

PROTECTION OF TRADITIONAL KNOWLEDGE OF INDONESIAN SOCIETY IN THE FIELD OF MEDICINES: IN THE DEVELOPMENT OF PHARMACEUTICAL INDUSTRY TECHNOLOGY

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The use of traditional knowledge in the pharmaceutical industry is an interesting issue that continues to be discussed at the international level. Where, the pharmaceutical industry has already benefits of using traditional knowledge in their products. Traditional knowledge is community knowledge that has been used for generations. This article examines how to protect traditional knowledge of Indonesian people in the development of pharmaceutical industry technology. The results of the study found, that the protection of traditional knowledge at the WIPO-IGC GRTKF has confirmed protection through the IPR system by mentioning the source of origin when registering patents. And, the CBD emphasizes the protection of traditional knowledge which must be incorporated into national legislation. However, in national legislation it has not specifically accommodated in relation to traditional knowledge and only mentions of origin in Patent law. Therefore, the protection of traditional knowledge in the development of pharmaceutical industry technology requires a system of control from the government in registration of patent medicines and the benefits of sharing to the community.

Keywords: traditional knowledge, protection, pharmaceutical industry

A. Preliminary

The issue of protecting traditional knowledge is a very complex issue ¹Where these issues arise with the development of the pharmaceutical industry. Pharmacy is the application of various sciences such as health, chemistry, physics, and biology, work in the field of pharmacy can be said to be complex, starting from research, manufacturing, compounding, provision of drug preparations, testing, and drug information services or related services to patients. Moreover, with the era of the industrial revolution 4.0 from and in several aspects. First, innovations and ideas can be disseminated and developed faster than ever before which is still relatively slow. Second, a significant reduction in production costs and the emergence of a platform that collaborates several concentration activities in several sectors and increases the yield income. Third,²

Pharmaceutical Industry 4.0. This is a new way in which to manage the pharmaceutical industry, combining the online as offline environment. This concept can be applied to pharmaceutical manufacturing problems to significantly increase productivity and quality, reduce risk and waste. In addition to improving real-time monitoring and traceability from the supply chain to the end

consumer. Also, it seeks to automate complex management and documentation processes, to make more efficient adaptations to regulatory requirements.³

Traditional knowledge relates to three categories, namely traditional knowledge in meaning (technical knowledge, practices, skills, and innovations related to, biodiversity, agriculture or health); traditional cultural expressions / folklore expressions (cultural manifestations such as music, art, designs, symbols and performances); and genetic resources (genetic material of actual or potential value found in plants, animals and microorganisms). Traditional knowledge includes knowledge, skills, innovation, practice, teaching and learning that are developed in indigenous or local communities and which are passed down from generation to generation.⁴

The geographical condition of Indonesia which consists of islands and tribes has made the diversity of people's traditional knowledge diverse. The characteristics of traditional knowledge in various regions are based on human resources, natural resources, environment, and infrastructure. The people of Java, Banten Kidul in Banten, the Community of Kota Banjar Baru in South Kalimantan, the Papuan Community in Papua, the Benuaq Dayak Community,

West Kutai, East Kalimantan, the East Kalimantan Dayak Community, and the Tiloko Community in Southeast Sulawesi are among Indonesians who have used various plants as medicine. For example, the Javanese use the samiloto plant in a mixture of herbs.⁵ This article will examine the existence of traditional knowledge of Indonesian society in the field of medicine in the development of pharmaceutical industry technology.

B. Discussion

1. Traditional Knowledge in International Instruments World International Property Organization

WIPO classifies traditional knowledge into agricultural knowledge, scientific knowledge, ecological knowledge, medicinal knowledge including related medicine and medicine, knowledge related to biodiversity, folklore in the fields of music, dance, song, handicraft, language elements, and objects. moving cultural objects.

