

# Commercialization of Knowledge Traditional Medicines in Indonesia

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[DOI: https://dx.doi.org/10.47772/IJRISS.2023.7725](https://dx.doi.org/10.47772/IJRISS.2023.7725)

Received: 09 June 2023; Accepted: 22 June 2023; Published: 18 July 2023

## ABSTRACT

Legal protection of traditional knowledge relating to the field of medicine generally aims to provide commercial utilization of traditional knowledge for the benefit of the national economy. This research aims to conduct an analysis related to legal protection and a comparison of commercialization policies regarding Indonesia's traditional medicinal knowledge with China. The research method uses a normative juridical approach that focuses on literature study, which is descriptive and analyzed qualitatively. The result of this research is that the legal protection of traditional knowledge related to the field of medicine in Indonesia does not yet have strict regulations and there are no rules regarding the commercialization of traditional medicinal knowledge in Indonesia. This becomes an urgent need because of the lack of adequate rules regarding the protection of traditional medicinal knowledge in Indonesia, causing the operation of law in Indonesia to not work optimally in providing legal protection that is justice, certainty, and usefulness in indigenous peoples as inventors and managers of traditional medicinal knowledge. In contrast to the protection of traditional Chinese medicinal knowledge which already has clear rules regulating the commercialization of the use of traditional medicine. So that now traditional Chinese medicine is used and studied in medical schools around the world.

**Keywords:** Legal protection, Commercialization, Knowledge of traditional medicines. Traditional Chinese medicine.

## INTRODUCTION

Indonesia is a country that consists of several islands. In 2020, there were 16,771 islands in Indonesia. [1] It can be seen that Indonesia is a country that has abundant biological and non-biological natural resources from the land and sea sectors. This abundant natural resource comes from genetic sources and ecosystems. In Indonesia, this biodiversity is found in the types of plants, animals, and microorganisms. With the existence of biodiversity owned by Indonesia, the potential for genetic resources is also diverse, it can be seen in its distribution in various regions. Each region in Indonesia has genetic resources that are unique and different in each region.

This potential can be utilized by the community to fulfill their needs. Where indigenous peoples and local groups in each region naturally utilize these genetic resources. The activities are in the form of producing fabrics, medicine, food processing, fisheries processing, agriculture, agriculture and so on which have been carried out from generation to generation until now. This is in accordance with Article 2 of PEMKUM Number 13 of 2017 containing: Indonesia's communal intellectual property data consisting of genetic resources, geographical indication potential, traditional cultural expressions, and traditional knowledge.

Traditional knowledge in the form of understanding that develops in the indigenous community is the result of the development of knowledge that contains the value of ancestors/tradition. Usually, the development of traditional knowledge is used from one generation to the next. The utilization of traditional knowledge development is used in agricultural cultivation methods, food management, agricultural management, drug

management, and the development of regional arts and culture of regional art plants.(Yulia et al., 2022)Literary, artistic, or other scientific works derived from human intellectual utilization are referred to as traditional knowledge in general.[2] This traditional knowledge is one of the topics of problems related to intellectual property because of the many traditional understandings that develop in the community where the amount of knowledge that develops in the community today has not received proper legality. Traditional knowledge that has long lived in the community lacks protection, especially with regard to traditional knowledge in the field of medicine.(Hawin et al., 2020)

The definition of traditional medicine is a medicine that is made naturally or manually from ancestors, traditions, beliefs, or behavior that is magic that is carried out for generations. These traditional medicines use conventional or natural stages that have long lived in the community and have selling value. In Indonesia, the development of traditional medicines is currently experiencing significant progress. The types of traditional medicines that are currently developing in Indonesia include herbal medicine, Standardized Herbal Medicines (OHT), and Phytopharmaceuticals. Jamu is a traditional medicine derived from natural spices that have properties that have been tested in clinical trials. Currently, Indonesia has 12,000 types of herbal medicine that have been recognized. Traditional medicines that have passed pre-clinical trials (animal experiments) and are standardized are called Standardized Herbal Medicines (OHT). Currently, 86 types of OHT have been registered in Indonesia. Meanwhile, Phytopharmaca is part of OHT that has passed pre-clinical trials (animal experiments) and clinical trials (human trials) with basic ingredients and standardized product results. These drugs are drugs included in more complete essential treatment.[3]

