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Legal Protection of Traditional Medicines Against Biopiracy and Misappropriation: Ensuring Fair Benefit Sharing for Local Communities

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Abstract

Indonesia possesses rich traditional medicinal knowledge that has been transmitted across generations and constitutes an essential part of local communities' cultural heritage. However, the modern commercial use of traditional medicines often occurs without fair benefit-sharing, leading to practices such as biopiracy and misappropriation. This research examines the adequacy of Indonesia's legal framework in protecting traditional medicines against such exploitative practices. The findings demonstrate that despite Indonesia's ratification of various international instruments—including the Convention on Biological Diversity, the TRIPs Agreement, and the Nagoya Protocol—legal protection for traditional medicinal knowledge remains fragmented and insufficient. Existing national regulations, particularly Law Number 36 of 2009 on Health and the Patent Law, provide only limited and indirect protection. Patent-based protection is difficult to apply due to the requirements of novelty and inventive steps, which are incompatible with the communal and hereditary nature of traditional knowledge. Although Article 26 of the Patent Law acknowledges traditional knowledge, it fails to offer comprehensive protection or ensure equitable benefit-sharing for local communities. This study concludes that Indonesia urgently requires a specific sui generis or umbrella legal framework to protect traditional medicines against biopiracy and misappropriation while ensuring justice, legal certainty, and fair distribution of benefits.

INTRODUCTION

Over the last decade, the development and protection of traditional knowledge have received significant attention at international, regional, and national levels, particularly regarding its recognition, utilization, and commercialization. The international community has increasingly acknowledged that traditional knowledge constitutes an essential element of cultural identity and

contributes to social welfare, sustainable development, and the preservation of cultural and environmental systems (WIPO, 2005). For many societies, traditional knowledge is inseparable from cultural values, spiritual beliefs, and customary legal systems, making its sustainability a matter of collective importance rather than merely economic interest (Twarog & Kapoor, 2004).

Traditional knowledge has also proven to be a valuable source of innovation, particularly in traditional medicine. Various traditional healing methods and medicinal practices originating from developing countries—such as Brazil, Peru, China, Malaysia, and Korea—have contributed significantly to modern pharmaceutical development (Correa, 2001). Similarly, Indonesia possesses extraordinary traditional medicinal knowledge, including *jamu* and other herbal formulations that have been transmitted across generations and form part of indigenous communities' cultural heritage.

Despite its potential, much of Indonesia's traditional medicinal knowledge remains informally managed by local communities. At the same time, the growing interest of researchers and multinational pharmaceutical companies in utilizing traditional medicine has not been accompanied by fair benefit-sharing mechanisms. This situation has led to practices of biopiracy and misappropriation, where traditional knowledge is used as the basis for commercial products or patent applications without the consent or involvement of the communities from which the knowledge originates. One notable example is the registration of patents related to the development of traditional Indonesian medicines in Japan (Redaksi Kompas, 2000).

Biopiracy and misappropriation represent systematic legal problems arising from the exploitation of traditional knowledge without prior informed consent and without fair and equitable benefit-sharing. Biopiracy generally refers to the appropriation of biological resources and associated traditional knowledge by individuals or corporations, often through the intellectual property system, particularly patents. Misappropriation, on the other hand, emphasizes the unauthorized use of traditional knowledge that disregards its communal ownership and cultural context. In practice, both concepts reveal how existing intellectual property regimes can be used to legitimize unjust control over traditional medicinal knowledge that has long existed within indigenous and local communities.

In the Indonesian context, biopiracy and misappropriation occur primarily due to regulatory gaps and weak enforcement mechanisms. Indonesian law does not explicitly define or criminalize biopiracy, nor does it establish clear procedures for access, prior informed consent, and benefit-sharing in relation to traditional medicinal knowledge. As a result, foreign researchers and corporations are able to access, document, and commercialize traditional medicine with minimal legal constraints at the national level. This legal uncertainty not only disadvantages local communities as the original knowledge holders but also undermines Indonesia's sovereign rights over its biological resources, highlighting the urgent need for a clear and enforceable legal framework to prevent biopiracy and misappropriation of traditional medicines.

The persistence of such practices is closely linked to the absence of adequate and comprehensive legal protection for traditional knowledge in Indonesia. Although Indonesia has ratified several international instruments relevant to the protection of traditional knowledge,

including the Convention on Biological Diversity, the TRIPs Agreement, and the Nagoya Protocol, their principles have not been fully translated into effective national regulations. Existing laws, such as Law Number 36 of 2009 on Health and the Patent Law, provide only partial and indirect protection and are limited by the incompatibility between patent requirements—such as novelty and inventive steps—and the communal, hereditary nature of traditional medicinal knowledge.

In contrast, several countries have developed specific legal mechanisms to address biopiracy and misappropriation, including the establishment of traditional knowledge databases and access and benefit-sharing regimes. These comparative experiences demonstrate the importance of a clear and specific legal framework tailored to the characteristics of traditional knowledge. Based on this background, this article examines the weaknesses of Indonesia's legal framework for protecting traditional medicine as part of traditional knowledge and argues for a more comprehensive legal approach to ensure legal certainty, justice, and fair benefit-sharing for local communities.

