

# LEGAL PROTECTION OF TRADITIONAL MEDICINES IN THE PERSPECTIVE OF HEALTH LAW AND INTELLECTUAL PROPERTY LAW IN INDONESIA

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## ABSTRACT

Advancements in health law mirror the progress made in health science. Presently, health law holds significant weight in addressing diverse challenges and legal matters within the health domain. Conversely, amidst the evolution of increasingly sophisticated technology, traditional medicine has garnered diminished attention. Yet, within the context of Indonesia's efforts to ensure the right to health, traditional medicine ought to be a crucial alternative to be acknowledged. This proposition finds support in Indonesia's rich natural environment, which boasts abundant biodiversity, including numerous plant species with potential applications in traditional medicinal practices. Consequently, ensuring legal safeguards for traditional medicines from the perspectives of both health law and intellectual property law becomes paramount. The research methodology adopted in this study is normative research, centered on the conceptualization of legislative principles or norms serving as the foundation for human conduct. The primary objective is to scrutinize the Legal Protection of Traditional Medicines within the framework of Health Law and Intellectual Property Law in Indonesia. The study's findings revealed that while Law No. 17 of 2023 does not explicitly delineate traditional medicine, it equates the term with "Natural Medicines." Article 321, paragraph (1), classifies natural medicine into distinct categories such as herbal medicine, standardized herbal medicine, phytopharmaca, and other natural remedies. The legal coverage for traditional or natural medicines is stipulated in Articles 324-325 of Law No. 17 of 2023 on Health. Conversely, within the Intellectual Property Rights (IPR) context, protection for traditional medicines is encompassed within the patent system, as outlined in Article 26 of Law No. 13 of 2016 on Patents.

**Keywords:** Health Law, Intellectual Property Law, Patent, Traditional Medicine.

## A. INTRODUCTION

The development of health law grows along with that of health science. Currently, health law is one of the important parts to overcome various legal problems and challenges in the health sector. (Burris et al., 2010) Some of the most common health law-related issues include malpractice committed by health workers, challenges in implementing health laws and regulations, access to health services, patients' rights, and legal issues related to the use of technology in health services. (Hukum et al., 2021) These problems indicate that health law is facing increasingly complex challenges.

Health law is generally understood as a branch of law that deals with various aspects of health care, including the practice of providing care and the rights of patients. (Etika, 2007) On the other hand, with the development of increasingly sophisticated technology, the issue of traditional medicine has received less attention. Whereas in the context of efforts to fulfill

the right to health in Indonesia, traditional medicine should be an important alternative to be considered. This is encouraged by Indonesia's natural conditions which have a wealth of biodiversity, including a variety of plant species that have the potential as raw materials for traditional medicines.(Sholikhah, 2016) Traditional medicine is one of the alternatives to medicine that many Indonesians choose because it is considered more natural, safer, and more affordable than synthetic drugs. In addition. Traditional medicine has also been used for generations in traditional medicine, so it is considered to have effectiveness in overcoming various diseases.(Organization, 2013)

The World Health Organization (WHO) also encourages the use of traditional medicines in health maintenance, prevention, or treatment of diseases in the community. WHO's support for the use of traditional medicine provides significant benefits for Indonesia in developing its traditional medicines. Given the great potential that Indonesia has in the field of traditional medicine, it is necessary to conduct comprehensive research to support the development of new traditional knowledge, which will benefit all parties, especially the community and the country.(N. K. Ayu & Wiryawan, 2019)

The efforts to protect traditional medicines can be seen from the health law that provides protection for traditional medicines in Indonesia through regulations related to registration, production, and distribution. Guidelines for the production of traditional medicines are also provided. Law No. 8/1999 on Consumer Protection is a law that provides a foundation for the protection of traditional medicines in Indonesia. The law regulates the rights and obligations of consumers and business actors, including those in the traditional medicine industry.(Kurnianingrum, 2018) In addition, the Ministry of Health has issued regulations related to the registration and supervision of traditional medicines, including Permenkes No. 007 of 2012 concerning Traditional Medicine Registration and Permenkes No. 006 of 2012 concerning Traditional Medicine Industry and Business. In addition, Law No. 36 of 2009 on health has been revoked and replaced with Law No. 17 of 2023 on Health signed by the President of the Republic of Indonesia on August 8, 2023.

