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PROTECTING TRADITIONAL MEDICAL KNOWLEDGE: A CRITIQUE OF SOUTH AFRICA'S *SUI GENERIS* FRAMEWORK

By

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Date: 28 February 2025.

DECLARATION

I, 2136040 ,declare that this Research Report is my own unaided work. It is submitted in partial fulfillment of the requirements for the degree of Master of Laws (by Coursework and Research Report) at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination in this or any other university.

I have submitted my final Research Report through TurnItIn and have attached the report to my submission.

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ABSTRACT

South Africa amended and implemented laws that are heavily based on Western and conventional intellectual property (IP) laws to protect Traditional Medical Knowledge (TMK). These laws have been found to be inadequate in catering to the unique nature of TMK, necessitating alternative protection mechanisms such as sui generis frameworks that fall outside the scope of the conventional IP system. South Africa has recently established its own sui generis framework under the Protection, Promotion, Development, and Management of Indigenous Knowledge Act 6 of 2019 (TK Act). Although the South African sui generis framework is a promising initiative to protect TMK, it is not without its challenges. This research report examines the challenges of protecting TMK in South Africa. It critically analyses both the conventional IP system and the TK Act for TMK protection. Findings reveal that neither the conventional IP system nor the sui generis framework alone provides a comprehensive solution for the protection of TMK. Instead, the report proposes a hybrid approach that integrates elements from both the conventional IP and sui generis systems. The report concludes by recommending a flexible and adaptable system that accommodates the dynamic nature of TMK while fostering innovation. It highlights the need for ongoing conversations between academics, policymakers, and indigenous communities to improve the mechanisms aimed at protecting TMK.

Key words: Conventional Intellectual Property, Traditional Medical Knowledge, *Sui Generis*.

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I INTRODUCTION

In recent years, the intersection between Traditional Knowledge (TK) and the conventional Intellectual Property (IP) system has resulted in increasing attention from policymakers, academics and indigenous communities. The term Traditional Medical Knowledge (TMK) which is a,subset of TK, does not have a distinct definition. However, the World Health Organisation (WHO) broadly defines it as the following:

> 'It is the sum of the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health and the prevention, diagnosis, improvement, or treatment of physical and mental illnesses.'[1]

TMK forms part of a specialised area of knowledge that falls under the broader category of TK. The term TK is a much broader definition and often complicated to define because the nature of TK is diverse and it is challenging to confine the term into a singular definition.[2] However, the World Intellectual Property Organisation (WIPO) describes TK as the knowledge, practices and skills that are cultivated and passed on through generations within a community, often serving as part of its spiritual or cultural identity.[3] While deeply intertwined with TK, TMK specifically refers to the subset of this knowledge related to health and healing. Therefore, in some contexts the terms TMK and TK are used interchangeably because the core characteristics of TK cannot be separated from those of TMK. However, TMK focuses on healthcare, while TK includes additional areas such as artistic, cultural expressions, agriculture and ecology.[4]

South Africa has implemented IP laws that are heavily based on Western and conventional IP laws to protect TK. However, scholars consider the current IP laws inadequate for addressing the nature of TK, thereby necessitating protection through alternative mechanisms. One such mechanism is the *sui generis* framework under the Protection, Promotion, Development and Management of Indigenous Knowledge Act 6 of 2019 (TK Act). While the TK Act specifically uses the term 'Indigenous Knowledge', this research report

1 World Health Organisation 'Traditional, Complementary and Integrative Medicine', available at: https://www.who.int/health-topics/traditional-complementary-and-integrative-medicine, accessed on 19 December 2024.
2 J.Janewa OseiTutu 'Emerging Scholars Series: A Sui Generis Regime for Traditional Knowledge: The Cultural Divide in Intellectual Property Law' (2010) 15 Marquette Intellectual Property Law Review 162.
3 WIPO, Glossary of Key Terms Related to Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions, https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_37/wipo_grtkf_ic_37_inf_7.pdf, accessed on 24 February 2025.
4 Ibid.

primarily uses the term TK and its subset TMK. However, indigenous knowledge is regarded as TK of an indigenous community, therefore being part of a category of TK.[5] TK is not always indigenous, but the terms may be used to refer to knowledge that itself is 'indigenous.'[6] In light of this, the terms can be used interchangeably.

While the South African *sui generis* framework presents a promising initiative for the protection of TMK, it is not without its challenges. The term '*sui generis*' is derived from Latin meaning 'of its own kind'.[7] The term is often used in IP law to refer to a regime specifically designed to protect rights that do not fit into the traditional trademark, patent, trade secrets or copyright doctrines.[8] The *sui generis* framework is intended to meet the distinct needs and challenges related to a particular issue.[9] This framework is particularly relevant to TK, since such knowledge often falls outside the scope of conventional IP laws, making a *sui generis* approach favourable.

This research seeks to contribute to the ongoing conversation on protecting TK and advocates for an effective legal approach that upholds and respects the rights of indigenous communities while incentivising innovation. This is done by exploring several critical research questions. First, what is the *sui generis* framework and how does it differ from the conventional IP systems? Secondly, what are the strengths and weaknesses of the proposed *sui generis* framework for safeguarding TMK in South Africa? Finally, against this backdrop, is the *sui generis* framework appropriate for protecting TMK in South Africa?

The research report begins by exploring the nature of TMK and its importance in South African healthcare. It also discusses the commercialisation and misappropriation of TMK, using the case of Hoodia Gordonii as an example of biopiracy. The next section analyses the current legal frameworks for protecting TMK. This includes the National Environmental Management Biodiversity Act 10 of 2004 (NEMBA), Patents, Trade Secrets, the Intellectual Property Laws Amendment Act 28 of 2013 (IPLAA) and the treaty on Intellectual Property, Genetic resources and Traditional Knowledge (GRATK Treaty). The shortcomings of the conventional IP system in protecting TMK are then examined, focusing on patents and trade secrets. The report proceeds to explain the concept of a sui generis framework and its implementation in South Africa, highlighting its strengths and weaknesses. Finally, the report

[5] Ibid.
[6] Ibid.
[7] Ibid.
[8] Ibid.
[9] Ibid.

evaluates whether South Africa's *sui generis* framework is the most appropriate form of protection for TMK, considering arguments on both sides.

II THE NATURE OF TRADITIONAL MEDICAL KNOWLEDGE, ITS COMMERCIALISATION AND MISAPPROPRIATION

African TMK is said to be one of the oldest and most diverse healing systems, although such systems are often inadequately recorded.[10] The foundation of TMK lies in the use of herbs, plants and other natural resources. TMK plays a vital role in the healthcare systems of many African countries, especially South Africa. It has been estimated that up to 60 per cent of the population uses traditional medicines as their primary source of healthcare.[11] The use of TMK is prevalent in rural communities especially where modern healthcare facilities may be inaccessible.[12]

Indigenous communities and traditional healers possess the knowledge of the healing properties found in plants, which they process to prepare remedies that treat varying ailments. The components of these remedies typically include natural resources that contain ingredients with medicinal properties.