These conditions provide a strong basis for this research. First, Indonesia's traditional knowledge, particularly in the field of traditional medicine, possesses clear economic value and has been extensively utilized by developed countries, including the United States and Japan, for pharmaceutical and cosmetic industries without equitable benefit-sharing mechanisms. Second, Indonesia continues to experience structural injustice as a developing country, as its traditional knowledge is not adequately protected under intellectual property regimes, while acts of biopiracy and misappropriation by developed countries persist (Sardjono, 2008). Third, many local and indigenous communities remain unaware of the economic value embedded in the traditional medicinal knowledge they have inherited across generations, leaving them vulnerable and reinforcing the state's responsibility to provide legal protection for their rights.

RESEARCH METHODS

This study employs legal research to examine the legal protection of traditional medicines as part of traditional knowledge against biopiracy and misappropriation in Indonesia. The research applies a statutory approach to analyze relevant international instruments and national regulations, a conceptual approach to examine key legal concepts related to traditional knowledge and benefit-sharing, and a comparative approach by referring to selected countries, such as India and Peru, that have developed specific mechanisms to prevent biopiracy. Legal materials are collected through library research and analyzed using teleological interpretation to assess whether existing legal frameworks effectively protect traditional medicines and ensure justice, legal certainty, and fair benefit-sharing.

ANALYSIS AND DISCUSSION

A. International Conventions on Traditional Medicine

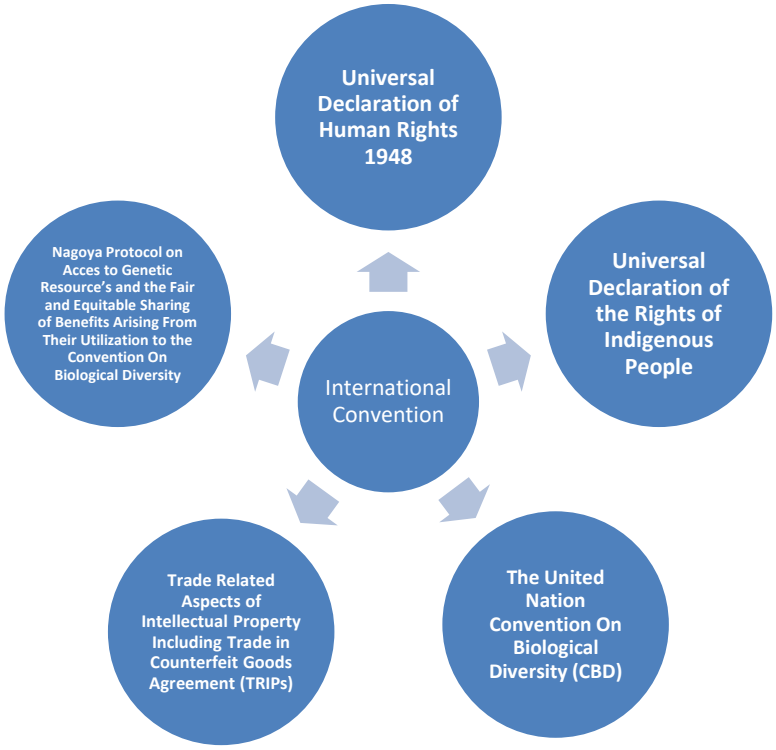
Traditional medicine is part of the broad umbrella of traditional knowledge. Experts are still trying to define traditional knowledge. However, traditional knowledge is a value system in the lives of indigenous peoples, including carving, weaving, medicinal plants and treatments,

plant breeding, and indigenous people's culture. Traditional knowledge encompasses the knowledge, innovative thinking, and practices of indigenous peoples and local communities. Traditional knowledge has certain characteristics that set it apart from common knowledge. It is not rare for non-traditional, generic information to have its roots in traditional knowledge. One such phenomenon is the knowledge of a plane's properties inherited from one's ancestors.

Therefore, traditional knowledge is characterized as a communal and collective right belonging to a community rather than to individuals, and it is transmitted from generation to generation as part of cultural continuity. Traditional knowledge also embodies local wisdom on environmental conservation and the sustainable use of biological resources, reflecting a close relationship between communities and their ecosystems. Its importance has been internationally acknowledged, particularly through its recognition in the 1992 Convention on Biological Diversity. Unlike conventional intellectual property, traditional knowledge is not market-oriented and is generally developed for communal welfare rather than commercial exploitation. Consequently, traditional knowledge is often not recognized within international trade systems, thereby increasing its vulnerability to misappropriation and exploitation (Aini, 2012).

Additionally, WIPO distinguishes Traditional Knowledge into "medicinal knowledge including related medicine and remedies, agricultural knowledge, biodiversity-related knowledge, ecological knowledge, scientific knowledge, folk expressions in the fields of music, handicrafts, movable cultural objects, dance, songs, elements of language."(WIPO, 2001). There are at least five conventions that regulate traditional medicine both generally and specifically.

Figure 1. International Legal Framework



Source: Processed by the Author(s) 2025

Referring to the five international legal frameworks illustrated in Figure 1, the first foundational instrument is The Universal Declaration of Human Rights of 1948. Although this declaration is an integral part of that convention ecosystem, it does not directly address the rights of traditional societies. According to the preamble of this declaration, the disregard and contempt for human rights have resulted in "barbarous acts which have outraged the conscience of mankind, and the advent of a world in which human beings shall enjoy freedom of speech and belief and freedom from fear and want has been proclaimed as the highest aspiration of the common people".