With the development of traditional medicine in Indonesia, more and more forms of traditional medicinal knowledge exist. But in the protection of this growing traditional knowledge, there is still a lot of traditional knowledge that has not been discovered by the general public, so often traditional knowledge related to these medicines is taken by unauthorized parties to commercialize IPR for their own benefit. This kind of thing should receive great attention because it contains economic values so it is very vulnerable to the act of being registered as someone else's property (misappropriation). The protection of traditional medicinal knowledge is a major concern. This is because this intellectual understanding can be commercialized and is part of the science that comes from human habits themselves. The cases of other countries patenting Indonesia's traditional medicinal knowledge include:[4]

1. The traditional knowledge of Javanese medicine is patented by a Japanese company, the Japanese Patent Office (JPO), which issued 39 patent certificates on Javanese medicine.
2. European countries such as Germany have patented medicinal plants in the form of turmeric. Meanwhile, America patented temulawak as cancer, liver, and heart medicine.
3. The keladi tikus plant originated in Indonesia and was cultivated in Malaysia without permission to cure tumors and cancer.

In the above case, the act of claiming is known as biopiracy. In Indonesia, biopiracy cases are a concern for the government in protecting the development of traditional medicines. In the 2016 Patent Law itself, the regulation regarding the protection of traditional medicinal knowledge in Indonesia has not provided strict rules regarding the protection of ownership of traditional knowledge. Many requirements in patenting traditional medicinal knowledge are considered very burdensome and inappropriate so a lot of traditional medicinal knowledge is not registered. Because traditional knowledge has communal, concrete, cash, and open characteristics where traditional knowledge is the property of the community contrary to the concept of the Patent Law where IPR is an individual property right.

This has led to much Indonesian traditional medicinal knowledge being patented by foreign researchers or multinational companies. Thus, the need for strict legal protection related to traditional medicinal knowledge in Indonesia. This means that regulations regarding the protection of traditional medicinal knowledge are needed so that legal violations related to biopiracy do not continue to occur. (Sudjana, n.d.)

Over the past 40 years, the protection of traditional knowledge in the field of medicine has been discussed internationally. The results of the discussion agreed that the protection of traditional medicinal knowledge, consisting of the Convention on Biological Diversity and the Nagoya Protocol on Access to Genetic Resources, and The Fair and Equitable Sharing of Benefits Arising from Their Utilization. Although traditional medicinal knowledge has been discussed in international forums, the fact is that there is no specific protection that regulates traditional medicinal knowledge in IPR.

From this explanation, it can be seen that the protection of natural or traditional knowledge, especially traditional medicine, has received protection but is not conducive. Although the protection of traditional medicinal knowledge in the realm of IPR has not yet received an international agreement relating to it. The protection of traditional medicinal knowledge in Indonesia is not in accordance with the theory of the operation of law in society.

According to Lawrence M. Friedman, the working of law (legal system) in a country is divided into three elements: legal structure, legal substance, and legal culture. (Ansori, 2017) The working system of law in society is influenced by these three elements, if these three elements are not fulfilled then there is injustice in society itself. Here it can be seen that the elements of the operation of law in society are not fulfilled, such as the legal substance, there is no specific regulation regarding Indonesian traditional medicinal knowledge, in terms of legal structure, the role of Indonesian government officials in handling cases of patented traditional medicinal knowledge is fast, firm and fair to the community and in terms of the culture of the people who still think that traditional knowledge is a common property right and does not need to be registered ownership. This is why the law does not work properly in Indonesian society.