Remedies derived from natural resources are not protectable in their raw composition under the conventional IP regime.[13] However, the potential for protection primarily lies in the intangible aspects of traditional medicine, specifically the accumulated wisdom and practices associated with these natural resources. This includes spiritual therapies and techniques designed to treat illnesses or maintain wellness.[14]

TK is generally communally owned, based on a belief system that has been practiced for a long time by a particular indigenous group or community. This communal ownership reflects the respect for ancestral knowledge and the collective responsibility of preservation and transmission.[15] Individuals, such as traditional healers commonly known as 'sangomas' or

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[10] Mmamosheledi E. Mothibe and Mncengeli Sibanda 'African Traditional Medicine: South African Perspective' (2019) 2

[11] Sandy Van Vuuren et al 'Microbial contamination of traditional medicinal plants sold at the Faraday *muthi* market, Johannesburg, South Africa' (2014) 94 *South African Journal of Botany* 95.

[12] Ibid.

[13]WIPO 'Intellectual Property and Traditional Medical Knowledge' available at: *https://www.wipo.int/edocs/pubdocs/en/wipo-pub-rn2023-5-6-en-intellectual-property-and-traditional-medical-knowledge.pdf*, accessed 18 July 2024.

[14] Ryan Abbott 'Documenting Traditional Medical Knowledge' (2014) 14 *WIPO Toolkit* 9.

41 World Health Organization [WHO/IUCN/WWF] 'Guidelines on the Conservation of Medicinal Plants' available at *http://apps.who.int/medicinedocs/documents/s7150e/s7150e.pdf*, accessed on 20 January 2025.

[15] E (WJ) du Plessis, 'Protection of traditional knowledge in South Africa: The troubled Bill, the inoperative Act and the common solution' in C Ncube & E du Plessis (eds) Indigenous Knowledge & Intellectual Property: Contemporary Studies in Law and Applied Research series, (2016) Juta & co. Cape Town 81.

'inyangas' in South Africa do innovate. However, such innovations are based on the collective heritage of a community, therefore regarded as community held.[16]

Traditional healers, together with local communities', manifest innovation in several ways. First, dreams and spiritual guidance may be seen as a source of innovation for developing new methods of medicine based on ancestral wisdom.[17] Secondly, as new illnesses emerge, traditional healers adapt new formulations for traditional remedies while adhering to the core principles passed down through generations.[18] Thirdly, through experimentation and observation, they refine existing treatments and develop new and innovative approaches to address emerging health issues.[19] Lastly, healers pass down their knowledge verbally, allowing new techniques and information to be incorporated over generations.[20]

Traditional communities' innovation is intertwined with the concept of TK and IP. The collective heritage often informs the foundation upon which innovations are built. However, determining ownership of IP rights to this innovation presents a complex challenge. Patent protection and trade secrets offer some form of protection to the extent that TMK meets the requirements. However, considering the communal, generational and dynamic nature of TK, attributing protection under the conventional IP regime is inadequate as discussed under part III*(d)*.

(a) The commercialisation and misappropriation of TMK

South Africa is home to an abundance of plant resources used for nutritional and medical purposes. These plant resources have been developed and nurtured for generations by various indigenous communities.[21] The rightful TMK holders and communities have identified medicinal values used to treat various ailments.[22] Medicinal plants have suffered from overexploitation by Western scientists and multinational pharmaceutical companies, a practice referred to as 'biopiracy'.[23]

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[16]Emeka Polycarp Amechi 'Leveraging Traditional Knowledge on the Medicinal Uses of Plants within the Patent System: The Digitisation and Disclosure of Knowledge in South Africa*' (2015) 18 Potchefstroom Electronic Law Journal* 3072.
[17]Ibid.
[18] Sarah Wild 'Bringing Traditional Healing Under the Microscope in South Africa', *Undark Magazine*, 30 December 2020, available at: *https://undark.org/2020/12/30/covid-19-south-africa-traditional-medicine/*, accessed on 22 January 2025.
[19] Ibid.
[20] Ibid.
[21] ibid.
[22] Patrick Agejoh Ageh & Namrita Lall 'Biopiracy of Plant Resources and Sustainable Traditional Knowledge System in Africa' (2019) 8 *Global Journal of Comparative Law* 2.
[23] Ibid at 1.

The term biopiracy is frequently used to describe instances where multinational corporations benefit financially from the medicinal properties used by indigenous communities without compensation.[24] It has generally been observed that developed countries are typically the perpetrators of biopiracy.[25] Multinational companies from these countries often exploit the genetic resources and TMK of communities in developing countries without consent, fair compensation or recognition of the original holders of TMK.[26]

Biopiracy exemplifies the pattern of exploitation and misappropriation which multinational pharmaceutical companies have engaged in for many years. It has been recorded that the estimated market value of pharmaceutical derivatives from TK amounted to approximately US$43 billion, representing thirteen per cent of worldwide pharmaceutical profits.[27]

Proponents of the commercialisation of plant resources argue that the pharmaceutical industry plays a crucial role in advancing healthcare and developing lifesaving medications.[28] Notably, Africa's plant resources have contributed to the discovery of more than 50 per cent of Western pharmaceutical drugs through research of the TK system in Africa.[29]

Moreover, studies have found that engaging with TMK can accelerate drug discovery processes. Chaachouay and colleagues argue that by collaborating with indigenous communities and researching their TMK reveals promising avenues for drug development.[30] By leveraging this knowledge, pharmaceutical companies can innovate to create products that address unmet medical needs, justifying the economic benefits derived from such practices.

Notwithstanding the potential benefits, the commercialisation of TMK without compensation or recognition of the TMK holders presents significant ethical concerns. The commercialisation of TMK can diminish its spiritual and cultural significance, potentially eroding the value of traditional practices.[31] Power imbalances between TK holders and multinational companies exacerbates these issues. Multinational companies typically have the legal and financial resources necessary to obtain patents, while TK holders lack access to such

[24] Ibid at 3.
[25] Riya Gulati 'Biopiracy, A Biological Theft?' (2019) 5 *International Journal of Legal Studies* 317.
[26] Ibid at 336.
[27] Ibid.
[28] Noureddine Chaachouay & Lahcen Zidane 'Plant-Derived Natural Products: A Source for Drug Discovery and Development' (2024) 3 *Drugs and Drug Candidates* 193-4.
[29] Ageh op cit note 22 at 3.
[30] Chaachouay op cit not at 28 at 189.
[31] Roshan Lal, Babita Baeraiya, Rashmi Thakur et al 'Traditional Knowledge in Drug Development and the Rights of Indigenous Peoples: A Legal and Ethical Perspective'(2024) 13 *Journal of Drug and Alcohol Research* 2.

resources.[32] This imbalance often leads to agreements that prioritise commercial entities and limits TK holders 'ability to assert their rights and substantially benefit from commercialisation.[33]

The historical context of exploitation and misappropriation is important to understanding the underlying dynamics involved in biopiracy. The commercialisation and misappropriation of Hoodia Gordonii exemplifies one of many cases of biopiracy in South Africa. [34]

(b)Hoodia Gordonii

The oldest inhabitants in South Africa, known as the Khoi San, traditionally used the properties found in the Hoodia Gordonii plant to suppress hunger and thirst, particularly during long hunting trips.[35] In 1995, the Council for Scientific and Industrial Research (CSIR) identified the active ingredient in the plant which acts as appetite suppressant and patented the constituents of the Hoodia Gordonii without the consent of the San community.[36] CSIR licenced this patent to Phytopharm, a pharmaceutical company, for the development of weight loss medications.[37] Large corporations sought patents for extracts derived from Hoodia Gordonii, notably P57, a compound responsible for the weight loss effects.[38] This resulted in a surge in the commercialisation and demand for Hoodia Gordonii products, mainly for weight loss supplements.

