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by Agung Sujatmiko

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A Model of Legal Protection for Traditional Medicines (Jamu) as Part of Traditional Knowledge

²³gung Sujatmiko

Department of Private Law, Faculty of Law, Universitas Airlangga
agung.sujatmiko@fh.unair.ac.id

Abstract

The present study¹⁵ as a general purpose of the creation of a special law governing the protection²⁷ of intellectual works in the form of traditional knowledge. The specific purpose is to find out the right legal protection model for traditional medicine (jamu) as part of traditional knowledge. The conceptual and legislative approaches with the deductive analysis are used as the methods of the study. The results of analysis showed that traditional knowledge in the form of jamu cannot be protected under the Patent Law since it does not fulfill the novelty requirements. Traditional knowledge requires protection in the form of a special law.

Keywords

Legal Protection, Jamu, Traditional Knowledge

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Introduction

Our people often refer traditional medicines as *jamu* (Yunus, 2003). *Jamu* is an alternative medicine that has been developed for a long period of time and for generations. Traditional medicines, such as *jamu*, are not only found in Indonesia, but also in such countries as China, Korea, and India (Yunus, 2003). The importance of traditional medicines as among the sources of health care is officially recognized by the World Health Organization (WHO). The WHO has a program called *The Traditional Medical Program of the WHO*. Under the program, traditional medicines are defined as "The sum total of knowledge and practices, whether applicable or not, used in diagnosis, prevention and elimination of physical, mental or social imbalance and relying exclusively on practical experience and observation handed down from generation to generation, whether verbally or in writing" (Yunus, 2003).

In a similar vein, the WHO stated that, currently, 65% of the population of developed countries have been using traditional medicines, including natural medicines. Data released by the Secretariat of the Convention on Biological Diversity showed that the global market for natural medicines, including raw materials, reached a fantastic figure of US\$ 43 billion in 2000 (Kotijah, 2009; Afonso & Silva, 2019; An et al., 2019; Akin Arikan, 2019). The use and development of traditional medicines in various regions in Indonesia constitute a heritage for generations based on experience (Kotijah, 2009).

Traditional medicines often used by the people are those derived from medicinal plants. Indonesian people have been using these herbs since the days of their ancestors. Several diseases such as diabetes mellitus, kidney stones, high cholesterol, rheumatism, and high blood pressure represent a scourge for some people. These diseases are related to an individual's lifestyle; therefore, the distribution is wider than other diseases. Proper prevention is required to deal with those disease but, once exposed, people can take alternative treatments of traditional medicine for the reason that long-term consumption of traditional medicines in will be safer than that of modern drugs (Alisha, 2012).

Other than that, there are patented and generic drugs in the health sector. The difference between them is that generic drugs are efficacious drugs with expired patents and are allowed to be produced by pharmaceutical companies, such as paracetamol, pantoprazole, and so on. These drugs are relatively cheaper and affordable for the public. On the contrary, patented medicines are those drugs that have been found efficacious by researchers, require huge research costs, and are protected by patent law (the patent period has not ended yet). The period of patent protection is 20 (twenty) years. Due to being protected by the Patent Law, the price of these drugs is relatively more expensive, for example, *Viagra*, *Candesartan* and so on. These drugs are also called originator manufactured drugs.

The literature categorizes *jamu* as traditional knowledge which is part of the Intellectual Property Rights (IPR) regime. Traditional knowledge is basically developed by an indigenous community or a tradition-based intellectual work. Such knowledge or works are used by one generation and passed on by the next generations and develop in line with the needs of certain regional communities. According to Hawin, traditional knowledge includes methods of cultivation and processing of plants (agriculture), healing, medicines, food and beverage recipe, arts, and so forth (2005). The medicines under this category are traditional medicines in the form of *jamu*, potions and so on (Hawin, 2005).

According to Hawin (2005), protection of traditional medicines (*jamu*) and potions categorized as traditional knowledge is deemed necessary, considering that traditional knowledge is an important source of commercialize knowledge related to human life. The value generated from utilizing genetic resources derived from traditional knowledge is estimated at US\$ 800 billion annually. Additionally, protection of traditional knowledge is of importance since a lot of traditional knowledge have been used by many researchers as the starting point of their research to obtain patents (Hawin, 2005). Traditional knowledge has been included as a subject matter into the Convention on Biological Diversity (CBD), which has been ratified by 170 countries, including Indonesia under Law No. 5/1994. Despite the ratification, the government of Indonesia has not been doing much effort with regard to traditional knowledge (Sarjono, 2005).