The protection of traditional medicine also relates to the protection of intellectual property rights, as traditional medicine is often based on traditional knowledge passed down through generations and it is important to preserve cultural heritage and promote the use of traditional medicine as a

complementary approach to modern medicine.(Anugerah & Santoso, 2022) Even the World Intellectual Property Organization (WIPO) is particularly concerned with the protection of traditional medicinal knowledge in the sense of intellectual property, namely protection against unauthorized use by third parties.(Intellectual & Organization, 2008) In Indonesia, protection related to medicines is included in the protection of patents because medicines are categorized as inventions in the field of technology. However, there are still challenges in protecting traditional medicines with patents due to the lack of fulfillment of values to obtain patent protection.(Lestari, 2012)

Therefore, the author is interested in conducting research related to the applicability of Law Number 17 of 2023 concerning the new health in regulating Traditional Medicine and the

patent regime in protecting traditional medicine as part of intellectual property. The research method used in this research is the normative research method. Normative legal research methods are conceptualized as what is conceptualized in legislation or conceptualized as norms or rules that serve as the basis for human behavior. The purpose of this study is to analyze how the Legal Protection of Traditional Medicines in the perspective of Health Law and Intellectual Property Law in Indonesia.

## B. RESULTS AND DISCUSSION

### 1. Legal Protection of Traditional Medicines in the perspective of Health Law in Indonesia

The development of health law in Indonesia is related to the development of health science and the need to regulate the practice of health care providers and protect the rights of patients. (Sampurno, 2011) The development of Health Law has been ongoing for decades, starting during the Dutch colonial period and continuing to the present day. Indonesia's current health laws include various regulations related to health services, as part of ongoing efforts to improve the implementation and enforcement of these health laws and regulations. (Wahyuni, 2022)

The regulations regarding health law and traditional medicine in Indonesia can be seen in the following table:

No.	Law	Description
1.	Law Number 29 of 2004 concerning Medical Practice	Regulates the practice of medicine in Indonesia
2.	Law Number 44 of 2009 concerning Hospitals	Regulates the establishment and operation of hospitals in Indonesia.
3.	Law Number 36 of 2009 concerning Health	Regulates health law in Indonesia
4.	Minister of Health Regulation No. 006 Year 2012 on Traditional Medicine Industry and Business	Provide guidelines for the production and circulation of traditional medicines in Indonesia
5.	Minister of Health Regulation No. 007 Year 2012 on Traditional Medicine Registration	Provide guidelines for the registration of traditional medicines in Indonesia
6.	Food and Drug Administration Regulation Number 25 of 2021 concerning the Implementation of Good Traditional Medicine Manufacturing Methods	Provide guidelines for the production of traditional medicines
7.	Law No. 17 of 2023 on Health	This has profound implications for the development and transformation of the health care system in Indonesia.

The enactment of Law No. 17 of 2023 has an impact on the revocation of the validity of several other laws such as Law No. 29 of 2004 concerning Medical Practices, Law No. 44 of 2009 concerning Hospitals, and Law No. 36 of 2009 concerning Health and several others. This is because Law No. 17 of 2023 has accommodated in it and is also new compared to the previous Health Law.