The commercialisation of Hoodia Gordonii raised ethical concerns. The San community, who hold the TMK of Hoodia Gordonii, were largely excluded from the benefits of the commercialisation and received little to no recognition or compensation for their TMK.[39] This exemplifies the issue associated with biopiracy, where multinational companies exploit TMK without fair benefit-sharing and recognition of the rightful holders TMK.[40]

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[32] Ibid at 3.
[33] Ibid.
[34] Ibid.
[35]Convention on Biological Diversity 'Hoodia Gordonii - Convention on Biological Diversity' available at: *https://www.cbd.int/doc/meetings/abs/abswg-06/other/abswg-06-cs-07-en.pdf*, accessed on 22 July 2024.
[36] Ibid.
[37] Ibid.
[38] Loretta Feris 'A legal framework for the protection of biodiversity related traditional knowledge' (2004) 11 *South African Journal of Environmental Law and Policy* 2.
[39] Rachel Wynberg 'Biopiracy: Crying wolf or a lever for equity and conservation?' (2023) 52 *Research Policy* 7.
[40] Ibid.

Following international attention and accusations of biopiracy, the CSIR and San community entered into a benefit-sharing agreement (BSA).[41] The CSIR and San council reached a memorandum of understanding where the San were recognised as the custodians of TMK of the plant. [42] Furthermore, the CSIR's role in developing the technology used to extract the active ingredients in the plant was also considered.[43] The CSIR agreed to pay the San community the money derived from the licence agreements during the drug's clinical development and royalties.[44]

The Hoodia Gordonii case represents a significant milestone in the fight against biopiracy. It set a precedent for the protection of TMK and established equitable benefit-sharing.[45] The agreement between the CSIR and San community was groundbreaking, representing one of the first formal BSA's.[46] This case emphasised the need for legal frameworks that respect TK rights and promote ethical research and commercialisation practices.[47]

III CURRENT LEGAL FRAMEWORKS FOR THE PROTECTION OF TMK

For the past few years, South Africa has made a continuous effort to develop laws protecting TK. South Africa has recognised the pressing need to address the challenges TK holders face in protecting their knowledge. In response to these challenges, South Africa has implemented legal frameworks to address these challenges. This section focuses on frameworks specifically aimed at the protection of TMK.

(a) National Environmental Management: Biodiversity Act 10 of 2004

NEMBA is the first national law to focus on protecting biodiversity.[48] Among its objectives, the Act includes provisions aimed at protecting TK and genetic resources from exploitation. While NEMBA does not explicitly mention TMK protection, TMK falls under the broader category of TK and therefore could be argued to be protectable under the Act. However, the

[41] Sarah Wild 'Bringing Traditional Healing Under the Microscope in South Africa', *Undark Magazine*, 30 December 2020, available at: *https://undark.org/2020/12/30/covid-19-south-africa-traditional-medicine/*, accessed on 22 January 2025.
[42] Feris op cit note at 38.
[43] Ibid.
[44] Ibid.
[45] Roshan op cit note 31 at 14.
[46] Ibid.
[47] Ibid.
[48] Endangered Wildlife Trust 'NEMBA', EWT laws, available at: *https://laws.ewt.org/legislation/species/nemba/t* ,accessed 7 January 2025.

lack of explicit mention of TMK creates troubling ambiguity, leaving room for interpretation and potential loopholes. This could undermine the comprehensive protection of TMK.

Furthermore, NEMBA defines a genetic resource as any genetic material, such as that found in animals, plants and other biological material containing functional units of heredity.[49] TMK is often linked to genetic resources because traditional medicine is mostly derived from genetic material inherent in plants and therefore protectable under the Act. Genetic resources are naturally occurring and not creations of the mind, therefore they cannot be directly protected under the conventional IP regime.[50] However, genetic resources are subject to access and BSA found under international instruments such as the Convention on Biological Diversity.[51]

The act aims to combat biopiracy by promoting fair and equitable BSA and recognises the importance of protecting TMK and genetic resources from exploitation.[52] Chapter 6 of NEMBA regulates bioprospecting activities in South Africa.[53] NEMBA refers to bioprospecting as:

> '[A]ny research on, or development or application of, indigenous biological resources for commercial or industrial exploitation'.[54]

Chapter 6 of NEMBA emphasises the sustainable use and development of South Africa's indigenous genetic and biological resources while ensuring fair and equitable BSA, particularly when TK is associated with these resources.[55] The Act prohibits bioprospecting activities without a permit, except when certain requirements are met.[56]

Before issuing a permit, the issuing authority must consider relevant stakeholders to ensure that their interests are protected.[57] Where stakeholders have an interest in bioprospecting, the issuance of a permit is conditional upon prior informed consent (PIC) for the use of TMK or genetic resource, a BSA and a transfer agreement.[58] Monies due to the stakeholders in terms of the BSA and transfer agreements are kept in a trust fund.[59] The trust

[49] National Environmental Management: Biodiversity Act 10 of 2004 s1.
[50]Vuuren op cit note 11 at 1.
[51] Ibid.
[52] 'Biodiversity and Traditional Knowledge - Candy Steyn of Spoor &amp Fisher', *Research Contracts and Innovation*, 1 April 2008, available at: *https://uct.ac.za/rci/articles/2008-04-01-biodiversity-and-traditional-knowledge-candy-steyn-spoor-amp-fisher*, accessed 26 July 2024.
[53] Act 10 of 2004 s80.
[54] Act 10 of 2004 s1.
[55] Act 10 of 2004 s80(1)*(d)*.
[56] Act 10 of 2004 s81.
[57] Act 10 of 2004 s82(1).
[58] Act 10 of 2004 s82(2).
[59] Act 10 of 2004 s85.

fund is established and administered by the government, from which payments are made to the relevant stakeholders.[60]

While well-intentioned, NEMBA's permit system creates a significant administrative challenge for indigenous communities. These communities often lack the legal expertise, financial resources and administrative capacity to navigate complex regulatory systems. This is further exacerbated by power imbalances in stakeholder consultations that favour larger and better resourced entities.

(b) The Conventional IP Frameworks

(i) Patent Amendment Act

Patent law includes regulatory requirements designed to ensure the ethical use and protection of TK and indigenous biological resources. The Patents Amendment Act No. 20 of 2005 closely reflects the recognition and protection of indigenous resources and TK as contained in NEMBA. According to the Amendment Act, an applicant for a patent is required to disclose whether or not the invention for which protection is sought is derived from TK.[61] Furthermore, the registrar shall call upon the applicant to prove the right to use the TK.[62]

The Regulations for the Amendment Act require every patent applicant to lodge a statement on form P26.[63] This statement must be submitted six months of initial patent application and must be accompanied by specific specifications.[64] When a P26 form contains a statement that the invention for which protection is claimed is based on TK, the applicant is required to furnish to the registrar proof of PIC or a title to use the TK.[65]

An applicant is required to provide evidence to satisfy the registrar's requirements. A copy of the permit issued under Chapter 7 of NEMBA must be lodged with the registrar.[66] Proof that PIC had been obtained as contemplated in s82(2)*(a)* or 82(3)*(a)* of NEMBA may be required.[67]This consent indicates that holders have agreed to the use of their TK, thus respecting their interests.