The Universal Declaration of the Rights of Indigenous People provides recognition of the traditional rights of indigenous peoples as regulated in Article 11, and collective recognition of traditional wealth is regulated in Article 31. The UNDRIP affirms that "indigenous peoples are equal to all other peoples, while recognizing the right of all peoples to be different, to consider themselves different, and to be respected as such". This declaration also emphasizes that indigenous peoples, in exercising their rights, must be free from all forms of discrimination, whatever the type.

The United Nations Convention on Biological Diversity (CBD) has established basic principles for managing biodiversity, which are of great significance as a primary ingredient in traditional medicine and as a raw material for medicines developed through genetic engineering. Developing countries recognize the economic value of biodiversity as a source of traditional medicine and its potential for future commercialization, and they recognize the need to improve technological control, protection, and regulation of access to genetic resources, as well as to ensure profit sharing. Developed countries prefer as few limitations as feasible on access to genetic resources. Developed countries highlight that technology held and protected by intellectual property rights, such as patents, cannot be distributed for free (Barber et al., 2002). As a middle ground to reconcile perspectives and in an effort to overcome the multiple difficulties of biopiracy (Khor, 2009; Knight)Therefore, CBD introduced a few basic principles to manage biodiversity.

According to CBD, there are five principles in managing biodiversity:

(1) State Sovereignty Over Genetic Resources. That state sovereignty over natural resources is recognized, and that the national government has the authority to determine access to genetic resources, which is subject to national regulatory laws. This article does not obligate member nations to limit access to genetic resources; rather, it recognizes their genetic resources. It is crucial that the acknowledgment of state sovereignty does not confer ownership rights over genetic resources. This will be the member states' national policy authority.

(2) To facilitate access on genetic resources between Member States. State sovereignty over genetic resources gives participating countries extensive opportunity to control and regulate access to genetic resources, but it is not an absolute right. According to Article 15

(2) of the CBD, each participating nation must aim to create conditions that promote access to genetic resources for use by other participating countries, without imposing limitations that are contrary to the CBD's goals. Participating nations may impose access restrictions on a particular genetic resource for certain reasons and for a limited period, provided they do not violate the terms of the CBD.

(3) The concept of access to genetic resources is subject to the terms of a reciprocal agreement reached by the parties. If access to genetic resources is provided, it will be based on a mutually agreed-upon reciprocal arrangement between the genetic resource supplier and the user. The agreement must be reflected in a formal agreement, such as a Material Transfer Agreement (MTA) or an agreement on the transfer of genetic resource material, which serves as:
   a) Authorized access to genetic resources;
   b) supervision of the further use of genetic resources;
   c) preparation of provisions and procedures for profit sharing (Barber et al., 2002: 363).

(4) Prior Informed Consent (PIC). According to Article 15 (5), to obtain access to genetic resources, the government must first grant authorization based on information submitted by potential users, including how the genetic resources would be collected, used, and transferred to third parties. Pre-approved permissions, as well as the process for acquiring them, must be explicitly set out in national legal rules. Article 15 (5) of the CBD requires the central government to grant authorization.

(5) Fair access and benefit Sharing, the sharing of benefits from the use of genetic resources for parties in various activities:
   a) Participation in scientific research activities;
   b) Profit Sharing from the Commercial Use of Genetic Resources;
   c) Access to genetic resources and technology transfer in the use of the resources;
   d) Participation in biotechnology research based on genetic resources;
   e) Priority access to the results and benefits derived from the use of genetic resources provided for biotechnology research.

The benefit-sharing regulation applies only if the parties are countries. However, the CBD makes no explicit provisions for a situation in which one of the parties to the agreement is a private company. As a result, each country must develop its own approach and negotiate its own agreement on the principle of Fair Access and Benefit Sharing.

The CBD's existence is highly strategic given Indonesia's position as a country with the world's second-largest genetic resources, which are also the primary ingredients in traditional medicine practices. The CBD's framework for managing genetic resources clarifies ownership and regulation of their use. Although the CBD does not explicitly and in detail regulate the recognition of the rights of traditional knowledge holders or traditional medicine. The CBD is an international convention that has been ratified by the Indonesian government through “Law No. 5 of 1994 about Ratification of the United Nations Convention on Biological Diversity”; therefore, the CBD’s basic principles of genetic resource management can be used as a

reference in developing forms of legal protection for traditional knowledge, including traditional medicine, in Indonesia. However, not all of these principles have been incorporated and described in Indonesian national legislation.

The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement provides a legal framework for the regulation of Intellectual Property Rights by imposing stricter obligations on member states while offering greater certainty and flexibility, and exceptions (Cullet (II), 2001).

TRIPs differ from other international agreements, especially those related to environmental, agricultural, and human rights issues, in that they tend to provide greater flexibility. TRIPs focuses more on the commitment of participating countries to implement its provisions. As a result, member countries have little freedom to interpret TRIPs provisions in line with their national interests. Therefore, adjustments are needed to interpret the provisions of TRIPs at the implementation level, in accordance with the situation and conditions of each member country, as regulated in Article 27 of TRIPs.