To prevent and optimize the operation of the law in society regarding the use of traditional medicinal knowledge in Indonesia, there is a need for an in-depth study of the issue of protection of Indonesian traditional medicinal knowledge, such as access to use, ownership, commercialization policies and a fair commercial sharing system for the use of traditional medicinal knowledge. It is hoped that with the study of this protection, there will be no more misuse and utilization by irresponsible parties in patent claims and a system of revenue-sharing rights for the use of Indonesian traditional medicinal knowledge. So that Indonesia as the property rights of traditional knowledge can still have and obtain a share of the profile (benefit sharing) of the creation or invention derived from genetic resources and knowledge of Indonesian natural medicines.

Research on the protection of this legality on natural medicinal knowledge has in fact been carried out. There are several studies that discuss the protection of knowledge of traditional Indonesian medicines that have been researched by: Mufarrijul Ikhwan, Djulaeka, Murni, and Rina Yulianti. This research discusses the protection of the potential of traditional knowledge by inventorying and efforts in the formation of law enforcement officers by the DPRD against Indonesian traditional knowledge. Second research Dian Devananda Akbar, Budi Santoso, Rinitami Njatrijani. Discusses the implementation of patent legality and government policies in protecting traditional herbal medicine. Third, the research of Dwi Martini, Hayyanul Haq, and Budi Sutrisno. Researching the type of protection on the understanding of natural medicine in the Sasak tribe. Fourth, Miqdad Abdullah Siddiq's research which discusses the protection and utilization of traditional knowledge in the Indonesian system.

Of the four studies, all discuss the protection of traditional medicine. In contrast to this study, researchers focused on the potential for legal protection of Indonesia's natural medicinal knowledge and a comparison of commercialization policies regarding Indonesia's traditional medicinal knowledge with China. Based on this background, the problem is formulated: First, how is the legal protection of traditional medicinal knowledge in Indonesia? and Second, how is the difference in commercialization policies on traditional medicinal knowledge in Indonesia and China ?. The purpose of this research can be expected as guidelines and input on legal protection and commercialization of traditional Indonesian medicinal knowledge.

## METHODS

This research uses a normative juridical approach that focuses on literature studies. (Mukti Fajar & Achmad, 2010) The sources of this research are library research, scientific books, laws and regulations, and other supporting documents such as journals related to the legal protection of Indonesian natural medicine knowledge and comparison of commercialization policies regarding Indonesia's traditional medicine knowledge with China. This research is descriptive in nature, namely describing the object's relationship with the subject matter. The data obtained will be analyzed qualitatively or described in several sentences. (Marzuki, 2017)

## RESULTS AND DISCUSSION

### • Legal protection relating to Indonesian traditional medicinal knowledge

With the demands regarding the protection of traditional medicinal knowledge. At this time meetings are often held around the world, especially meetings with the World Intellectual Property Organization (WIPO) in these meetings there are several formulations regarding how to protect the understanding of natural medicine. Especially the Indonesian state which is a participant in the CBD (Convention Biological Diversity) and a member of WIPO in dealing with the problem of protecting knowledge of traditional medicines does not yet have clear and firm rules.

The concept from the CBD (Convention Biological Diversity) is that natural understanding is an understanding of practices, innovations, and technologies that come from indigenous or local communities. According to the CBD, traditional knowledge can be divided into two types, namely: (Purba et al., 2005)

1. Traditional knowledge derived from biodiversity in the form of medicine.
2. Traditional knowledge derived from works of art.

So it can be concluded that natural medicine is a group of traditional understanding that has economic value. Therefore, knowledge of traditional medicines is categorized within the scope of IPR protection. Because it is the result of the creativity and reasoning of the creator or inventor whose creation contains a moral value and high economic value in the IPR system. (Dharmawan, 2018) This economic value is the result of hard work from the creator and inventor both in terms of energy, time, and cost. IPR protection regarding the understanding of Indonesian natural medicine can be seen in the 2016 Patent Law which is one type of protection on IPR.