Article 8 (j) of the CBD states that "the participating countries shall respect, preserve, and safeguard traditional knowledge; seek approval from and involve the holder with regard to the utilization; and support the fair distribution of benefits from the users". However, there has been no international agreement regarding the implementation of those provisions, either in the TRIPS agreement or other agreements, to date (Hawin, 2005). This research will attempt to analyze the

legal protection model for traditional medicine (*jamu*) as a part of traditional knowledge.

Literature Review

Results Of Existing Research

A study entitled *The Development of a Documentation Model of Book Format for Legal Protection of Intellectual Property Rights in Traditional Knowledge and Traditional Cultural Expressions of Balinese People* (Dharmawan et al, 2012) showed that the protection of traditional knowledge remains weak due to the lack of evidence of ownership rights to it. On the contrary, many people are still unaware that traditional knowledge has a high economic value and obtains legal protection for IPR. This is due to the fact that people have not yet understood the concept of IPR in traditional knowledge.

The focus of the study was on the formation of a documentation model of several book formats that contains traditional Balinese stories as part of traditional knowledge. In a work entitled *Protection of Indonesian Medicinal Plants* (Mas Rahmah, 2012) was more focused on the study of the relationship between IPRs and traditional knowledge including medicinal plants. The two works did not address the protection of intellectual works of Traditional Medicine (*jamu*) as an inseparable part of Traditional Knowledge. Furthermore, traditional medicine has a crucial role and meaning for improving people's welfare due to its function to cure certain diseases. Therefore, traditional medicine as part of traditional knowledge shall be provided with adequate legal protection in order for utilization by the community, given its communal nature of ownership and the community's long-standing knowledge of it for generations. On that basis, the present study would focus on the protection of *jamu*. The importance of legal protection is also related to the enormous economic potential.

Theoretical Framework

The approaches and studies undertaken produced three models of legal protection of traditional knowledge (Hawin, 2005). The first is the public domain position. This model approach argues that traditional knowledge must become a public property that can be enjoyed by all inhabitants of the world. Therefore, its advocates oppose the efforts to make traditional knowledge a commercial and tradable commodity. In general, they advocate traditional social structures to maintain and control the use of traditional knowledge. Therefore, they generally do not agree with the creation of IPRs for traditional knowledge since IPRs are more concerned with protecting the rights of individuals, representing a means that would damage traditional institutions and structures in traditional knowledge.

The second is the appropriation position approach model. This approach fully supports the ownership of the exclusive right of traditional knowledge by an institution or legal entity to determine its commercial use and other uses. The advocates adopt the principle that, since traditional knowledge is part of IPR, traditional knowledge can be used as a commodity and is commercially tradable in the market. Therefore, they believe that the IPR regime is crucial to determine how and who has the right to use traditional knowledge. Consequently, the ownership of traditional knowledge is generally claimed by multinational companies and occurs in developed countries.

The third is the moral rights position approach model. The latter model basically argues that traditional knowledge must be protected and given full ownership rights in order to prevent or oppose the claims of the beneficiaries or users of traditional knowledge, including even multinational companies. The advocates are of the opinion that traditional knowledge can be commercialized, but only by those who are entitled to traditional knowledge. According to Hawin (2005), in this case the IPR law can be used to determine who has the right to ownership of and utilize traditional knowledge. The three types of approach have their own implications for legislation in of IPRs. Thus, it is necessary to find out which model is most appropriate to protect the work of traditional knowledge of *jamu*. On that basis, an in-depth study is needed to address the problems.

Methodology

The present study is a legal research. It uses the conceptual and legislative approaches. The analysis is based on the deductive analysis departing from the existing laws and regulations subsequently analyzed by utilizing the facts within in the community.

Results And Discussion

Protection Of Jamu Under the Patent Law

Patents are among the Intellectual Property Rights (IPR) regimes that provide many benefits to human life. One type of patents related to medicines is pharmaceutical patents. In accordance with Regulation of the Minister of Health No. 1575/MenKes/Per/XI/2005, the Directorate General of Pharmaceutical and Medical Devices Development is in charge of formulating and implementing policies and technical standardization in pharmaceutical and medical devices development. In order to perform this task, the Directorate General of Pharmaceutical and Medical Devices Development serves to formulate policies with regard to traditional drug use.

Meanwhile, Article 7 of the Trade Related Aspects of Intellectual Property (TRIPS) reads "The Protection and enforcement of intellectual property right should contribute to the promotion of technological innovation and the transfer and dissemination of technology to the mutual advantage of producer and user of technological knowledge and in a manner conducive to social and economic welfare, and to balance of rights and obligations".