Article 27, paragraph (1) of TRIPs broadens the scope of patents to all fields of science, including new products and/or processes containing inventive steps that can be used in the industrial sector. The element of novelty is a requirement that must be met in a patent application; thus, if an invention lacks the element of novelty as defined in this Article, it is not an invention. This Article also requires that patent rights be granted and that patent owners enjoy their exclusive rights regardless of where the invention was made, the technological field of the invention, or the Patent-based product, whether produced in the country granting the Patent or imported from another country. The provisions of this Article align with the wishes of multinational companies that oppose exceptions to patentable technological fields and the obligation to produce patent-based goods within the country granting the patent.

Article 27, paragraph (2) of TRIPs clearly stipulates exceptions to patents for reasons of public order or morality; however, the definitions of public order and morality are not clearly defined in TRIPs, despite the fact that they refer to protection for humans, animals, plants, health, and the environment. This paragraph is more similar to how the European Patent Convention (EPC) defines public order and morality. Meanwhile, in Europe, the true meaning or limits of public order and morality have not yet been determined. However, the French government interprets the term public order as a general policy. Meanwhile, the European Patent Office also does not determine how it should interpret the meaning of 'contrary to morality' when it is associated with an invention.

The debate over granting or rejecting patents for genetically modified organisms (GMOs) based on public order and morality exemplifies the term's contrary interpretation. The release of genetically engineered seeds is strongly opposed by European Union member states, who argue that it can harm the environment and endanger human or animal health. Furthermore, representatives of indigenous tribes expressed concerns about multinational corporations' actions in patenting products derived from biological resources communally owned by indigenous tribes, which undermines their economic, moral, and spiritual authority. The

ambiguity of the term, contrary to public order and morality, will cause its own problems, because each member state must interpret the term on a case-by-case basis. This will also have an impact on dispute resolution if, at some point, this becomes a dispute between member states (Mckeough & Stewart, 1997: 16-17).

Article 27, paragraph (3), of TRIPs can be interpreted as follows: in (A), there is no issue, as all member States agree with the article's contents. Meanwhile, in (B) of this Article, there are many controversies surrounding the matter, as there are different perspectives among developing and developed Member States.

There are three major components under Article 27 TRIPs:

(1) Patent exceptions for animals and plants. In general, member States agree on the provisions of Patent exceptions for plants and animals that are bred conventionally;
(2) relating to microorganisms and biological processes essential for producing plants or animals, except that non-biological processes and microbiological processes may be granted patents. This means that TRIPs recognize patents for living things.
(3) the obligation of member states to provide protection for plant varieties either through plant patents or an effective sui generis system or a combination of both. The choice of a sui generis system is an important provision for member states to provide a model law that is certainly different between developed and developing countries. This is what allows developing countries not to apply the legal framework developed by developed countries, or in other words, developing countries have the opportunity to develop a new legal framework in the context of IPR protection by prioritizing the objectives of food security, environmental security, and social interests, so that the requirements in Patent law can be avoided (Blakeney et al., 1999).

The TRIPs Agreement does not address legal protection for traditional knowledge or traditional medicine, but it opens opportunities for developing countries to use existing flexibilities to create patent laws that recognize patents on plants that are the main sources of traditional medicine or the use of genetic resources for medicinal plants. Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity updates and emphasizes the application of the basic principles of the CBD. This Protocol has been ratified by Indonesia through Law No. 11 of 2013 on the Recognition of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization under the Convention on Biological Diversity. The important aspect of the Nagoya Protocol is that it establishes clear regulations for sharing benefits from the commercialization of genetic resources for future knowledge development, including agriculture and medicine.

Following the ratification of various international instruments on traditional knowledge and genetic resources, Indonesia faces significant legal and institutional challenges in translating these commitments into effective national implementation. Although the Convention on Biological Diversity, the TRIPs Agreement, and the Nagoya Protocol provide normative frameworks for access regulation, benefit-sharing, and intellectual property

protection, Indonesia has yet to comprehensively harmonize these principles within its domestic legal system. The absence of a specific, integrated legal framework for traditional knowledge and traditional medicine has led to fragmented regulation across sectoral laws, creating legal uncertainty and weak enforcement. As a consequence, Indonesia remains vulnerable to biopiracy and misappropriation despite its formal compliance with international obligations.

In addition, Indonesia faces structural challenges similar to those encountered by other developing countries, particularly the imbalance of bargaining power between local communities and multinational corporations. The implementation of access and benefit-sharing mechanisms requires strong institutional capacity, legal awareness among indigenous communities, and clear procedures for prior informed consent, all of which remain limited in practice. Moreover, the dominance of patent-based intellectual property regimes under TRIPs continues to place pressure on Indonesia to accommodate commercial interests, often at the expense of communal rights over traditional knowledge. These challenges demonstrate that ratification alone is insufficient to protect traditional medicine and underscore the urgent need for Indonesia to develop a coherent national legal framework that aligns international commitments with local realities and the interests of indigenous and local communities.

