of both governments and academic communities worldwide in protecting not only traditional medicines themselves but also the knowledge, i.e., the intellectual property on which they are based.<sup>2</sup>

### **Traditional Medicine Knowledge and Main International Conventions**

Traditional medicines have been used in many countries throughout the world for many centuries. Today, these medicines still represent an important part of healthcare in some countries. For example, more than 100 countries have regulations for herbal medicines, but the practices of traditional medicine vary greatly from country to country and from region to region, as they are influenced by factors such as culture, history, personal attitudes, and philosophy. While customization of legislation and implementation to align with the unique needs and traditions of individual countries is frequently essential, several universal themes and concerns persist. These include the crucial emphasis on practitioner training, the challenges associated with ensuring safety, the imperative to advance research in both product development and practices, and the significance of clear and informative labeling.<sup>3</sup> In the United States of America, 66% of women had confidence in the safety of herbal medicines and 37% of women believed that herbal medicine was effective. Even 57% of doctors believed herbal medicines had good benefits.<sup>4</sup>

Article 8(2) of the “Protection of Traditional Knowledge states that “[i]n particular national authorities may exclude from the principle of prior informed consent the fair use of traditional knowledge that is already readily available to the general public, provided that users of that traditional knowledge provide equitable compensation for industrial and commercial uses of that traditional knowledge”.<sup>5</sup>

The Government of Myanmar recognizes health as an inherent right for all its citizens and, more broadly, for all individuals.<sup>6</sup> Two primary international agreements pertain to the legal protection of traditional knowledge, and Myanmar is a party to both. They are the Convention on Biological Diversity (CBD) (1992), and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (1994).

Biodiversity comes from two words Bio meaning life and diversity meaning variability. Biodiversity is the variety of all living things; the different plants, animals, fungi, and

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<sup>1</sup> Ibid.

<sup>2</sup> Ibid.

<sup>3</sup> <https://www.sciencedirect.com/topics/medicine-and-dentistry/traditional-medicine>, Pierre-Louis Lezotre MS, International Cooperation, Convergence and Harmonization of Pharmaceutical Regulations, 2014.

<sup>4</sup> WHO, EM/RC49/13, Agenda item 12, The WHO Strategy for Traditional Medicine: Review of the Global Situation and Strategy Implementation in the Eastern Mediterranean Region, August 2002.

<sup>5</sup> WIPO/GRTKF/IC/17/5, Article 8 (2) of the “Protection of Traditional Knowledge: Revised Objectives and Principles”.

<sup>6</sup> <https://www.fao.org/3/ad813e/ad813e.pdf>, Dr. Yin Yin Htwe, FDA Myanmar Department of Health.



microorganisms, the genetic information they contain and the ecosystems they form. Biodiversity is usually explored at three levels: genetic diversity, species diversity and ecosystem diversity. These three levels work together to create the complexity of life on Earth.<sup>1</sup>

Genetic diversity is the variety of genes within a species. Each species is made up of individuals that have their own particular genetic composition. This means a species may have different populations, each with different genetic compositions.<sup>2</sup> Species diversity is the variety of species within a habitat or a region. Some habitats, such as rainforests and coral reefs, have many species. Others, such as salt flats or a polluted stream, have fewer.<sup>3</sup> Ecosystem diversity is the variety of ecosystems in a given place. An ecosystem is a community of organisms and their physical environment interacting together. An ecosystem can cover a large area, such as a whole forest, or a small area, such as a pond.<sup>4</sup> The Convention on Biological Diversity has created a new environment for the protection of biodiversity and indigenous knowledge and for benefit sharing, because it differs substantially from other treaties in that it takes a comprehensive, rather than a sectoral approach to the conservation and sustainable use of biological resources.<sup>5</sup>

Article 3 of the Convention on Biological Diversity recognizes that “states have the sovereign right over their biological and genetic resources”.<sup>6</sup> Article 8 (j) of the Convention on Biological Diversity confirms that “subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices”.<sup>7</sup> Article 10 (c) of the Convention on Biological Diversity recommends protecting and encouraging customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements.<sup>8</sup> The Convention on Biological Diversity advocates for the fair and equitable sharing, under mutually agreed upon terms, of benefits derived from the utilization of genetic resources and associated knowledge.