Thus, the protection and law enforcement of intellectual property rights basically aim to promote innovation, transfer and dissemination of technology by creating social and economic welfare and a balance between rights and obligations. With regard to pharmaceuticals and traditional medicines, the provisions of Article 7 of TRIPs are really significant, considering that the production and use of traditional medicines are being intensified as an alternative medicine. This is also supported by Indonesian culture. The people of Indonesia are in general spread in various regions and remote areas and are no stranger to traditional medicines.

In general, traditional medicines often used by the community are those medicines derived from herbs. Located in the tropics, Indonesia certainly has a wealth of plants, which constitute a distinct advantage since each plant has an active ingredient that turns out to be beneficial for body health. This is evidenced by the use of herbs since the days of ancestors. The use of herbs as traditional medicines for a long time is safer than the consumption of modern drugs, given that the side effects are relatively smaller. On that basis, traditional medicines can be developed into alternative medicines in the future. Some traditional medicines existing within the community, such as *jamu gendhong* and *jamu sepet Madura* have long been known by the community as *jamu* that can have a positive effect for health. Those *jamu* derive from herbal potions originating from

A patent is an exclusive right granted by the state to an inventor for his invention in technology, which for a certain period of time undertakes the invention itself or grants his approval to another party to undertake it (Article 1 of Law Number 13 of 2016 on Patents, hereinafter abbreviated as UUP). In order for a patent to be granted there must be the subject (inventor), object (invention) and the nature of the invention. The requirements for the granting of a patent are:

The Invention Shall Be Novel;

Novelty in this case is defined as an invention that is not the same as the previous ones. The UUP adopts the standard of worldwide novelty, meaning that it is novel throughout the world, not only novel in a single country (locally).

The Invention Shall Contain Inventive Steps;

The invention is something that cannot be predicted beforehand for someone with a certain expertise in engineering.

The Invention Can Be Applied to The Industrial Sector;

An invention of medicines can be granted a patent since medicines fulfill the requirements for a patent. The issue is whether traditional medicines can also be granted patents, given the word 'traditional' attached to it is a reflection of the word 'communal', that is, the ownership is a shared one, while the patent regime which is part of the IPR regime in principle is individual in nature. Thus, a contradiction exists between the two. Therefore, a further study is required with regard to the requirements for the granting of patents for traditional medicines.

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According to Hawin (2005), protection of traditional medicines and potions categorized as traditional knowledge is deemed necessary, considering that traditional knowledge is an important source of commercializable knowledge related to human life. The value generated from utilizing genetic resources derived from traditional knowledge is estimated at US\$ 800 billion annually. Additionally, protection of traditional knowledge is of importance since a lot of traditional knowledge have been used by many researchers as the starting point of their research to obtain patents (Hawin, 2005).

Traditional knowledge has been included as a subject matter into the Convention on Biological Diversity (CBD), which has been ratified by 170 countries, including Indonesia under Law No. 5/1994. Despite the ratification, the government of Indonesia has not been doing much effort with regard to traditional knowledge (Sarjono, 2005). Article 8 (j) of the CBD states that "the participating countries shall respect, preserve and safeguard traditional knowledge; seek approval from and involve the holder with regard to the utilization; and support the fair distribution of benefits from the users". However, there has been no international agreement regarding the implementation of those provisions, either in the TRIPs agreement or other agreements, to date (Hawin, 2005).

Is it possible to protect traditional medicines that are part of traditional knowledge by Patent Law? In terms of the requirements for patents, especially those relating to novelty, the traditional medicine is not possible to be protected by patent, given that there is no novelty. This is because

traditional medicines in the form of *jamu* and herbal medicines have been known to the general public for years. Nor can it meet the inventive step requirements where the invention must be previously unknown from the technological point of view. In fact, traditional medicines in the form of herbs and the like are traditional knowledge passed on from generation to generation, making it difficult to fulfill the inventive step requirements. Traditional medicines are different from patented medicines in terms of the character, the latter being usually found through a process of research and development, which bases itself on certain scientific methods, such as pharmacology, the science of drugs. With regard to the last requirement for granting a patent to an invention, the invention must be industrially applicable. That is, the invention can be produced by a variety of industries, meaning that the claim stated in the patent document can be performed by following the instructions described in the patent specifications.