### According to article 1 number 1 of Law Number 13 of 2016 concerning Patents:

“A patent is an exclusive right granted by the state to an inventor for his/her invented work in the field of technology for a certain period of time to implement the invention himself/herself or to give consent to other parties to implement it”.

An invention is the idea of an inventor who has ownership rights in the product, process, technology, and completion of a product. Meanwhile, Article 26 paragraph (1), (2), and (3) of the Patent Law provides protection for traditional knowledge:

- If the Invention relates to and/or derives from genetic resources and/or traditional knowledge, the origin of the genetic resources and/or traditional knowledge must be clearly and correctly mentioned in the description.
- Information on genetic resources and/or traditional knowledge as referred to in paragraph (1) is determined by an official institution recognized by the government.

- The sharing of results and/or access to the utilization of genetic resources and/or traditional knowledge as referred to in paragraph (1) shall be carried out in accordance with laws and regulations and international agreements in the field of genetic resources and traditional knowledge.

The concept of traditional medicinal knowledge is in direct contrast to Article 26. Because the understanding of natural medicine has certain characteristics that are communal and intellectual results of the community that are maintained continuously. So that it creates a mismatch in the system of protection of the understanding of natural medicine with the provisions of the patent law.

Furthermore, as for the weaknesses in the Patent Law, there are no explicit and clear rules regarding the obligation of benefit sharing regarding this traditional medicine knowledge. And also in the Patent Law Article 26 paragraph (3):

“The sharing of results and/or access to the utilization of genetic resources and/or traditional knowledge as referred to in paragraph (1) shall be implemented in accordance with laws and regulations and international agreements in the field of genetic resources and traditional knowledge”.

So far, Indonesia personally does not have the expertise in developing accurate benefit-sharing procedures in the use of genetic resources and understanding of traditional medicine. So the protection of Indonesia's traditional medicinal knowledge does not yet have clear rules for its protection against other countries. In fact, patent rights here are actually said to be a weapon of legitimation because it is a powerful weapon in developing biopiracy actions of foreign countries related to the understanding of Indonesian traditional medicine.

1. Government policy on commercialization and benefit sharing of traditional medicinal knowledge.
2. Commercialization and Benefit-sharing policies on Indonesia's traditional medicinal knowledge

Because the provision of protection of traditional medicinal knowledge on patents is still not clear and firm. So there are still many irresponsible parties who commit acts of misappropriation of Indonesia's traditional medicinal knowledge. Therefore, there needs to be an active role of the government in protecting the traditional knowledge of the community. The way the government implements the provision of IPR protection, namely:

#### • **Positive protection**

It is a very suitable policy to prevent the transfer of ownership of knowledge related to traditional medicinal knowledge. Then rules are needed to support these policy activities. This rule, it provides certainty regarding mechanisms and efforts to provide maintenance and profit sharing for the natural understanding. The Positive protection method is in the form of reviving the use of IPR rules and forming new rules (*sui generis law*) specifically discussing traditional understanding which is used as a legal product.

Indonesia itself has currently made efforts to protect the law regarding traditional medicinal knowledge. Which has been formed legislation specifically for local communities so that their traditional knowledge can be recognized as their property rights. This regulation is still in the form of the Bill on Traditional Cultural Expressions and Traditional Knowledge. This bill was passed by the government.

Before the bill is passed, it must pay attention to its protection in the form of objectives, conditions, rights, how to obtain rights to traditional knowledge, and how and when the rights expire.

#### • **Defensive protection**

Defensive protection is a way of preventing the granting of IPRs relating to genetic resources or traditional

knowledge without the permission of the owner of the traditional knowledge. This can be done by documenting traditional knowledge in the field of medicine. The documentation of traditional medicinal knowledge is a formal protection that affects whether or not traditional medicinal knowledge exists.