B. Regulations on Traditional Medicine in Indonesia

Traditional medicine is not unique to Indonesia; it is also practiced in many countries, including China, several African and Latin American countries, Australia, New Zealand, and Scandinavian states. However, in Indonesia, traditional medicine has a long history and has been practiced since before the colonial period as part of the indigenous communities' cultural heritage. Despite its long-standing existence, the legal recognition and regulation of traditional medicine in Indonesia developed gradually after independence through sectoral health regulations. Below is the definition and the scope of traditional medicine.

Table 1. Definition and Scope of Traditional

No.	Regulation	Description
1.	UU No. 36 Tahun 2009 tentang Kesehatan (Law No. 36 of 2009 Concerning Health).	Health is divided into above: 1. Regular healthcare (*mainstream*); 2. Traditional healthcare: a. Empirical traditional healthcare; b. Complementary traditional healthcare and integrated traditional healthcare. Traditional medicine is part of traditional healthcare.

2.	UU No. 23 Tahun 1992 tentang Kesehatan (Law No. 23 of 1992 Concerning Health).	Traditional medicine is treatment and/or care using methods, medicines, and healers that draw on hereditary experience and skills, and are applied is accordance with the norms of the society.
3.	UU No. 36 Tahun 2016 tentang Tenaga Kesehatan (Law No. 36 of 2016 Concerning Healthcare Workers).	Rules on the legal status of traditional healers.
4.	Peraturan Presiden No. 72 Tahun 2012 tentang Sistem Kesehatan Nasional (Presidential Decree No. 72 of 2012 Concerning National Health System).	Complementary traditional medicine services are a subsystem of health efforts.
5.	Peraturan Pemerintah No. 103 tahun 2014 tentang Pelayanan Kesehatan Tradisional (Governmental Regulation No. 103 of 2014 Concerning Traditional Healthcare Services).	Traditional health services are divided into 3 forms: 1. Empirical traditional healthcare services; 2. Complementary traditional healthcare services; 3. Integrated traditional healthcare services.

Source: Processed by the Author(s)2025

According to WHO, Traditional Medicine is a set of knowledge, skills, and practices based on theories, beliefs, and experiences from a specific culture, whether or not they can be explained, that are used to maintain health and prevent, diagnose, improve, or treat physical and mental illnesses (WHO, 2009). Meanwhile, Article 1, point 16 of Law No. 36 of 2009 defines Traditional Medicine as "treatment and/or care using methods and medicines that refer to empirically passed down experiences and skills that can be accounted for and applied in accordance with societal norms."

Therefore, the definition of "traditional healthcare services" encompasses several essential elements. It refers to a medical or therapeutic activity that involves the use of specific procedures or medicines rooted in generational experiences and inherited knowledge. Such practices must be empirically accountable, meaning that their benefits and safety can be justified by experience or evidence, and that their application must conform to the norms

prevailing in society (Kartika et al., 2016). Accordingly, not all forms of treatment or care based merely on experience and skills fall within the scope intended by the law; only those that meet empirical standards and do not contravene societal norms are legally recognized. In practice, traditional medicine in Indonesia is widely acknowledged and utilized by the community to fulfill health needs and is often prioritized in disease treatment. It is one of the primary alternatives sought by the public to address health problems, particularly because it is relatively easy to access and more affordable than modern medical treatment.

In order to be widely used by the community, traditional medicine in health services must meet the following criteria:

(1) Traditional medicine is empirical, as its benefits and safety are empirically proven. Empirical traditional medical service can use one treatment method or a combination of treatment methods in one Traditional Empirical Health Services system. While the treatment method is carried out using skills and/or herbs.
(2) Complementary traditional medicine is a traditional health service that employs biocultural and biomedical sciences. Its benefits and safety have been scientifically proven. Complementary Traditional Health Services may employ one or more methods of treatment/care within a single Complementary Traditional Health Services unit. Meanwhile, complementary traditional medicine employs two approaches: skill-based methods such as manual techniques, energy therapy, and/or mental therapy. Meanwhile, those using herbal techniques include plants, animals, minerals, and/or galenic preparations or ingredient combinations.
(3) Traditional integrated treatment is a type of health service that combines conventional and complementary traditional health services.

However, in practice, there are numerous overlaps between traditional medicine and supernatural concepts. Within this context, standards often differ in clarity, reliability, and evidentiary basis, hindering the standardization of quality health services. This situation necessitates further government intervention to regulate and implement appropriate healthcare practices to protect the nation’s citizens.

Traditional medicine, a facet of Traditional Health Services, is used in conjunction with conventional health services to create an efficient, independent, and just society, in line with Indonesia's cultural history and reality. According to the 2010 Basic Health Research, 59.12% of the population, across all ages, genders, and both rural and urban areas, use herbal medicine, a traditional Indonesian medicine. According to the study, 95.60% reported benefits from herbal medicine.

Among the various biodiversity riches, totaling around 30,000 species, there are 1,600 types of medicinal plants with potential as traditional health potion products or modern medicines. Along with the biodiversity mentioned earlier, there are hundreds of different traditional Indonesian healing and/or treatment skills. These potions and skills will be

developed to maintain and improve health, prevent disease, treat illnesses, and enhance quality of life, in accordance with the healthy paradigm and treatment efforts.