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of 1994 does not impose uniform legal requirements on WTO member countries. Countries must meet the minimum standards it calls for, but are left with considerable leeway within which to develop their own laws according to the characteristics of their legal systems, public health situations and development needs.<sup>9</sup> Article 1(1) confirms Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.<sup>10</sup> Article 8 states that “Members may, in formulating or amending their laws

<sup>1</sup> <https://australian.museum/learn/science/biodiversity/what-is-biodiversity> , Australian Museum, 8.11.2023.

<sup>2</sup> Ibid.

<sup>3</sup> Ibid.

<sup>4</sup> Ibid.

<sup>5</sup> Dr. Nu Nu Yi, Study on Protection of Traditional Knowledge.

<sup>6</sup> Article 3 of the Convention on Biological Diversity, 1992.

<sup>7</sup> Ibid.

<sup>8</sup> Article 10 (c) of the Convention on Biological Diversity, 1992.

<sup>9</sup> United Nations, Printed in Switzerland, ISSN 1816-5540, Training Module on the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), 2010, P-6.

<sup>10</sup> Article 1 (1) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) 1994, Morocco on 15 April 1994.

and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement”.<sup>1</sup>

Under Article 27(3) (b), it mentions among other things that “Members may also exclude from patentability plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof”.<sup>2</sup>TRIPS mandates the provision of protection for plant varieties but allows countries to choose between utilizing the patent system or implementing an effective *sui generis* system for this purpose.

There is no statutory law specifically dedicated to intellectual property (IP) protection in Myanmar, which may result in higher risk or perceived risk for businesses intending to set up shop in Myanmar or work with local companies. Some forms of IP protection are offered for certain patents and designs but these are considered outdated and offer limited protection for intellectual property (WIPO, 2016[12]).<sup>3</sup>

### **Importance of Traditional Medicine knowledge and MSMEs in Myanmar**

The role of traditional medicine has played an important part in Myanmar’s history. Although the use of modern medicine has dramatically increased, it is not easily accessible for much of the population due to prohibitively high costs and limited availability, especially in rural areas. Even when it is readily available, many people are reluctant to use it because of cultural differences and concerns about side effects. Traditional medicine has been used for generations and is more affordable and easily obtainable – even in rural areas – therefore it continues to be widely used and plays a significant role in health care in Myanmar.<sup>4</sup>

In accordance with Myanmar's traditional beliefs, it is acknowledged that there are 96 diseases that can affect humans. The traditional knowledge and medicinal practices in Myanmar are reputed to possess the capability to remedy all these ailments, utilizing various ingredients such as fresh or dried roots, stems, leaves, buds, and flowers. Rooted in akin traditional medicine systems found in neighboring countries, Myanmar's traditional medicine has evolved over centuries, incorporating a wealth of traditions, adapting to changing circumstances, and adopting diverse practices that have contributed to its richness and efficacy.<sup>5</sup>

In Myanmar, a drug is defined as any substance, whether administered internally or externally, utilized for the purposes of diagnosis, prevention, and treatment of diseases, birth control, or for producing any beneficial effect in both human beings and animals. This term also encompasses substances officially designated as drugs by the relevant Ministry through periodic

<sup>1</sup> Article 8 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) 1994, Morocco on 15 April 1994.

<sup>2</sup> Article 27.3 (b), *ibid*.

<sup>3</sup> <https://www.oecd-ilibrary.org/sites/9789264305434-10-en/index.html?itemId=/content/component/9789264305434-10-en#endnotea7z2> .

<sup>4</sup> [https://www.wipo.int/web/ip-advantage/w/stories/providing-affordable-traditional-medicine?p\\_1\\_back\\_url=%2Fweb%2Fip-advantage%2Fsearch%3Fdelta%3D20%26start%3D14](https://www.wipo.int/web/ip-advantage/w/stories/providing-affordable-traditional-medicine?p_1_back_url=%2Fweb%2Fip-advantage%2Fsearch%3Fdelta%3D20%26start%3D14) , August 31, 2010.