Proof of a BSA as contemplated in s82(2)*(b)(ii)* or 82(3)*(b)* of NEMBA may be required.[68] Such an agreement ensures that the benefits derived from it are equitably shared

[60] Ibid.
[61] Patents Amendment Act 20 of 2005 s3A.
[62] Act 20 of 2005 s3B.
[63] Patent regulations in GoN R2470, G. 6247 (corrected by R697, G. 6379) of 1 January 1979.
[64] Ibid.
[65] Ibid.
[66] Ibid.
[67] Ibid.
[68] Ibid.

with the TK holders. In order to ensure that the negotiations for the BSA are on equal footing, those issuing the permit may facilitate the negotiations between the parties.[69] Alternatively, the Minister may require that measures be in place to ensure the arrangements are fair and equitable.[70]

Where an applicant makes a false statement or representation which they knew or ought to have reasonably known to be false at the time when the statement was made, may result in the revocation of the patent. [71]

(ii) Trade Secrets

A trade secret is a form of IP right on confidential information which may be licenced or sold.[72] South Africa does not have specific legislation regulating trade secrets, however the misappropriation of trade secrets is *prima facie* wrongful.[73] Legal protection for trade secrets primarily arises from contractual or fiduciary obligations.[74] The unauthorised use or misappropriation of trade secrets is actionable under the law of delict or the law of contract, particularly in cases involving breaches of confidentiality or unlawful competition.[75] The protection of trade secrets generally lasts for so long as the secret is kept confidential.[76]

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) recognises and protects confidential information or trade secrets. Article 39 of the TRIPS Agreement provides that member states shall protect undisclosed information from unauthorised use as long as the information meets the following criteria:

> '(a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question.
>
> (b) has commercial value because it is secret; and
>
> (c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.'[77]

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[69] Department of Environmental Affairs and Tourism 'Briefing of The Portfolio Committee Briefing: National Environmental Laws Amendment Bill, B66 of 2008' available at: *https://pmg.org.za/files/docs/080826briefingnelab.doc*.
[70] Ibid at 7.
[71] Patents Act 57 of 1978 s61.
[72] WIPO 'Trade Secrets', available at: *https://www.wipo.int/web/trade-secrets* ,accessed 26 September 2024.
[73] Madelein Kleyn & Joanne van Harmelen 'Trade Secrets' (2021*) 56 Journal of the Licensing Executives Society* 137.
[74] Ibid.
[75] Ibid.
[76] Ibid.
[77] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) art 39.

In the context of Article 39 and the protection of TMK, it can be argued that many traditional practices and medications are shared within indigenous communities. This knowledge is only known and accessible to certain individuals or groups within the indigenous community, such as traditional healers or elders. Healers are generally known to use undisclosed traditional medications passed down through generations, representing collective wisdom.[78] The use of such medication may be protected as trade secrets, especially when the remedies or preparation methods are not widely known.

(iii) The Intellectual Property Laws Amendment Act 28 of 2013

The IPLAA was enacted to specifically protect TK through the current IP system.[79] The IPLAA amends several existing IP Laws such as the Trademarks Act, Copyright Act and Performers Protection Act. However, the IPLAA does not include the Patent Act, presumably because the Patent Amendment Act already incorporates relevant amendments. To address the challenges indigenous communities face in protecting TK from misuse and exploitation, it introduces concepts and definitions related to indigenous knowledge.

While the Act does not include protection for TMK, it was introduced following the release of a policy framework detailing the rationale for protecting TK as a distinct category of IP within the existing IP system. In 2004, Cabinet adopted the Indigenous Knowledge Systems Policy (IKS Policy).[80] Subsequently, in 2008, the Department of Trade and Industry (DTI) published the Intellectual Property System policy framework.[81]

The adoption of the IKS policy has resulted in various government departments being assigned specific responsibilities aimed at developing legislative amendments and policies for the protection of indigenous knowledge.[82] A key development was the Amendment of the Patent Act in 2005, which introduced PIC and equitable BSA. The IKS policy also emphasises the importance of documenting indigenous knowledge that is in the public domain to prevent its use by unauthorised parties and create benefit-sharing frameworks.[83] This documentation facilitates the establishment of minimum standards for information to be included in transfer

[78] P Andanda & H Khademi, 'Protecting traditional medical knowledge through the intellectual property regime based on the experiences of Iran and South Africa' in C Ncube & E du Plessis (eds) Indigenous Knowledge & Intellectual Property: Contemporary Studies in Law and Applied Research series, (2016) Juta & co. Cape Town, pp.48-73.
[79] The Intellectual Property Amendment Act 28 of 2013.
[80] The Policy Framework for The Protection of Indigenous Traditional Knowledge Through the Intellectual Property System and the Intellectual Property Laws Amendment Bill (GN552 in GG31026 of 5 May 2008).
[81] Ibid.
[82] Ibid.
[83] Ibid.

agreements as outlined in the Patents Amendment Act. The IKS policy proposed the promulgation of a s*ui generis* IP regime for the protection of TK to be administered by the DTI, to provide for positive protection.[84] Notably, the DTI Policy of 2008 stated that the existing IP regime was a suitable framework for protecting the rights of traditional healers.[85]

(c) International Instrument

On 24 May 2024, WIPO member states adopted the GRATK Treaty.[86] This groundbreaking treaty is the first international agreement to address the interplay between IP, TK and genetic resources.[87]

Article 3 of the GRATK Treaty introduces a crucial disclosure requirement.[88] In summary, it provides that when a patent application claims an invention derived from genetic resources, contracting parties must disclose the source of the genetic resource or country of origin.[89] Similarly, if the invention is based on TK associated with genetic resources, disclosure of the indigenous peoples or local communities from whom the TK originated is obligatory.[90]

Although the GRATK Treaty does not explicitly establish a *sui generis* framework for TK protection, it can be considered *sui generis* to the extent that it introduces elements that deviate from the conventional IP system by incorporating the disclosure requirement. However, the treaty's protection of TK is limited compared to the scope of protection offered by the TK Act as discussed under part V. The treaty remains largely rooted within the frameworks of the conventional IP system, primarily focusing on improving the efficacy, transparency and quality of the patent system.[91]

The treaty primarily offers defensive protection for TK. Defensive protection is described as a mechanism that aims to prevent parties outside a traditional community from acquiring the IP rights over TK.[92] The treaty establishes a disclosure requirement which aims to prevent the erroneous grant of patents for inventions derived from genetic resources and

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[84] Ibid.
[85] Ibid at 67.
[86] WIPO 'WIPO Member States Adopt Historic New Treaty on Intellectual Property, Genetic resources and Associated TK', available at: *https://www.wipo.int/pressroom/en/articles/2024/article_0007.html*, accessed on 3 September 2024.
[87] Ibid.
[88] WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge (GRATK/DC/7, Geneva, 13 May 2024) art 3.
[89] Ibid.
[90] Ibid.
[91] Ibid.
[92] WIPO 'Traditional Knowledge and Intellectual Property' available at: *https://www.wipo.int/edocs/pubdocs/en/wipo_pub_tk_1.pdf*, accessed on 20 January 2025.

associated TK.[93] In contrast to the TK Act, the treaty falls short in establishing positive protection mechanisms. These mechanisms would encourage communities to promote their TK, control its use and benefit from its commercial exploitation through provisions related to access and benefit-sharing.[94] It could be argued that the lack of positive protection stems from resistance by influential stakeholders from developed countries who prioritise individual ownership and economic gain.

Although the treaty aims to establish a comprehensive framework for the protection of IP, genetic resources and associated TK, it is important to evaluate the extent to which it addresses three main concerns. First, the intangible aspects inherent in TMK. While the treaty does not directly address the intangible aspects of TMK, the requirement to disclose the origin of utilised TK indirectly recognises their significance. By mandating patent applicants to identify the source of TMK, the treaty ensures a degree of respect for the intangible elements within the patenting process.