Regarding traditional medicine, Law No. 17 of 2023 does not specifically mention traditional medicine. However, traditional medicine is defined as the same as "Natural Medicines" as mentioned in the general provisions of article 1 number 17 that:

*"Natural Medicines are materials, ingredients, or products derived from natural resources in the form of plants, animals, microorganisms, minerals, or other materials from natural resources, or a mixture of these materials that have been used for generations, or have been proven efficacious, safe, and of quality, used for health maintenance, health improvement, disease prevention, treatment, and/or health recovery based on empirical and/or scientific evidence."*

In addition, in article 321 paragraph (1), natural medicines are classified into herbal medicine, standardized herbal medicines, phytopharmaca and other natural medicines. Furthermore, the guarantee of protection for traditional medicine or natural medicine is contained in articles 324-325. As mentioned in article 324 paragraph (1) that:

*"The Central Government and Regional Governments are responsible for the implementation of research, development, utilization, and maintenance of Natural Medicinal Materials."*

The article above provides an explanation that the government seeks to protect traditional medicine in the field of health law by conducting research and sustainable use of natural ingredients. This is certainly a positive step to continue to develop traditional medicines or natural medicines sourced from Indonesia's natural resources to be more widely accepted.

## **2. Legal Protection of Traditional Medicines in the perspective of Intellectual Property Law in Indonesia**

Traditional knowledge is the result of intellectual work that arises and develops in a community that lives together, and is maintained from generation to generation. (Sukandar & Windia, n.d.) If Traditional Knowledge is analyzed comprehensively, it has significant strategic importance for Indonesia, including in the cultural, social and economic dimensions. From a cultural perspective, the protection of Traditional Knowledge will contribute positively to the preservation of the nation's cultural wealth. From a social perspective, the protection of Traditional Knowledge will support in maintaining the integrity of social values that are the foundation of society. In the economic context, the protection of Traditional Knowledge has great potential to increase the country's foreign exchange earnings. (Sukihana & Kurniawan, 2018).

The principles embodied in traditional knowledge are in line with the views expressed in the Convention on Biological Diversity (CBD), where traditional knowledge includes knowledge of innovations, practices used by indigenous and local communities, and technologies derived from local traditions. In accordance with the CBD, traditional knowledge can be grouped into two categories:

1. Traditional knowledge related to biodiversity such as medicines.
2. Traditional knowledge related to art. (Purba et al., 2005)

Based on this classification, it can be concluded that traditional medicine is one of the aspects covered in the area of traditional knowledge. Among the diverse traditional knowledge that exists, knowledge on traditional medicine is the focus of special attention because it has significant economic value, making it vulnerable to unauthorized use.

Intellectual Property Rights (IPR) are essentially rights that arise as a result of human intellectual work. Products derived from IPRs are the result of the creative brain effort, rational thinking, and reasoning of the individual who invented or created them, which have significant economic value. (Dharmawan, 2018) This emerging economic value is the result of the investment of labor, time, and financial resources expended. Traditional medicine refers to medicine prepared by traditional methods and passed down through generations based on beliefs and customs, including magical elements or traditional knowledge. In the knowledge of traditional medicine, there is a creative process of combining natural ingredients into a healing tool. Therefore, its relationship with Intellectual Property Rights (IPR) can be recognized. *Based on the international debates concerning the protection and preservation of TK and TCEs, it can be recognized that the protection of TK and TCEs has been sometimes classified as a matter of intangible heritage and intellectual property.* (Dharmawan, 2017)

However, the Intellectual Property Rights (IPR) system is considered less effective in protecting traditional knowledge because of its individual focus, while traditional knowledge tends to be collective. According to the view of Insan Budi Maulana, IPR is a type of intangible property law that is categorized into various groups as follows:

- a. Copyright
- b. Industrial Property Rights include, trademark patents, industrial designs, integrated circuit layout designs, and trade secrets. (Dharmawan, 2018)