<sup>5</sup> [https://www.wipo.int/web/ip-advantage/w/stories/providing-affordable-traditional-medicine?p\\_1\\_back\\_url=%2Fweb%2Fip-advantage%2Fsearch%3Fdelta%3D20%26start%3D14](https://www.wipo.int/web/ip-advantage/w/stories/providing-affordable-traditional-medicine?p_1_back_url=%2Fweb%2Fip-advantage%2Fsearch%3Fdelta%3D20%26start%3D14) , August 31, 2010.

notifications.<sup>1</sup> An Essential Drug is identified by the Board of Authority and is deemed crucial for the healthcare needs of the majority of the population.<sup>2</sup>

The small and medium enterprises development agency shall collaborate with relevant departments and organizations to boost the production capacity and competitiveness of small and medium enterprises. This coordination aims to facilitate the transition of new technologies derived from research results, progressing from the pilot stage to full-scale commercial production.<sup>3</sup>

The Ministry of Industry, Central Department of Small and Medium Enterprises Development, has released the list of the top 100 SMEs in Myanmar on its official website. Among them, 34 are involved in the food and food-related sectors, while 20 focus on non-food enterprises, specializing in the production of traditional and indigenous medicine, shoes, slippers, clothing, and more.<sup>4</sup> A Small Enterprise is defined as a business primarily engaged in wholesale operations, with a workforce not exceeding 30 permanent employees, and an annual income from the previous year not exceeding 100 million kyats.<sup>5</sup> A Small Enterprise is characterized as a business involved in retail operations, with a limit of 30 permanent employees and an annual income from the previous year not exceeding 50 million kyats.<sup>6</sup>

Small-scale Industry refers to cottage industries that employ no more than nine workers, utilizing power ranging from 0.25 horsepower and above but under 5 horsepower. Additionally, it encompasses cottage handicraft industries employing more than three workers, and engaging in the production or processing of goods either by family members, hired workers, or through collective efforts.<sup>7</sup>

A Medium Enterprise is characterized as a business primarily engaged in wholesale operations, with a workforce not surpassing 60 permanent employees, and an annual income ranging from 100 million to 300 million kyats from the previous year.<sup>8</sup> A Medium Enterprise is defined as a business primarily involved in retail operations, with a workforce not exceeding 60 permanent employees, and an annual income ranging from 50 million to 100 million kyats from the previous year.<sup>9</sup> An entrepreneur is defined as an individual or a business entity that operates a small enterprise, a medium enterprise, or both, utilizing full percent of the capital owned by citizens.<sup>10</sup> Entrepreneurship involves the innovation of marketable and highly functional technology, products, manufacturing processes, and services.<sup>11</sup> And also the Promotion of Cottage

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<sup>1</sup> Section 2 (b) of the National Drug Law 1992, (The State Law and Order Restoration Council Law No. 7/92).

<sup>2</sup> Section 2 (c), Ibid.

<sup>3</sup> Section 25 (f) of the Small and Medium Enterprises Development Law, (The Pyidaungsu Hluttaw Law No. 23, 2015).

<sup>4</sup> <https://www.mdn.gov.mm/en/supporting-and-promoting-msmes-myanmar-personal-thought>, Aug 28, 2019.

<sup>5</sup> Section 2 (a) (3) of the Small and Medium Enterprises Development Law, (The Pyidaungsu Hluttaw Law No. 23, 2015).

<sup>6</sup> Section 2 (a) (4), Ibid.

<sup>7</sup> Section 2(a) of the Promotion of Cottage Industries Law 1991, (The State Law and Order Restoration Council Law No. 13/91).

<sup>8</sup> Section 2 (b) (3) of the Small and Medium Enterprises Development Law, (The Pyidaungsu Hluttaw Law No. 23, 2015).

<sup>9</sup> Section 2 (b) (4) of the Small and Medium Enterprises Development Law, (The Pyidaungsu Hluttaw Law No. 23, 2015).

<sup>10</sup> Section 2 (c), of the Small and Medium Enterprises Development Law, (The Pyidaungsu Hluttaw Law No. 23, 2015).