The second concern is the communal ownership of TMK. The treaty acknowledges the communal nature of TMK to the extent that it requires the disclosure of the indigenous group or local community who provided the TMK.[95] However, the treaty falls short in addressing how communal ownership should be protected beyond the disclosure requirement.

The last concern pertains to determining ownership of IP rights when collective heritage is used for innovation. Although the disclosure requirement promotes transparency about the sources of TK, it does not provide for how ownership derived from TK is determined. This may lead to disputes over ownership and benefit-sharing particularly where multiple parties claim rights on innovations which are based on shared TMK.

While the treaty is narrow in its protection of TMK, it is important to highlight that it allows for broader national regulations.[96] This allows for national laws to expand the scope of protection, address the three concerns and contribute to protecting TMK in South Africa.

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[93] WIPO 'Diplomatic Conference to Conclude an International Legal Instrument Relating to Intellectual Property, Genetic resources and Traditional Knowledge Associated with Genetic resources', available at: *https://www.wipo.int/diplomatic-conferences/en/genetic-resources/index.html*, accessed on 3 October 2024.
[94]WIPO op cit note 86.
[95] Jefferson, David J. "The World Intellectual Property Organization Treaty on genetic resources and traditional knowledge: Implications for plant science." *Plants, People, Planet* (2024), available at: *https://doi.org/10.1002/ppp3.10615* ,accessed on 25 February 2025.
[96] Syam, Nirmalya and C. Correa. "Understanding the new WIPO Treaty on intellectual property, genetic resources and associated traditional knowledge." *Policy Brief* (2023) available at: *https://www.southcentre.int/wp-content/uploads/2024/07/PB131_Understanding-the-New-WIPO-Treaty-on-Intellectual-Property-Genetic-Resources-and-Associated-Traditional-Knowledge_EN.pdf23* accessed on January 2025.

(d) The shortcomings of the conventional IP framework

Protecting TMK within the conventional IP system presents a complex and critical issue regarding the intersection of customs, law and innovation. The unique characteristics of TMK make it difficult to fit into the conventional IP system. This section discusses the shortcomings of patents and trade secrets for protecting TMK.

(i) Patents

A patent is defined as:

> 'An exclusive right granted for an invention, which is a product or a process that provides, in general, a new way of doing something, or offers a new technical solution to a problem.'[97]

A patent may be granted for any new or novel invention that involves an inventive step and is capable of being used or applied in industry, trade, or agriculture.[98] This exclusive right usually extends for 20 years from the date of the application.[99] A patent allows the inventor to benefit from the invention by preventing others from using, making or commercially exploiting the patented invention without permission.[100]

TMK holders encounter significant challenges in meeting the requirements of novelty and inventiveness, as most traditional medicines have been used for generations and are known to local communities, potentially disqualifying such knowledge from patent protection.[101] Furthermore, because traditional medicines are typically naturally occurring substances, often excluded by patent law, proving an inventive step is challenging.[102] In comparison to pharmaceutical medicine, the process of altering the natural composition of traditional medicine often deems it eligible for patent protection.[103] The patent system standard of novelty favours altered natural substances over naturally occurring substances inherent in TMK. This allows for patenting of modified natural substances while excluding the natural and communally known substances from patent protection.

It is argued that the conventional IP system with its emphasis on individual ownership enables the misappropriation of TMK.[104] TMK does not particularly conform to the

[97] WIPO 'Patents 'available at: *https://www.wipo.int/web/patents*, accessed 22 July 2024.
[97] Ibid.
[98] Act 57 of 1978 s25.
[99] Act 57 of 1978 s 46.
[100]WIPO op cit note 13 at 4.
[101] Ibid at 5.
[102] Ibid.
[103] Ibid.
[104]Amechi op cit note 16 at 3073.

conventional IP system, since such knowledge has existed for generations, therefore failing to meet the threshold for novelty.[105]

Overall, the shortcomings of the patent law fail to recognise and accommodate alternative cultural and non-Western scientific narratives in the patenting process.[106] The inadequacy identified in patents has resulted in scepticism from indigenous communities, which call for a TMK inclusive system.[107]

(ii) Trade Secrets

TMK can be protected as confidential information provided it meets the requirements discussed under part III*(b)(ii)*. However, there are inherent difficulties for TK holders who seek to rely on trade secrets to protect TK.[108] Since trade secrets are generally protected through the laws of delict and contract, secrecy alone is insufficient to protect TK in the South African context.[109] The legal remedies offered by delict and contract are not as useful in instances where information has been disclosed, as they are time-consuming and costly to enforce.[110] Furthermore, the legal remedies offered by contract and delict cannot address instances where secrecy is lost through independent research or without blameworthiness.[111] It is suggested that TK holders should consider alternative means of protection and consider trade secrecy as a supplementary measure of protection rather than a primary mechanism.[112]

The commercialisation of TMK by multinational companies poses a significant threat. When TK is extracted and commodified without respect, it diminishes the cultural significance of that knowledge. Furthermore, IP laws restrict availability of TMK to the very communities that have historically depended on it. In instances where TK is reclassified under the conventional IP framework, holders find themselves barred from using their knowledge, resulting in further deprivation and marginalisation.

IV UNDERSTANDING THE *SUI GENERIS* FRAMEWORK

A *sui generis* framework is designed to address the unique characteristics and needs for protecting TK, which often does not fit adequately within the conventional IP system. The

[105] Oseitutu op cit note 2.
[106] Ibid at 3072.
[107] Ibid.
[108] Lee-Ann Tong 'Protecting traditional knowledge – Does secrecy offer a solution?' (2010) 13 *PELJ* 174.
[109] Ibid.
[110] Ibid.
[111] Ibid.
[112] Ibid.

concept of a *sui generis* framework for protecting TK dates as far back as 2001.[113] During WIPO's second session, the African-led group proposed establishing categories of TK that could be protected under existing legislation while developing a specialised system for comprehensive protection.[114] In response, during the third session in 2002, WIPO prepared a paper outlining the elements of a *sui generis* framework aimed at protecting TK.[115]

In the context of the IP system, the term *sui generis* refers to a special kind of protection that falls outside the conventional IP system.[116] What makes an IP system *sui generis* is the modification of some of its qualities to accommodate the unique characteristics of its subject matter. [117]

The framework must integrate several key elements, beginning with clear policy objectives. These objectives must define the framework's goals, ranging from defensive protection against misappropriation to broader objectives aligned with the Convention on Biological Diversity, particularly regarding fair and equitable benefit-sharing arising from the use of genetic resources.[118]

Secondly, the framework must identify both the subject matter requiring protection and its relationship to the policy objectives.[119] Approaches to defining this scope of protection may include an open-ended list of eligible TK elements, either as a general concept redefined through national laws or an inclusive approach encompassing a type of TK, subject to refinement of the eligibility criteria.[120]

Thirdly, a crucial aspect involves outlining the eligibility criteria for protection.[121] Given the broad definition of TK, not all forms of TK would necessarily be eligible for protection under the *sui generis* framework. Therefore, it is important to determine the requirements for such protection.