Thus, traditional medicines have not yet been patent-protected, considering that they do not meet the requirements of novelty, inventive steps, and industrial applicability. All three requirements are cumulative, meaning that all three must be fulfilled all together. If one of them is not fulfilled, a patent cannot be granted. For this reason, it is necessary to have breakthroughs and concrete steps from the government to protect traditional medicines with a Patent Law. This can be pursued by amending the Patent Law or, if it is not possible, by making a separate law governing the protection of traditional knowledge as an umbrella for the regulation of traditional medicines which are part of traditional knowledge. Many participating countries proposed that TRIP agreements regulate traditional protection. At the fourth meeting of The WTO Ministerial Conference in Doha (November 2001) it was proposed that the TRIPs agreement be improved by referring to the CBD to protect traditional knowledge of various forms, including *jamu*. Meanwhile, the WIPO is currently negotiating an international treaty on traditional knowledge and folklore (Griffith, 2012).

Legal Protection of Traditional Knowledge in The Form of Jamu

With regard to law enforcement in case of violation, traditional knowledge can basically be protected by two mechanisms: legal protection and non-legal protection. Legal protection is the protection of traditional knowledge by embedding legal forms, for example, IPR law, regulations governing genetic resources, especially traditional knowledge, contracts and customary law. Non-legal protection can be undertaken by means of a mechanism of non-binding protection of traditional knowledge, which includes a code of conduct adopted by international organizations, governments, and non-governmental organizations, professional communities, and the private sector. In addition, it can also be undertaken by compiling traditional knowledge findings, registrations, and databases. When combined and synergized, both of these protections will provide positive and effective benefits to anticipate and provide solutions for law enforcement of violations of traditional knowledge. When combined, the first and second mechanisms would provide effectiveness to a strong and complementary law enforcement (Rosandy, 2011).

One of the countries that has provided legal protection for traditional knowledge is the Philippines, as set out in Section 17 of Article 14 of the Constitution which reads as follows (Rosandy, 2011): *"The state shall recognize, respect and protect the rights of the indigenous cultural communities to preserve and develop their cultures, traditions and institutions. It shall consider these rights in the formulation of national plans and policies"*.

Furthermore, these provisions are set out in the 1997 Indigenous People Rights Act, which includes the following provisions: *"Indigenous cultural communities/indigenous peoples have the right to practice and revitalize their own cultural traditions and customs. The state shall preserve, protect and develop the past, present and future manifestation of their culture as well as the right to the restitution of cultural, intellectual, religious and spiritual property taken without their free and prior informed consent or in violation of their laws, tradition and customs."* These provisions are basically not only declarative but also normative in nature which regulates and contains compensation for the community whose rights are utilized by other without permission or contrary to the law, tradition and customs of the community.

The Draft Law on Traditional Knowledge and Traditional Cultural Expressions (RUU PTEBT), Article 1 paragraph (3) states that the use of traditional knowledge by foreigners or foreign legal entities or Indonesian legal entities for foreign investments must pass through the mechanism of an access permit for utilization and utilization agreement. Utilization of traditional cultural expressions does not require an access permit for utilization permission and utilization agreement.

The RUUPTEBT defines traditional knowledge as intellectual works in knowledge and technology

which contains elements of traditional inherited characteristics, which are produced, developed, and maintained by the custodian. Traditional cultural expressions are intellectual works in the arts, including literary expressions that contains elements of traditional inherited characteristics produced, and developed by the custodian. Custodians of traditional knowledge and/or traditional cultural expressions are local communities or indigenous peoples who live in a certain territorial area, have similar values and social cohesion, and maintain and develop traditional knowledge and traditional cultural expressions traditionally and communally.

The protection of traditional knowledge will still last as long as it remains maintained by the custodian. That is, as long as the custodian preserves and utilizes the work of traditional knowledge and traditional cultural expressions, it would be protected by the state. Thus, other parties are not allowed to own it. In principle, the form of protection may include prevention and prohibition of:

- Utilization of traditional knowledge by foreigners or foreign legal entities or Indonesian legal entities for foreign investments, without an access permit for utilization and agreements;
- Utilization of traditional knowledge and traditional cultural expressions by any person or legal entity, both foreign and Indonesian without clearly stating the origin of traditional knowledge and/or traditional cultural expressions and their custodians, representing the sources and owners of traditional knowledge and traditional cultural expressions;
- Utilization of traditional knowledge and traditional cultural expressions by any person or legal entity, both foreign and Indonesian, which is performed improperly, in a distorted manner and generates an incorrect impression of the relevant community, or which leads the community to feel offended, insulted, despicable and/or blackened.