In the framework of Intellectual Property Rights (IPR), knowledge about traditional medicine receives protection through the Patent system. As an important element in IPR, the definition of a patent is governed by Article 1 number 1 of Law Number 13 Year 2016 on Patents, which explains that "A patent is an exclusive right granted by the state to an inventor for his innovation in the field of technology for a certain period of time, which allows the inventor to carry out the innovation himself or to grant permission to other parties to carry it out." In the context of patents, innovation refers to an idea that the inventor has to solve a particular problem in the field of technology, whether it is in the form of a product, process, or improvement of an existing one. Patents are only granted for innovations that qualify as new, have innovative elements, and can be applied in industry. In addition, there are also simple patents granted for innovations that are the development of an existing product or process and can be applied in industry. The protection of traditional knowledge is contained in Article 26 paragraphs (1), (2) and (3) which explain that:

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

Article 26 paragraph (1) only indicates that innovations related to traditional knowledge must include the origin of the knowledge, without providing further explanation, especially in the context of knowledge about traditional medicines. The protection afforded by patents to traditional medicines faces several obstacles, as patents have certain requirements that must be met, including the element of new innovation, the degree of novelty, and the ability to be applied in an industrial context. In addition, simple patents must also fulfill certain requirements, namely as a new innovation, development of an existing product or process, and applicability in the industry. (Dharmawan, 2018) Knowledge of traditional medicine is an intellectual form that is passed down from generation to generation, making it impossible to fulfill patentability requirements.

The mismatch between patents and knowledge of traditional medicine is as described below:

1. Not fulfilling the requirement of novelty, traditional knowledge, especially traditional medicine, is passed down from generation to generation so it is not known who discovered it and when it was discovered.
2. The inventive step is not fulfilled because traditional medicine is often discovered accidentally and developed based on experience from generation to generation without following modern steps, making it difficult to prove the inventive step.
3. It is difficult to fulfill the requirement of "applied in industry" because traditional medicine knowledge does not have commercial content, making it difficult to describe the application of such knowledge in industrial activities.

In addition, there are other arguments that explain why the patent law system is not suitable for protecting traditional knowledge, such as: (M. R. Ayu et al., 2022)

1. Patents protect individual inventions whereas traditional knowledge is developed and owned collectively by the community.
2. The patent application must provide evidence of the act of invention.
3. The registration is required to meet the stipulated technical specifications.
4. Expensive patent registration fees.

## **C. CLOSING**

### **1. Conclusion**

Regarding traditional medicine, Law No. 17 of 2023 does not explicitly mention it as traditional medicine. However, the definition of traditional medicine is equated with the term "Natural Medicines." In Article 321 paragraph (1), natural medicine is divided into several categories, including herbal medicine, standardized herbal medicine, phytopharmaca, and other natural medicines. Legal protection for traditional medicine or natural medicine is regulated in Articles 324-325 of Law No. 17 of 2023 on Health.

On the other hand, in the context of Intellectual Property Rights (IPR), legal protection for traditional medicines is included in the patent system, as stipulated in Article 26 of the Patent Law. However, this protection is still limited because patents are only granted to innovations that are considered new, contain innovative steps, and can be applied in industry.

## 2. Suggestion

Based on the discussion above, the suggestions that can be given by the author are as follows:

1. In its implementation, Law Number 17 of 2023 concerning Health must continue to be guarded in order to realize the legal values of justice, legal benefits, and legal certainty.
2. Second, the Government must be wise and wise in receiving input related to the implementation of Law Number 17 of 2023 concerning Health.
3. It is necessary to establish a "Special Judicial Body" (for example, the "Medical Profession Court") with Human Resources and regulations that are able to sort out, understand and analyze the legal aspects of the medical profession, so as not to overlap with disciplinary and ethical aspects. The establishment of this "Specialized Judicial Body" must be based on the Law. The judges can come from elements with legal and non-legal backgrounds.
4. In the legal protection of traditional medicine in Intellectual Property Law, the government is expected to immediately enact the PTEBT Bill, so that the protection of traditional knowledge, especially traditional medicine, is regulated more specifically, especially in terms of recognition and community involvement as owners and developers of traditional medicine.
5. Need documentation that shows that traditional medicine is something that has existed for a long time in the community, so as to maximize the protection of traditional medicine.

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