Fourthly, the framework must address the issue of ownership of TK.[122] IP rights originally vest in individual originators who may transfer their rights by way of contracts or

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[113] WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, *Elements of a Sui Generis System for the Protection of Traditional Knowledge* (WIPO/GRTKF/IC/3/8, 2002).
[114] Ibid.
[115] Ibid.
[116] Moni Wekesa 'What Is Sui Generis System of Intellectual Property Protection? '(2006) *African Technology Policy Studies Network 3.*
[117] WIPO/GRTKF/IC/3/8 at 13.
[118] Convention On Biological Diversity, Development of Elements of Sui Generis Systems for the Protection of Traditional Knowledge, Innovations and Practices (UNEP/CBD/WG8J/4/7, 24 November 2005) art12.
[119] WIPO/GRTKF/IC/3/8 at 23.
[120] Ibid.
[121] Ibid
[122] Ibid.

alternative legal arrangements.[123] Considering the nature of TK, a similar rationale would suggest that rights in TK be vested in the communities as collective rather than individuals. [124]

Fifthly, the framework must define what rights it protects.[125] TK encompasses artistic, cultural, technical and medical aspects. TK rights should include both economic and moral rights.[126] Strong moral rights are crucial for preserving the cultural identity and protecting non-commercial aspects of TK.[127] TK rights should be transferable to enable benefit-sharing and include exceptions for academic or private use.[128]

The sixth element asks the question how the rights are acquired and enforced.[129]This could be achieved by creating mechanisms for registration, implementing measures to prevent unauthorised use and/or documentation.[130] Moreover, the *sui generis* framework should be designed to incorporate means of enforcement such as remedies for violation which could consist of prohibitions against improper use or monetary compensation.[131]

Lastly, the framework must outline the duration for protection. Many national laws favour indefinite protection, acknowledging the intergenerational nature of TK.[132] However, limited protection may apply for commercially exploitable elements of TK for the purpose of balancing the incentive to innovate and protecting TK holder's interests while preventing indefinite monopolies.[133]

V SOUTH AFRICA'S *SUI GENERIS* FRAMEWORK

Nationally, South Africa has supported developing countries' stance at WIPO, advocating for *sui generis* legislation as the preferred form TK protection. On the 12th of August 2019, the TK Act was signed into law. The adoption of the TK Act represents a groundbreaking development in South Africa's legal framework as it is a *sui generis* legislation designed to safeguard TK.

The Act seeks to protect TK from unauthorised use and misappropriation.[134] It also aims to foster equitable benefit-sharing, promoting commercial use of indigenous knowledge in the development of new services, products, processes and the recognition of prior art under

[123] Ibid at 24.
[124] UNEP/CBD/WG8J/4/7 art 17.
[125] WIPO/GRTKF/IC/3/at 25.
[126] Ibid.
[127] Ibid.
[128] Ibid at 26.
[129] Ibid at 29.
[130] Ibid.
[131] Ibid.
[132] Ibid.
[133] Ibid.
[134]Protection, Promotion, Development and Management of Indigenous Knowledge Act 6 of 2019 s3.

the law of IP.[135] The Act establishes the National Indigenous Knowledge Systems Office (NIKSO) within the Department of Science and Technology to implement its provisions.[136]

Section 9 protects registered TK as property outlined under s25 of the Constitution of South Africa 1996.[137] Section 11 outlines three criteria for protection. First, the TK must have been passed from generation to generation.[138] This requirement acknowledges the cultural and historical continuity of TK within a community, emphasising its intergenerational nature. In contrast, the conventional IP systems require inventiveness and novelty, focusing on individual creations that do not align with communal and historical transmission of TK.

Secondly, the knowledge must have been developed within a community.[139] This recognises the ongoing process of developing TK rooted in the community cultural experiences and practices. The conventional IP system, on the other hand, often requires an inventive step, focusing on the individual inventor.[140] Development is usually attributed to a single inventor or a defined group, which does not reflect the communal evolution of TK.

The last criterion is association with the social and cultural identity of the indigenous community.[141] This emphasises the link between TK, cultural heritage and social practices. The conventional IP frameworks, however, are primarily focused on market value, often neglecting the social and cultural significance of TK.

The term of protection runs for as long as the indigenous knowledge meets the criteria set out in s11 of the Act.[142] In contrast to the conventional IP systems, protection is typically granted for a fixed period, for example, 20 years for patents. If indigenous knowledge ceases to meet the eligibility criteria, it falls into the public domain from the date on which eligibility was proven.[143]

Section 13 of the TK Act grants exclusive rights to any benefits that arise from its commercial use, acknowledgment of its origin and limitations of any authorised use of the knowledge.[144] This ensures that communities are fairly compensated and recognised for their TK.

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[135] Ibid.
[136] Act 6 of 2019 s4.
[137] Act 6 of 2019 s9.
[138] Act 6 of 2019 s11(a).
[139] Act 6 of 2019 s11(b).
[140] Act 57 of 1978 s25.
[141] Act 6 of 2019 s11(c).
[142] Act 6 of 2019 s10(1).
[143] Act 6 of 2019 s10(2).
[144] Act 6 of 2019 s13.

A licence may be granted to external or third parties who wish to use the indigenous knowledge by applying in the prescribed manner and by entering into a licence agreement with the trustee of the relevant indigenous community as facilitated by NIKSO.[145] The Act further provides that NIKSO must consult with the relevant trustee regarding the licence agreement for the intended use of the indigenous knowledge and the benefits which the licence holder would be liable to pay.[146]

The TK Act protects the rights of the indigenous communities as holders of their knowledge by establishing a Dispute Resolution Committee, offenses and penalties. Section 27 of the Act provides that subject to the prescribed terms and conditions, the Minister may appoint members of a Dispute Resolution Committee with the duty of resolving any disputes that may arise from the Act on an ad hoc basis.[147] When resolving a dispute, the committee is obligated to consider customary laws relevant to the subject matter of the dispute.[148] Any party involved in a dispute may appeal to the High Court for a review.[149] Furthermore, the committee has the authority to impose sanctions such as warnings, prohibiting the unauthorised use of indigenous knowledge and recommending to NIKSO to cancel, suspend or revoke licensing rights. These measures ensure a controlled and organised approach to managing disputes under the Act.[150]

The TK Act is a significant milestone in South Africa's legal framework in establishing a standalone *sui generis* legislation which seeks to protect various forms of traditional knowledge including TMK. Considering the brief overview of the TK Act, it is carefully designed to accommodate to the unique characteristics of TK.

In contrast to the conventional IP system, the *sui generis* framework is significant for its recognition of the cultural importance of TK by acknowledging communal ownership and perpetual protection. One of the key components of the framework is its emphasis on providing positive protection. Pharmaceutical companies have long exploited TMK for commercial gain without compensating the rightful traditional communities that have preserved this knowledge for generations. This framework necessitates fair distribution of commercial benefits derived from the use of TK and facilitates inclusivity, allowing for community participation in the processes of knowledge production.

[145] Act 6 of 2019 s26.
[146] Ibid.
[147] Act 6 of 2019 s27.
[148] Ibid.
[149] Ibid.
[150] Act 6 of 2019 s27(4).

VI THE SHORTCOMINGS OF SOUTH AFRICA'S *SUI GENERIS* FRAMEWORK

The promulgation and implementation of the TK Act represents a significant step toward safeguarding TK. Despite its noble intentions, the dynamic nature of TMK poses a complex challenge even for South Africa's *sui generis* framework. This section explores the major shortcomings of the TK Act in protecting TMK.