<sup>11</sup> Section 2 (o), Ibid.

Industries Law of 1991, mentions that “an entrepreneur is defined as an individual who has received registration approval to operate a Small-scale Industry under this Law. This definition also extends to include heirs, legal representatives, and any succeeding lawful organization”.<sup>1</sup>

The fundamental principles of the Small and Medium Enterprises Development Law of 2015 mention fostering innovation among small and medium entrepreneurs, promoting the creation of cutting-edge products, enhancing service development, augmenting production capacity, and advocating the adoption of advanced technology and facilities in both production and distribution processes.<sup>2</sup>

### **Regulations for Traditional Medicine Knowledge in MSMEs**

Invention is the act of creating a product or process that offers a resolution to a particular issue within the realm of technology. This definition also encompasses utility models.<sup>3</sup> An individual engaged in or aspiring to undertake a Small-scale Industry, and seeking registration under this Law, must submit an application in the manner specified by the Cottage Industries Department.<sup>4</sup> The duties of the entrepreneur include abiding by the existing laws.<sup>5</sup>

One significant regulatory challenge faced by policymakers is the potential lack of familiarity among MSMEs with formal business practices. Some may even opt for informal operations to evade administrative burdens and taxation. This situation poses challenges for regulatory authorities, particularly when MSMEs show reluctance to participate in the initial stage of the regulatory process, which involves registering their businesses. The government has introduced various policies and programs to encourage SMEs to register including capacity building, access to loans, lower tax rates, tax holidays and business matching.

The agency, in alignment with the guidance of the Working Committee, shall provide recommendations to relevant departments and organizations for the development of small and medium enterprises and the enhancement of their competitiveness. This includes advising on tax exemptions and reliefs for the manufacturing of advanced new products through research.<sup>6</sup> While both the Cottage Industries Law and the SME Law indicate financial penalties for failure to register, these penalties are rarely enforced in practice.<sup>7</sup> Anyone engaging in small-scale industries without completing registration under the Promotion of Cottage Industries Law 1991, shall, upon conviction, face a penalty ranging from a minimum of fifty thousand kyats to a maximum of one hundred thousand kyats.<sup>8</sup>

The patent applicant shall, if necessary, provide a statement regarding legal access and use of genetic or biological resources, as well as traditional knowledge associated to with or not with

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<sup>1</sup> Section 2(b) of the Promotion of Cottage Industries Law 1991, (The State Law and Order Restoration Council Law No. 13/91).

<sup>2</sup> Section 4 (f) of the Small and Medium Enterprises Development Law, (The Pyidaungsu Hluttaw Law No. 23, 2015).

<sup>3</sup> Section 2 (j) of the Patent Law 2019, (The Pyidaungsu Hluttaw Law No. 7, 2019).

<sup>4</sup> Section 4 of the Promotion of Cottage Industries Law 1991, (The State Law and Order Restoration Council Law No. 13/91).

<sup>5</sup> Section 7(e), *ibid*.

<sup>6</sup> Section 27 (a) of the Small and Medium Enterprises Development Law, (The Pyidaungsu Hluttaw Law No. 23, 2015).

<sup>7</sup> <https://www.oecd-ilibrary.org/sites/9789264305434-10-en/index.html?itemId=/content/component/9789264305434-10-en#endnotea7z2>.

<sup>8</sup> Section 22 of the Promotion of Cottage Industries Law 1991, (The State Law and Order Restoration Council Law No. 13/91).

those resources, directly or indirectly utilized in the creation of the claimed invention.<sup>1</sup> The Patent Law 2019 in Myanmar provided that “Pharmaceutical products or processes are not eligible for patent protection until January 1, 2033, unless specifically determined otherwise by the Union Government in accordance with the policies of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Council under the World Trade Organization (WTO)”.<sup>2</sup>