Attempts to misdocument traditional knowledge can deprive it of formal protection. Documenting traditional understandings provides a guardian of the property rights of traditional understandings and biological resources in indigenous or local communities.(Purwandoko, 2008)

The utilization of Indonesian traditional medicine knowledge is also contained in Law No. 36 of 2009 concerning Health, which in Article 1 number 9 states that:

“Traditional medicines are materials or ingredients in the form of plant materials, animal materials, mineral materials, galenic preparations, or a mixture of these materials that have been used for generations for treatment, and can be applied in accordance with the norms prevailing in the community”.

From the explanation above, it explains that traditional medicines that have developed in Indonesian society have been tested to be safe and efficacious so these existing traditional medicines must be preserved, treated, and maintained so that they are preserved, Previously there has been a book related to the National Traditional Medicine Policy in 2007 or abbreviated as KOTRANA Shas also described policies in the development of the utilization of traditional Indonesian medicines, namely cultivation, human resources in the development of traditional medicines, the safety of traditional medicines, quality of traditional medicines, conservation of traditional medicine resources, documentation and registration in the database, accessibility, appropriate use, supervision and development of research, industrialization of traditional medicines, and monitoring and evaluation of traditional medicines.

Therefore, the role of the government in ensuring the improvement and preservation of the basic ingredients of traditional medicine, and the government is given the opportunity for the community to develop, use, manage, produce, and distribute these traditional medicines. Responsibility for the utilization and safety of traditional medicines is the duty of the government which is regulated in government regulations.

Generally, commercialization of the use of traditional understandings is given to improve the national economy of the community. Aiming to improve the welfare of the indigenous people who own the traditional understanding. For many of these traditional medicinal understandings, Indonesia must increase its duties strictly in the process of providing the benefits of using these traditional understandings.(Sardjono, 2004) To carry this out, there is a body that oversees the running of the commercialization system in collaboration between the government and (non-governmental organizations) NGOs that exist in the indigenous community itself. There are activities that can be carried out in carrying out the commercialization of traditional medicine knowledge, namely:(Kalpavriksh, 2002)

1. Bioprospecting is a cooperative activity in finding the origin of the new drug between the owner and the user of traditional medicine understanding.
2. Biopiracy is the activity of controlling and seizing the understanding of traditional medicine without the owner's permission and using it for profit.

An activity that can be developed by the government and is in line with Indonesia's national development goals is bioprospecting. Although in general the sharing of the benefits of traditional medicinal knowledge, Indonesian indigenous people prefer to apply their customs, but in certain cases they do not want to give up their traditional medicinal understanding. This is because the traditional understanding contains beliefs and sacredness that they believe in.

Therefore, there is a right to respect the traditions of indigenous peoples. For this reason, the government must make implement rules relating to how to obtain prior informed consent and give the right to agree or

refuse to indigenous peoples granting permits for the use of traditional knowledge. With the prior informed consent given by the indigenous people, the party using it gets legal certainty and there is no debate between the government and the indigenous people who own the traditional understanding. (Kusumadara, 2011)

The provision of benefits to indigenous peoples who own traditional medicinal knowledge can take the form of providing compensation in cash or sustainable royalties to indigenous peoples and customary institutions. The provision of benefits to indigenous peoples by users and developers of traditional understanding must be affirmed in a Government Regulation as an implementing regulation of the Cultural Promotion Law.