The government transforms traditional health services based on a comprehensive biocultural body of knowledge into a traditional Indonesian health service system that adheres to the community's religious and cultural norms. Traditional health services are a treatment/care system based on the philosophy and fundamental concept of the whole person, meaning that patients/clients are viewed holistically and culturally, and are treated more humanely.

With this approach, traditional health services will complement modern services that emphasize a more biomedical approach, creating synergy across health services in Indonesia. Traditional health services that use methods grounded in empirically accountable hereditary experiences and skills, in accordance with the religious and cultural norms of the community, are developed scientifically through efforts to scientize their products and practices, and to build academic competence for Indonesian traditional healers as part of the health workforce. It will also develop complementary medical services so that all components (health workers, their practices, and traditional health products) are more widely accepted and recognized by the wider community for their benefits, quality, and safety.

> "The right to life, the right not to be tortured, the right to freedom of the individual, to freedom of thought and conscience, the right not to be enslaved, the right to be acknowledged as an individual before the law, and the right not to be prosecuted retroactively under the law are human rights that cannot be diminished under any circumstances whatsoever."

C. Protection of Traditional Medicine as Traditional Knowledge: A Comparison between Indonesia and Several Countries in Addressing Biopiracy and Misappropriation

1. Protection of Traditional Medicine in Indonesia

Indonesia has integrated traditional health services into its national health system by referring to the World Health Organization (WHO) Traditional/Complementary Medicine Strategy 2014–2023. This policy reflects state recognition of traditional medical practices as part of formal health-care services. However, such recognition has not been accompanied by adequate legal instruments to protect raw materials for traditional medicines and traditional healing knowledge held by indigenous communities.

Compared to several other jurisdictions—such as African countries, Australia, New Zealand, Scandinavian countries, and South American countries—Indonesia lags behind in recognizing traditional medicine as legally protected traditional knowledge under intellectual property-related frameworks (Oguamanam, 2006). In these countries, medicinal plant resources and traditional healing techniques are increasingly acknowledged as deserving of specific legal protection. The renewed global interest in traditional medicine is closely linked to developments in pharmaceutical research and the rapidly expanding herbal medicine market. Discoveries of bioactive compounds derived from plants, such as turmeric and taxol, have reignited industrial and commercial interest

in traditional medicinal knowledge, particularly as potential sources of anti-cancer agents (Hansen, 2011). This development has simultaneously intensified concerns over biopiracy and misappropriation of traditional knowledge, prompting resource-rich countries to seek appropriate legal protection models.

Despite WHO's historical role in promoting traditional medicine—beginning with WHO Resolution 29.72 (1970) and reinforced through subsequent initiatives such as the Beijing Declaration on Traditional Medicine (2008)—the organization has been criticized for its limited success in empowering traditional medical systems. This limitation stems from its continued reliance on Western biomedical paradigms and the absence of binding international legal instruments specifically governing the protection of traditional medicine (Oguamanam, 2006). Consequently, states remain responsible for developing domestic legal mechanisms to protect traditional medicinal knowledge.

In Indonesia, the most relevant legal instrument remains Law Number 13 of 2016 on Patents. Article 26 of the Patent Law requires disclosure of the origin of genetic resources and/or traditional knowledge in patent applications. However, this obligation is administrative in nature and does not provide substantive protection for traditional medicine as traditional knowledge. The provision does not further elaborate on the scope or legal consequences of such disclosure, particularly in relation to traditional medical knowledge, rendering it insufficient to prevent biopiracy and misappropriation.

The patent regime is fundamentally designed to protect individual inventions that are novel, involve an inventive step, and are industrially applicable. These requirements are incompatible with the nature of traditional medicine, which is communal, transmitted intergenerationally, and cannot be attributed to a specific inventor or a clearly identifiable time of creation. Traditional medical practices constitute a collective body of experience that has long been known within communities, making it difficult to satisfy the novelty and inventiveness requirements under patent law (Saidin, 1997). Moreover, the requirement of industrial applicability is problematic, as traditional medicine is not generally intended for standardized mass production. Healing methods and medicinal compositions often vary among practitioners and are adapted to local knowledge systems and cultural contexts. As a result, applying patent protection to traditional medicine risks transforming communal knowledge into individual property, potentially generating horizontal conflicts between patent holders and indigenous communities.

Trade secret protection is similarly ineffective in this context. While Indonesian law recognizes trade secrets under Law Number 30 of 2000, such protection requires confidentiality, economic value, and reasonable efforts to maintain secrecy (Antariksa, 2012). Traditional medical knowledge, however, is typically disseminated openly within communities as part of cultural transmission. Once knowledge enters the public domain or is shared across generations without confidentiality safeguards, it no longer qualifies for trade secret protection. This condition significantly limits the applicability of the trade secret regime in protecting traditional medicine. Overall, reliance on conventional

intellectual property regimes—particularly patents and trade secrets—fails to accommodate the communal, cultural, and intergenerational characteristics of traditional medicine in Indonesia. This legal mismatch underscores the need for alternative protection mechanisms that recognize indigenous communities as collective rights holders and prevent the continued misappropriation of traditional medicinal knowledge.