Generally speaking, patents are the most important type of IP protection for medicines. To obtain a patent, an invention must be novel, inventive and industrially applicable. A patent grants a set of exclusive rights for a limited time, usually 20 years, that allow the inventor to prevent others from making, using, selling, offering for sale or importing the patented invention without permission. Patents based on traditional medical knowledge include patents based on maca, a traditional Peruvian food and medicine first cultivated by the Incas, and a patent based on kava, a medicinal plant first domesticated in Vanuatu. In China, patent law protects new traditional medicine-based products, methods of processing and new uses of traditional medicine, including herbal preparations, extracts from herbal medicines, foods containing herbal medicines and methods for preparing herbal formulas.<sup>3</sup>

In Myanmar, enterprises of all sizes, including SMEs, are subject to all business-related laws, notifications, regulations, and directives. Given that SMEs constitute the majority of domestic private sector businesses in Myanmar, one can assert that the existing business regulatory framework is effectively comprehensive for accommodating local SMEs.<sup>4</sup> The Small and Medium Enterprises Agency is tasked with collaborating with relevant departments and organizations to boost the production capacity and competitiveness of small and medium enterprises. This involves coordinating efforts to identify and disseminate suitable technologies that can contribute to these objectives.<sup>5</sup> When determining compensation for the issuance of a compulsory license for a patent covering a pharmaceutical product or its manufacturing process, especially when an alternative process is either unknown or unavailable, one may take into account the terms and conditions outlined in the decision of the General Council of the World Trade Organization dated August 30, 2003.<sup>6</sup>

In 1997, the World Health Organization (WHO) drafted the Declaration on Health Development in the South-East Asia Region in the 21st Century (the Declaration), in which member states laid out their proposals for health reform. An important focus has been on traditional medicine, and the Myanmar government has implemented measures to increase the role of traditional medicine as a globally recognized and natural alternative to modern medical practices. As part of this initiative, the Myanmar Ministry of Industry and the Myanmar Food and Drug Administration (MFDA) actively advocate for policies that benefit private pharmaceutical companies involved in producing high-quality traditional medicine.<sup>7</sup>

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<sup>1</sup> Section 20 (vii) of the Patent Law 2019, (The Pyidaungsu Hluttaw Law No. 7, 2019).

<sup>2</sup> Section 14 (b), of the Patent Law 2019, (The Pyidaungsu Hluttaw Law No. 7, 2019).

<sup>3</sup> WIPO, Intellectual Property and Traditional Medical Knowledge, Background Brief No. 6, p- 4.

<sup>4</sup> <https://www.oecd-ilibrary.org/sites/9789264305434-10en/index.html?itemId=/content/component/9789264305434-10-en#endnotea7z2>.

<sup>5</sup> Section 25 (a) of the Small and Medium Enterprises Development Law, (The Pyidaungsu Hluttaw Law No. 23, 2015).

<sup>6</sup> Section 69 (a) of the Patent Law 2019, (The Pyidaungsu Hluttaw Law No. 7, 2019).

<sup>7</sup> [https://www.wipo.int/web/ip-advantage/w/stories/providing-affordable-traditional-medicine?p\\_1\\_back\\_url=%2Fweb%2Fip-advantage%2Fsearch%3Fdelta%3D20%26start%3D14](https://www.wipo.int/web/ip-advantage/w/stories/providing-affordable-traditional-medicine?p_1_back_url=%2Fweb%2Fip-advantage%2Fsearch%3Fdelta%3D20%26start%3D14).

The Food and Drug Administration was established in 1995, and notifications are currently in progress.<sup>1</sup> The Food and Drug Administration (FDA) is responsible for safeguarding public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, the nation's food supply, cosmetics, and products that emit radiation. Additionally, the FDA offers accurate, science-based health information to the public.<sup>2</sup> The Food and Drug Administration (FDA) holds the responsibility for the registration of domestically produced food, issuing the Import Recommendation (IR) and Import Health Certificate for imported food, licensing both food and drugs, and conducting quality control assessments for registered drugs, processed food, imported food, and items intended for export. The FDA comprises five divisions, namely the Administrative Division, Drug Control Division, Food Control Division, Cosmetic and Medical Device Control Division, and Laboratory Division.<sup>3</sup> Myanmar has been a longstanding member of the WHO, FAO, CAC (Codex Alimentarius Commission), and WTO. Myanmar actively engages in the ASEAN Trade Protocol and regional agreements such as the Sanitary & Phytosanitary Agreement (SPS) and the Technical Barrier to Trade Agreement (TBT). The FDA serves as the contact point for CAC.<sup>4</sup> There is currently no specific provision for business registration for small and medium businesses in the traditional medicine sector in Myanmar. Additionally, there is no mention in the Patent law, 2019 to protect creativity in this context. As a result, the sole avenue for registration and protection is through the FDA.