#### • Utilization policy towards commercialization of traditional medicine knowledge in China

Traditional Chinese Medicine (“TCM”) is a treatment that has existed for thousands of years with a traditional system of diagnosis, prevention, and treatment. In practice, traditional Chinese medicine has various types of treatments such as acupuncture, herbal medicine, and Tui Na massage. These treatments are grouped into Eastern medicine or traditional Middle East Asian medicine. The Chinese government itself protects its classical traditional medicine and is also regulated in the TCM Variety Protection Regulation and other related regulations. (Gibert-Tisseuil, 1998)

In granting commercial benefits to traditional medicinal knowledge, the Chinese government undertakes special matters such as quality documents, safety and security evaluation, and special labeling criteria. The herbal medicine must be approved according to the Drug Administration Law. (Okoro Kingsley N, 2021) There are also other requirements in granting commercial utilization to other parties regarding traditional medicine China conducts systems such as:

1. Entry of foreign investment, where foreign investors are prohibited from investing in the application of steaming, frying, boiling, calcining, and other processing techniques for Chinese herbal medicines and the production of proprietary Chinese medicine secret recipe products.
2. Protected TCM classifications or varieties should be classified into first-class and second-class. Chinese medicinal varieties that meet any of the following conditions can be applied for first-class protection, viz:
3. With a curative effect on certain diseases.
4. Products made from varieties of wild Chinese medicinal materials under national first-class protection.
5. Applicable for prevention, and treatment of specific diseases.

Chinese medicinal varieties that meet any of the following conditions can be applied for second-class protection, namely:

1. Varieties that fulfill the conditions of first-class protection or varieties with first-class protection that are revoked.
2. With remarkable curative effects on certain diseases.
3. Efficacious ingredients or special preparations extracted from natural pharmaceutical ingredients.
4. Protection time limit for TCM varieties under first-class protection: 30 years, 20 years, or 10 years for TCM varieties under second-class protection 7 years.

In China itself, the government’s policy of protecting traditional medicine by conducting formal training taught in almost all medical schools in China is an integral part of the national health program, which helps ensure quality standards in providing health services. China has been successful in integrating TCM into the national healthcare system. A science-based approach is used and instilled in TCM education with an emphasis on research. TCM-empowered hospitals treat more than 200 million outpatients and nearly 3 million inpatients annually. About 95% of public hospitals in China have traditional medicine departments.

[5]

Here it can be seen that China already has rules on the utilization by others of their traditional medicine.

And some of the government agencies responsible for the provision of medicines (including traditional medicines) and medical devices are as follows:(Commission, 2002)

1. The National Medical Product Administration (“NMPA”), formerly known as China Food and Drug Administration, is responsible for issuing drug and medical device distribution licenses and monitoring product quality.
2. The National Health Commission (“NHC”), which is responsible for the overall guidance of healthcare reform, maintains China’s Essential Drug List (“EDL”) and manages drug tendering and procurement policies.
3. Ministry of Human Resources and Social Security (“MOHRSS”), the lead authority in formulating the National Drug Replacement List (“NRDL”).

In the field of medicine, the use of traditional Chinese medicine is studied and used by foreign countries and China itself. So that the development of traditional Chinese medicine is even more advanced because it is already known in various parts of the world.

## CONCLUSIONS

That the legal protection of the understanding of Indonesian traditional medicine can be included in IPR on the type of patent is explained in the Patent Law Article 26. However, its maintenance is still low in the IPR system because, in the patent law, the protection of traditional medicinal knowledge is given to new inventions, inventions whose steps and management are carried out industrially. Unlike the understanding of Indonesian natural medicine, which is passed down from generation to generation and has no new discoveries.

The government implements the protection of natural medicinal knowledge by establishing new rules and documentation of natural medicinal knowledge. Commercialization policies related to medicinal knowledge in Indonesia have no specific rules related to commercialization. It can be seen here that the operation of the law in Indonesia has not been appropriate, especially with regard to traditional medicinal knowledge so justice, certainty, and usefulness have not been fulfilled in the traditional medicinal knowledge of the Indonesian people. In contrast to China, which already has rules regarding its traditional medicine policies. Which is contained in the regulations on the Protection of TCM Varieties and the Drug Administration Act. With these rules, the commercialization of their traditional medicine is clearer in providing benefits to the community.

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