(a) Uncertainty on section 13 exclusive rights

As mentioned, s13 provides for exclusive rights of indigenous communities. Tong highlights a few complexities and ambiguities surrounding the implementation and enforcement of exclusive rights vested in indigenous communities.[151]

First, s13(2) provides for the exclusive rights to any benefit arising from commercial use of TK, requiring third parties to apply for a licence from NIKSO.[152] Tong highlights that there is no clear indication of whether the default licence is exclusive or non-exclusive, or whether the community has full discretion over the terms.[153] In other words, it is unclear whether the licences issued by NIKSO allow one or multiple third parties to use the TK.

Secondly, Tong considers the right to be acknowledged as the origin of traditional knowledge. She highlights that this provision places an obligation on licence holders to declare the community or geographical place from which the TK originated.[154] She argues that it is uncertain whether, in other circumstances, the community must claim this entitlement or whether there is an obligation to declare the community at every instance of use.[155]

Lastly, Tong analyses the right to limit any unauthorised use, arguing that the lack of a clear definition for the term 'use' raises significant questions.[156] Although the TK Act defines commercial use as 'the use of indigenous knowledge for financial gain,'[157] such a definition is insufficient in clarifying what constitutes the term "use" in a broader context.[158] Consequently,

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[151] Lee-Ann Tong 'South Africa adopts sui generis indigenous knowledge protection legislation' (2019) 14 *Journal of Intellectual Property Law & Practice* 936.
[152] Act 6 of 2019 s13(2).
[153] Tong op cit note 151 at 936.
[154] Ibid.
[155] Ibid.
[156] Ibid.
[157] Act of 2019 s1.
[158] Tong op cit note 151 at 936.

users may find it difficult in understanding what actions require consent, especially in cases where an independent creation resembles the TK.[159]

In the context of TMK, the lack of clarity regarding unauthorised use may raise potential conflicts and critical questions. Consider an instance where an individual independently develops a health product that incorporates elements of TMK without obtaining PIC from the relevant indigenous community. On the one hand, it could be argued that the mere incorporation of the TMK into the product, irrespective of how it was acquired, constitutes use and therefore requires consent. On the other hand, an opposing argument could contend that if a product is developed independently without direct reference to a specific TMK origin, it does not fall under the protection of indigenous knowledge and within the scope of the Act.

(b) Fragmented legal frameworks

As observed, TMK is protected by statutes such as the NEMBA, the Patents Amendment Act and under the conventional IP system such as patents and Trade Secrets. This would raise the question of where the TK Act finds itself amongst established legislation? Section 32 of the TK Act answers this question, providing that the Act does not alter or detract from any right in respect of any statute or the common law.[160] Section 32(2) further provides that following the procedures or requirements outlined in the Act does not mean that the procedures or requirements in other Acts are automatically satisfied.[161]

Section 32 implies that any creation or innovation that relates to TK may result in it being regulated by more than one law.[162] This has the potential to cause confusion for users and indigenous communities as innovations that involve TK may fall under the jurisdiction of various legal frameworks.

Kariyawasam and Guy noted that the considerable overlap with existing IP laws and *sui generis* laws often causes confusion for litigants and creates uncertainty in the law.[163] The fragmentation of laws creates a challenge whereby individuals or organisations that intend to utilise TK, struggle to navigate a complex maze of legal obligations. Consequently, this discourages TK users and holders from understanding their rights, responsibilities and procedures to comply with.

[159] Ibid.
[160] Act 6 of 2019 s32(1).
[161] Ibid.
[162] Tong op cit note 151 at 937.
[163] Kanchana Kariyawasam & Scott Guy 'Intellectual Property Protection of Indigenous Knowledge: Implementing Initiatives at National and Regional Levels' (2008) 12 No2 *Deakin Law Review* 114 .

For example, an indigenous community develops a traditional remedy to treat headaches. This remedy has been passed down through generations and they wish to protect this knowledge. The TK Act provides a framework for protecting the TMK, which includes the provision for the registration of the TK and protection afforded under the Act. Given that the remedy involves the use of natural resources, NEMBA may also apply. The community may also consider protecting the TMK as a trade secret where such knowledge is privy to a group of people within a community and steps are taken to prevent disclosure. Where a traditional healer develops a new formulation for the remedy, patent law may apply when the requirements of inventiveness and novelty have been met.

This hypothetical example demonstrates the potential confusion as to which law to follow when protecting TMK. Confusion may arise when determining whether the TK Act provides sufficient protection or if compliance with either NEMBA or patent law is also required. In addition, complying with multiple laws can be expensive and time-consuming considering that the community would need to register their TMK under the TK Act, file patent applications and obtain licences or permits in terms of NEMBA.

Additionally, parties falling outside of indigenous communities who have been making commercial use before the commencement of the TK Act are subjected to Section 33 of the Act, which provides for the following:

> '(1) An indigenous community wishing to register indigenous knowledge already in existence at the time of commencement of this Act, must register such indigenous knowledge in terms of this Act.
>
> (2) Any continued use of indigenous knowledge, after the commencement of this Act, must be regulated in terms of a licence agreement between the trustee of the relevant indigenous community and the potential licence holder, entered into within 12 months from the date of commencement of this Act.'[164]

This section does not provide a clear indication on whether users who relied on TMK prior to the commencement of the Act will be granted a licence to continue using the knowledge or will find themselves in a challenging position of renegotiation of the terms and agreements.

(c) Ownership of Traditional Knowledge

The TK Act defines indigenous communities as recognisable people who historically settled or developed from a certain geographical area or are located within the Republic.[165]Such people

[164] Act of 2019 s33.
[165] Act 6 of 2019 s1.

are characterised by their economic, social and cultural conditions, which distinguish them from other sections of the national community and they distinctively identify themselves as a collective.[166] However, it is not uncommon for varying indigenous communities to share similar practices and knowledge. Therefore, an issue may arise where an item of knowledge is shared amongst different indigenous communities.

Kariyawasam and Guy noted that one of the inadequacies presented by a *sui generis* framework is the identification of the owner of the knowledge in instances where the knowledge belongs to more than one region, community or territory.[167] However, where a dispute arises, the Dispute Resolution Committee is tasked with resolving any issues that arise and are guided by customary laws that have a bearing on the subject matter of the dispute.[168]

The TK Act acknowledges the communal nature of TK, which is typically held in groups rather than by individuals. Communal recognition is crucial as it recognises the collective and cultural identity of communities that develop and maintain this knowledge over generations. However, this presents a significant gap by failing to address individual protection rights.

As rightfully pointed out by Zondi, purely focusing on *sui generis* legislation for the protection of TK has the potential to stagnate indigenous culture because individual creation is not encouraged.[169] This argument is particularly relevant to TMK given that it can be held by individuals such as 'sangomas' or 'inyanga' who have developed remedies. Where TMK is protected under a *sui generis* framework, there may be less emphasis on individual contribution as exemplified by the TK Act. Although individual innovations by traditional healers reflect the collective heritage of the community, the TK Act falls short in answering the question to what extent individual TMK is protected under the Act. Over time this could lead to stagnation of TMK as there may be fewer incentives for individuals to continue exploring and expanding TMK.

In order to continually protect and develop TMK, it is essential to strike a balance between protecting collective TK as well as recognising individual contributions. This may be made possible through a combination of the *sui generis* regime and other IP frameworks such

[166] Ibid.
[167] Kariyawasam op cit note 163.
[168] Act 6 of 2019 s 27(2).
[169]Nokwanda Bathabile Zondi A dissection of the Protection, Promotion, Development and Management of indigenous Knowledge Systems Act 6 of 2019: substantive issues and foreseeable.
consequences for creative industries in South Africa (LLM thesis, University of Cape Town 2021) 22.

as patent protection or trade secrets, that accommodate individual innovation while safeguarding collective TMK.