Regarding the efforts to protect *jamu* as part of traditional knowledge, the following should be performed (Najmi, 2013):

1. To form laws and regulations in accordance with the needs of the local community; such as, amending IPR arrangements and adjusting them to the characteristics of local communities (such as the concept of individual ownership in exchange for collective rights, maximizing the system of community benefit sharing in the use of traditional knowledge and biological resources by foreign parties);
2. To form a *sui generis* law; due to the very diverse characteristics of Indonesia, special provisions are required and should be tailored to the characteristics of the traditional community concerned.
- 3.

The foregoing needs to be undertaken by considering the very large and hugely significant economic potential of traditional knowledge in enhancing people's welfare. The commercial value of utilization is at least US\$ 500-800 billion a year (Paserangi, 2013). Such a value makes traditional knowledge immensely important for the country to protect it.

Protection of traditional knowledge has at least four objectives: First, preservation or conservation of traditional knowledge; second, improvement of innovations; third, fair and equitable distribution of profits; fourth, sustainable development. From a different point of view, the four objectives can be further classified into commercial and non-commercial purposes (Paserangi, 2013).

On that basis, there are currently at least three options for establishing legislation linking defensive protection to the IPR regime: (a) protection in the current IPR Law; (b) establishment of a protection regime outside the IPR context, such as using an *access and benefit-sharing* mechanism; (c) establishment of a protection regime through changes in the IPR system (Jinangkung, 2013). On the basis of the above-mentioned options, the government currently prepared a draft PTEBT by considering (Draft RUUPTBT Manuscript, 2009):

First, Indonesia is a state of law that promotes the rule of law in all social, national and state life arrangements based on Pancasila and the Constitution;

Second, Indonesia has an ethnic diversity and intellectual works which is a rich cultural heritage that needs to be protected and preserved;

Third, the ethnic diversity and intellectual works which constitute the high-value cultural heritage, in reality, have become an attraction for commercial use, requiring regulation of the utilization for the benefit of the people;

Fourth, enforcement of and respect for the rule of law constitute the main foundations for national

stability to realize national development goals of equity, justice and prosperity.

The foregoing considerations should guide the preparation and discussion of the Draft PTEBT, given that a law on traditional knowledge is crucial and urgent. The realization of a law specifically regulating traditional knowledge is crucial for Indonesia with its very large biodiversity and non-biodiversity potential. The presence of the laws would not only protect the potential of traditional knowledge, but also benefit the development of traditional knowledge in the future.

Those efforts should be done by taking into account the existence and rights of indigenous peoples who have not received full attention from the government. That is because of the fact that even though local people and the state can be custodian of traditional knowledge and traditional cultural expressions, it is indigenous people who play an important role in their development. They develop their unique local wisdoms, ceremonies, art, culinary, medicines, and folklore adapted to the ecosystem in which they live. When they lose their land or forests where they live, the indigenous people can no longer practice their traditions. Consequently, Indonesia will also lose its intellectual property and wisdoms to understand an ecosystem (Kusumadara, 2011).

In general, traditional knowledge is commercially utilized with the aim of increasing the interests of the national economy, specifically improving the welfare of indigenous peoples as the owners of traditional knowledge. The goal is very noble and in accordance with Article 33 of the 1945 Constitution. The government needs and is required to monitor the implementation in order to achieve the goal (Utomo, 2009). Furthermore, there are three activities that always underlie the commercialization of traditional knowledge (Utomo, 2009):

- Bioprospecting, or activities related to efforts to find sources of new drug manufacture through collaboration between the user and the provider of traditional knowledge and genetic resources;
- Biopiracy, or activities to extract and exploit traditional knowledge and genetic resources without the permission of the provider and for use to benefit the user;
- Biotrade, or trading or transferring genetic resources to foreign parties through collaborative efforts without involving the participation of traditional communities as the GRTKF owners.

The foregoing should be considered well and anticipated for impacts on the continued ownership of traditional knowledge in the future. Bioprospecting activities should be carried out carefully and in a mutually beneficial manner with the benefit-sharing concept. Furthermore, biopiracy and biotrade activities should be prevented and prohibited by expressly regulating them in a *sui generis* law (Utomo, 2009).

Conclusions

Several conclusions can be drawn. First, protection of traditional knowledge in Indonesia requires a specific law separate from the current IPR law since the latter does not accommodate the substances of traditional knowledge. Second, violations of traditional knowledge should be resolved on the basis of local customary law and in the future those violation should be regulated firmly and in detail in the Law on Traditional Knowledge and Traditional Cultural Expressions.

Recommendations

The current Draft Law on Traditional Knowledge and Traditional Cultural Expressions (RUU PTEBT) should contain local wisdoms that live and develop within the incredibly diverse communities.

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