### Protection of Traditional Medicine Knowledge in Myanmar

Some countries have implemented specific *sui generis* laws and measures designed explicitly to safeguard traditional medical knowledge. For example, Thailand's Act on Protection and Promotion of Traditional Thai Medicinal Intelligence protects "formulas" of traditional Thai drugs and "texts on traditional Thai medicine". Only individuals or entities who have registered their intellectual property rights are permitted to conduct research, development, and production of drugs utilizing traditional medical knowledge. At the international level, the legal instrument on the protection of traditional knowledge negotiated by the WIPO IGC is designed to encompass a *sui generis* approach.<sup>5</sup>

For Indigenous and local communities to safeguard their knowledge, they may find it necessary to align with Western constructs of order, such as *sui generis* systems of protection, databases, and/or Western education systems. *Sui generis* systems, denoting 'a special kind' or 'of its own kind,' are specialized measures or laws designed exclusively to address the unique characteristics of specific subject matter.<sup>6</sup>

The *sui generis* system of protection for Traditional Knowledge (TK) may grant exclusive rights in an effort to ensure fairness and equity, particularly in the face of neo-liberal market forces affecting primarily Indigenous peoples. The comprehensive and distinctive nature of TK

<sup>1</sup> <https://www.fao.org/3/ad813e/ad813e.pdf>, Dr. Yin Yin Htwe, FDA Myanmar Department of Health.

<sup>2</sup> <https://www.usa.gov/agencies/food-and-drug-administration#:~:text=The%20Food%20and%20Drug%20Administration,and%20products%20that%20emit%20radiation.>

<sup>3</sup> Swe Mon Aung, Food and Agricultural Import Regulations and Standards, BM 8001, 1.11.2018.

<sup>4</sup> <https://www.fao.org/3/ad813e/ad813e.pdf>, Dr. Yin Yin Htwe, FDA Myanmar Department of Health.

<sup>5</sup> WIPO, Intellectual Property and Traditional Medical Knowledge, Background Brief No. 6, p- 6.

<sup>6</sup> <https://link.springer.com/article/10.1007/s11196-023-09989-8>, Jacqueline Paul, Traditional Knowledge Protection and Digitization: A Critical Decolonial Discourse Analysis, 25 April 2023.

under a *sui generis* system permits the development of specialized measures or laws tailored exclusively to address the distinctive characteristics of specific subject matter.<sup>1</sup>

A *sui generis* system of protection aims to safeguard Traditional Knowledge (TK), foster the equitable distribution of benefits, guarantee that the utilization of the knowledge occurs with the prior informed consent of Indigenous peoples or local communities, and prevent misappropriation.<sup>2</sup>

### Conclusion

Policies and regulations play a vital role in shaping the involvement of Traditional Medicine Knowledge (TMK) and Complementary and Alternative Medicine (CAM) within national healthcare delivery systems. They are instrumental in establishing effective regulatory and legal frameworks to foster the production of herbal medicines while upholding standards of quality and good practices. Policies are also essential for addressing concerns related to safeguarding the knowledge of indigenous traditional medicine and the preservation of natural resources.

As a member of TRIPs and CBD, Myanmar must respect, protect, and maintain Intellectual Property Rights (IPRs). Existing laws in Myanmar do not protect sufficient intellectual property rights (IPRs), and conventional IPRs are also not designed for the protection of traditional medicine. According to Article 27(3) of TRIPs, countries are permitted to establish *sui generis* protection mechanisms for intellectual property, allowing them to implement customized and specific approaches to safeguarding rights. the *sui generis* system proves beneficial in Myanmar. In Myanmar, a *sui generis* system should be implemented to protect traditional medicine knowledge.

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