2. Approaches Adopted by Other Countries in Protecting Traditional Medicine

In contrast to Indonesia, several countries have developed more progressive legal approaches to protect traditional medicine as an integral part of traditional knowledge. Countries in Africa, Australia, New Zealand, Scandinavia, and South America generally recognize that traditional medicinal resources and healing techniques constitute knowledge deserving of special legal protection, beyond the confines of conventional intellectual property regimes (Oguamanam, 2006).

This recognition has been driven in part by renewed global interest in traditional medicine following the discovery of bioactive compounds derived from plants, such as turmeric and taxol, as well as the rapid expansion of the herbal medicine market (Hansen, 2011). As a result, states possessing medicinal plant genetic resources have increasingly sought legal models capable of preventing biopiracy and ensuring equitable benefit-sharing with indigenous communities.

While patent protection remains a central instrument within intellectual property law, many countries acknowledge its structural incompatibility with traditional medicine. Patent regimes are designed to protect individual inventions that satisfy the requirements of novelty, inventive step (non-obviousness), and industrial applicability. These requirements are difficult—if not impossible—to reconcile with traditional medicine, which is communal in nature, transmitted intergenerationally, and lacks identifiable inventors or precise moments of creation (Saidin, 1997). The novelty requirement poses a fundamental obstacle, as traditional medical knowledge is often considered prior art due to its long-standing use within communities. Similarly, the inventive step requirement presupposes a level of creative technological advancement that exceeds routine knowledge, whereas traditional medicine often develops incrementally through accumulated experience rather than deliberate scientific innovation. The requirement of industrial applicability further limits patentability, given that traditional healing practices vary among practitioners and are not intended for standardized mass production.

Comparative experiences demonstrate that reliance on patent protection risks converting communal knowledge into individual property, thereby creating potential conflicts of ownership between patent holders and indigenous communities. For this reason, countries that recognize traditional medicine as traditional knowledge generally avoid positioning patents as the primary protective mechanism.

Trade secret protection has also been considered as an alternative mechanism. Under Indonesian law and comparative intellectual property doctrine, trade secrets require

confidentiality, economic value, and reasonable efforts to maintain secrecy (Antariksa, 2012). While certain forms of traditional knowledge may initially satisfy these criteria, protection collapses once knowledge is disclosed to the broader community or transmitted across generations. Comparative practice shows that trade secret regimes are ill-suited to protect traditional medicine, as cultural transmission inherently contradicts the secrecy requirement. Once traditional medical knowledge enters the public domain, is independently discovered, or reverse-engineered, trade secret protection is lost. This limitation reinforces the broader conclusion that conventional intellectual property mechanisms fail to capture the cultural and communal dimensions of traditional medicine.

Recognizing the inadequacy of patent and trade secret protections, several countries have adopted sui generis legal regimes tailored to the characteristics of traditional knowledge. These regimes link the protection of traditional medicine with genetic resources, prior informed consent (PIC), and benefit-sharing mechanisms, positioning indigenous communities as the primary legal subjects rather than individual inventors (Blakeney et al., 1999). The Philippines provides a notable example through the Indigenous Peoples' Rights Act of 1997, which explicitly recognizes indigenous peoples' rights to preserve, develop, and control their traditional knowledge. The Act further provides for restitution and compensation in cases of unauthorized appropriation or use without free, prior, and informed consent (Daoas, 1999; Wiradirja, 2013).

New Zealand adopts a collaborative protection model based on prior informed consent, exemplified by partnerships between Māori communities and research institutions. Through initiatives such as the Kimihauora Trust, traditional knowledge is utilized in scientific research with the possibility of jointly owned patents, ensuring mutual benefit and community participation (WIPO, 2001b). Other countries, including Brazil, India, and Thailand, have implemented sui generis frameworks that integrate traditional knowledge protection into biodiversity and genetic resource governance. Brazil's Provisional Act No. 2.186-16 (2001), India's Biological Diversity Act (2002), and Thailand's Act on the Protection and Promotion of Traditional Thai Medicine Intelligence collectively emphasize access regulation, benefit-sharing, and state recognition of communal ownership.

Comparative experiences also underscore the importance of defensive protection mechanisms. High-profile biopiracy cases, such as the turmeric patent dispute in India and the patenting of *Banisteriopsis caapi* (ayahuasca) in the Amazon region, illustrate how undocumented traditional knowledge may be deemed novel under Western patent standards (Hansen, 2011). In the absence of formal documentation, traditional medicinal knowledge fails to qualify as prior art, enabling third parties to secure patent rights. Consequently, many countries complement sui generis regimes with defensive protection measures, including systematic documentation, traditional knowledge databases, and registries accessible to patent examiners. These mechanisms aim to prevent the

misappropriation of traditional medicine while preserving community control over knowledge disclosure.

Overall, comparative analysis demonstrates that effective protection of traditional medicine requires legal frameworks that transcend classical intellectual property models. Countries that have reduced the risk of biopiracy are those that adopt community-centered, sui generis approaches grounded in customary law values, prior informed consent, and equitable benefit-sharing.