(d) Exclusive Jurisdiction

Section 1 of the TK Act provides that the Act applies to all persons in the Republic, including the State.[170] The Act does not entirely apply outside of the Republic. This means that indigenous communities cannot rely on national legislation to claim commercial benefits of their TMK when utilised by pharmaceutical companies outside the Republic.

The global nature of the pharmaceutical industry permits multinational companies to access resources and TK, often without the consent of the indigenous communities. In cases where TMK leads to the development of successful drugs, these pharmaceutical companies make large profits without compensating the originating indigenous communities. The inability to enforce protection beyond the borders of the republic results in a loss of control over TMK, undermining the cultural integrity and value of such knowledge.

This issue highlights the compelling need for implementing international frameworks for the protection of TK. International legal frameworks such as the Convention on Biological Diversity and the Nagoya Protocol offer guidelines on benefit-sharing and bioprospecting that include TK rights.[171] The GRATK Treaty may protect TMK to the extent of providing defensive protection through the disclosure requirement.

(e) Enforcement

Section 28 of the TK Act makes provision for the enforcement of rights. It stipulates that a third party who knowingly and commercially uses TK in a manner not agreed upon with the indigenous community, thereby infringing upon their rights, shall be guilty of an offense and upon conviction, be liable to a fine.[172] As Zondi argues, the fines for violations of TK rights may prove inadequate for effective enforcement, because they often fail to sufficiently redress TK holders.[173] Furthermore, considering that the TK Act applies territorially, those who infringe from outside the Republic may be beyond the reach of financial penalties.[174]

[170]Act 6 of 2019 s1.
[171] Biosafety Unit 'The Nagoya Protocol on Access and Benefit-Sharing', available at: *https://www.cbd.int/abs/default.shtm*l, accessed on 1 October 2024.
[172] Act of 2019 s28.
[173] Zondi op cit note 169 at 23.
[174] Ibid.

Zondi further argues that civil suits may offer a viable solution to this issue, enabling TK holders to seek damages, restraining orders, or reasonable royalties on profits attributable to the infringement.[175] In support of this argument, it can be argued that civil suits could effectively combat biopiracy, the unauthorised use and exploitation of genetic resources and TK. In this context, civil suits may play a crucial role in preventing pharmaceutical companies from misappropriating TMK without authorisation or compensation.

However, it is important to acknowledge that civil litigation presents its own set of challenges. Pursuing civil litigation can be complex and expensive, particularly for indigenous communities with limited resources and legal expertise. The defendants of infringement are likely to be large corporations with substantial financial resources to access the best legal services.[176] This power imbalance remains a significant concern in the context of TMK protection, given that pharmaceutical companies often possess considerable financial and legal resources compared to TK holders. Another challenge posed by civil litigation is the adversarial nature of the legal process, which may not always align with the values and principles embedded within customary laws.[177] Therefore, it is paramount to develop alternative dispute resolution mechanisms that are not only efficient but also culturally sensitive.

(f) The suitability of the sui generis framework for protecting TMK

There are three general views on the protection of TK. As Dean puts it, the first view is that special protection is not required and the existing IP laws provide adequate protection to TK.[178] A second view, acknowledges the adequacy of existing laws, however provision should be made in instances where third parties claim rights over property and the rights of traditional communities to continue using their TK should not be affected.[179] Lastly, the third view advocates for a special form of protection, particularly positive protection which is adapted under a *sui generis* legislation as well as amending existing IP laws to afford special protection for TK.[180] In light of this, the report favours the third approach for the protection of TMK.

While the *sui generis* framework addresses many shortcomings of the conventional IP systems in protecting TMK, it has its limitations. The TK Act represents a significant step in

[175] Ibid.
[176] Ibid.
[177] Ibid.
[178] Xoliswa Mpanza 'Intellectual Property Laws and the Protection of Traditional Knowledge in South Africa: An evaluation of the current Intellectual Property system and its protection of Traditional and Indigenous Knowledge' (LLM thesis, University of Kwazulu-Natal 2014) 11.
[179] Ibid.
[180] Ibid.

acknowledging the unique nature of TMK and establishing a tailored framework for protecting various forms of TK. However, the *sui generis* framework is disadvantaged by ambiguities in implementation, jurisdictional limitation and potential conflicts with current legal framework aimed at protecting TMK.

As observed, the *sui generis* approach is indeed more aligned with holistic nature of TMK. The *sui generis* framework caters for indigenous perspectives on ownership of TMK, offers more comprehensive protection in terms of duration and recognition of cultural significance. Generally, developed countries are observed to be the primary perpetrators of biopiracy.[181] Therefore, the effectiveness of the *sui generis* framework is limited by its national scope when TMK is exploited across national borders.

In light of these considerations, it becomes apparent that neither *sui generis* nor the conventional IP system alone provides a comprehensive solution for the protection of TMK. An ideal solution could be a hybrid approach that combines both the elements of the conventional IP and *sui generis* regime. This could involve refining the TK Act to address its shortcomings. In order to afford TMK protection beyond national borders, a viable solution would lie in developing comprehensive international agreements that extend protection beyond national borders. Furthermore, such agreements should protect the interest of indigenous communities by not only affording defensive protection but by also ensuring that such communities benefit economically as well.

In light of this, it is recommended that a mixed legal system of *sui generis* protection of TK and the use of the conventional IP system allows for different strategies for protection.[182] Scholars argue that indigenous communities are dynamic, ever-changing and continuously respond to the different historical and socio-economic conditions that shape their experience.[183] Therefore, for certain types of TK, the conventional IP system offers adequate protection. Essentially, a hybrid approach has the potential of recognising the unique nature of TMK while leveraging the strengths and benefits of conventional IP system.

VII CONCLUSION

This report examined the complex challenge of protecting TMK in South Africa, analysing both the conventional IP system and *sui generis* framework established by the TK Act. It revealed that although the *sui generis* framework addressed the major shortcomings of the

[181] Gulati op cit note 25 at 317.
[182] Zondi op cit note 169 at 22.
[183] Ibid.

conventional IP system in protecting TMK, it is not without its challenges. Ambiguities, fragmentation of the legal landscape, challenges related to ownership across communities, limited recognition of individual innovations, enforcement difficulties and territorial constraints pose significant challenges to the effectiveness of the *sui generis* framework.

The report reveals that neither the conventional IP regime nor sui generis framework alone provides a comprehensive solution for the protection of TMK. The conventional IP system struggles to accommodate the communal and intergenerational nature of TMK, while the sui generis framework faces its own shortcomings. Therefore, a hybrid approach that combines elements of both systems may offer the most sufficient protection for TMK. This hybrid approach could involve refining the TK Act to address its current shortcomings, further developing international agreements and integrating appropriate aspects of conventional IP protection.

Moving forward, policymakers could consider developing a hybrid system, ensuring it is flexible enough to adapt to the dynamic nature of TMK, where appropriate. This approach would not only protect TMK more effectively but also promote innovation while respecting the cultural and spiritual significance of TMK. Ultimately, the goal should be to establish a balanced system that protects the rights of indigenous communities, fosters innovation and ensures that the benefits derived from TMK are equitably shared amongst the rightful holders. In an ever-evolving legal landscape, policymakers, academics and the international community will require ongoing conversation with indigenous communities to develop and improve protection mechanisms for TMK.

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