3. Identifying the Most Appropriate Legal Protection Model for Traditional Medicine

A comparative analysis of traditional medicine protection across various jurisdictions demonstrates that no single conventional intellectual property regime can fully accommodate the unique characteristics of traditional medicine. The communal nature of traditional medical knowledge, its intergenerational transmission, and its close connection to cultural identity necessitate a legal protection model that extends beyond patents and trade secrets. Accordingly, this section seeks to identify the most appropriate model of legal protection for traditional medicine, drawing upon comparative practices and normative legal principles relevant to Indonesia's legal system.

In implementing the new rules on Traditional Knowledge, it is necessary to review the values that underpin Indonesian society so that the legal rules benefit all Indonesian people. The rules must include: the scope of protection of Traditional knowledge, the criteria for objects and subjects of traditional knowledge, and the forms of protection of traditional knowledge.

(1) Related to encompassing ideas/concepts, concepts, skills, learning and other customary practices, and innovations that shape the lifestyle of traditional communities, including knowledge of medicine including related medicines and healing procedures, knowledge of space and time, agricultural knowledge, knowledge of the natural environment, knowledge of flora and fauna, knowledge of substances and raw materials, knowledge of body anatomy, knowledge of astronomy, and knowledge related to genetic resources;

(2) Regarding the object of protection of traditional knowledge, it can be protected based on new provisions, which can refer to countries that have implemented sui generis provisions for their traditional knowledge, for example, Panama. In the context of protecting traditional knowledge, Panama requires that only traditional knowledge with commercial value and traditional value be protected, and that this knowledge be owned by one or more indigenous communities in Panama. In addition to these requirements, other criteria to be considered include that the traditional knowledge must be authentic, new, and owned by an individual or a community collectively.

(3) Regarding the subject of ownership, often the ownership of this traditional knowledge is owned collectively, but it does not rule out the possibility that traditional medical knowledge is owned by a small group of people who are part of the community. This

needs to be taken seriously because if, at some point this traditional knowledge is commercialized, the distribution of profits will also be clear, so that the owners of this traditional knowledge do not suffer losses in their rights.

(4) Regarding the form of legal protection for traditional knowledge, it can be in declarative form (the state as recorder) or constitutive (registration) by considering the advantages and disadvantages.

A traditional knowledge registry is a collection of official documentation that describes traditional knowledge. A registry can also be created and maintained locally (within the community) or outside the community itself (externally). With a locally managed registry, the community can collectively decide what to include and what knowledge to share and/or disclose to people outside the community.

External registers are maintained outside the community, often at the national or international level, by governments, non-governmental organizations, museums, or libraries. These registers may be collections of TK specific to a particular community or to several communities. The local community may control what is included in the register but may not be responsible for maintaining it, with the distinction between local and external registers determined by stakeholders.

The most important aspect of implementing legal protection for traditional knowledge is to adhere to the National Legal Ideals (Simanjuntak, 2005):

(1) The state protects the entire Indonesian nation and all of Indonesia's territory based on unity;

(2) The state seeks to realize social justice for all of Indonesia's territory. Indonesia is based on unity, a state with people's sovereignty, based on democracy and representative deliberation, and a state based on God, according to the principles of just and civilized humanity.

Finally, the government is responsible for protecting traditional health service providers and users. The Health Law's provisions do, in fact, provide clients with legal protection. As a result, if an error or noncompliance with this regulation occurs, the provider of traditional health services may face sanctions under the Health Law. However, with the growing prevalence of traditional medicine concepts involving the supernatural, where treatment standards differ from what should be, the government must be more cautious and supervise health service practitioners as a form of citizen protection.

The government must also immediately increase legal protection efforts, both defensive protection, which refers to efforts aimed at preventing the granting of intellectual property rights over traditional knowledge or genetic resources related to traditional knowledge by other parties without the knowledge and permission of the owner of traditional knowledge, and positive protection, which includes the formation of special laws related to traditional knowledge. To ensure that new regulations on traditional knowledge benefit all Indonesians, the government should review the values ingrained in Indonesian society.

CONCLUSION

This study demonstrates that conventional intellectual property regimes are insufficient to protect traditional medicine due to its communal ownership, intergenerational transmission, and deep cultural significance. These characteristics do not align with the core requirements of classical intellectual property systems, such as novelty, inventiveness, and individual ownership. Consequently, a protection model that extends beyond patents and trade secrets is required. A sui generis legal regime emerges as the most appropriate framework for protecting traditional medicine in Indonesia. Such a regime should clearly define the scope of protection, establish criteria for protected objects and subjects, recognize collective ownership, and ensure fair benefit-sharing mechanisms. While documentation and traditional knowledge registries play an important role in preventing misappropriation, they cannot replace positive legal protection provided by comprehensive regulation. Ultimately, the effective protection of traditional medicine requires a legal framework that balances legal certainty, social justice, and cultural preservation. The development of a sui generis regulatory framework grounded in Indonesia's national legal ideals is therefore essential to ensure that traditional medical knowledge is protected from unauthorized exploitation while remaining beneficial to the communities that sustain it.

DECLARATION OF GENERATIVE AI AND AI-ASSISTED TECHNOLOGIES USE

The author(s) declare(s) that no artificial intelligence (AI) tools, generative AI, or AI-assisted technologies were used in the research, data analysis, writing, or editing processes of this manuscript. All content and ideas presented are entirely the original work of the author(s).

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