In the international discourse it is agreed that the term traditional knowledge is divided into three types: Traditional Medical Knowledge, Traditional Agricultural Knowledge and Traditional Ecological Knowledge.⁶ Traditional knowledge is part of the category of traditional knowledge that is owned and used by the community of origin. Traditional knowledge includes agricultural knowledge, scientific knowledge, technical knowledge, ecological knowledge, medicinal knowledge, biodiversity knowledge, folklore expressions in the form of music, dance, songs, crafts, form engineering, stories, and works of art, language elements, such as names, geographical indications and symbols, and the nature of mobile culture.⁷

2. Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC GRTKF)

IGC GRTKF is a committee initiated by WIPO in order to discuss issues of access to genetic resources, traditional knowledge and traditional cultural expressions. This committee was founded in 2000 and in the first IGC GRTKF meeting in 2001, began discussing the draft goals and principles proposed by Australia, Canada, New Zealand, Norway and America in the context of protection of genetic resources through sui generis because there is a clear link. between genetic sources and IPR under TRIPS.⁸

Meeting fourth, one of the discussions is the need to mention the source of origin related to genetic resources and traditional knowledge. The IGC GRTKF also accompanied the invitation to the COP-6 CBD, to give views regarding the mention of the

source of the origin of genetic resources. IGC GRTKF has responded to the CBD invitation by affirming the mention of the source of origin in the patent application for the protection of genetic resources and traditional knowledge.⁹

During the IGC GRTKF discussions, WIPO members committed to implementing the mention of the source of origin in the IPR system. however, the GRTKF IGC in 2010, has reserved guidelines for patent application procedures with the mention of source of origin. The GRTKF IGC has also defined the term 'traditional knowledge'. In general, traditional knowledge consists of skills, innovations, and practices that are rooted in indigenous communities and are usually passed down orally from generation to generation. It is related to the traditional culture of indigenous peoples and is used by the community in their daily life. Traditional knowledge of indigenous peoples includes knowledge of healing properties, farming methods, migration of wild animals and birds and traditional hunting and fishing techniques.¹⁰

Committee in meeting at Geneva, on 17-21 June 2019 has committed to protecting traditional knowledge, which emphasizes that the protection of traditional knowledge must contribute to the promotion of creativity and innovation and for the transfer and dissemination of knowledge must mutually benefit the holders and users in a balanced manner of rights and obligations. This has been emphasized in the draft April 2019 article in Geneva that recognizes and reaffirms the role of the IPR system in promoting innovation and creativity, transfer and dissemination of knowledge from stakeholders, providers and users of traditional knowledge.¹¹ So IGC GRTKF is committed to protecting traditional knowledge through the IPR system.

3. Convention on Biological Diversity (CBD)

Convention on Biological Diversity (CBD) is the approval of the countries at a conference on Environment and Development in Rio de Janeiro Brazil, in 1992. At the conference, the issue of First, the objective is to ensure the sharing of benefits from the use of biodiversity. And second, the goal of allowing indigenous peoples or legal owners to share benefits from the commercial use of biodiversity.¹² The two issues are the obligations that need to be implemented in terms of access to biodiversity.

This has been affirmed in article 8 (j) CBD that: Each Contracting Party shall, as far as possible and as appropriate: Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles for the

conservation and sustainable use of relevant biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.

Article 8 (j) of the CBD provides a reference to the traditional knowledge of society which must be respected, protected and defended. Traditional knowledge is knowledge of indigenous and local people from generation to generation in the use of biodiversity which includes information about various types of plants processed for medicine (KR Srinivas; 2008).¹³ So, traditional knowledge that reflects the traditional styles and characteristics of the original and local people in meeting the needs of life, including medicine.

Indonesia has ratified the CBD through Law No. 5/1994. This ratification has strengthened Indonesia to realize the mandate of article 8.j in national legislation. This is because the use of traditional knowledge in the pharmaceutical industry is increasing and the more sophisticated pharmaceutical technology in the 4.0 era.

4. In IPR legislation in Indonesia Plant Variety Protection Act

In Law Number 29 of 2000 concerning Protection of Indonesian Plant Varieties (PVP Law) does not protect traditional varieties that have been cultivated by farmers, which is the knowledge of the community in the agricultural sector. This is because plant cultivation does not use biotechnology and only uses traditional agricultural knowledge that has been passed down from generation to generation. Article 1 paragraph (4) states, plant breeding is a series of research and testing activities or variety discovery and development activities, in accordance with standard methods for producing new varieties and maintaining the purity of seeds of the varieties produced. Furthermore, Article 2 has reaffirmed that plant varieties that are given protection must meet new, unique, uniform, stable varieties and be given names. Therefore,

However, Article 7 states that the state controls local varieties owned by the community. These local varieties refer to existing varieties that have been cultivated by farmers from generation to generation and are based on traditional agricultural knowledge and belong to the community. In Government Regulation No.13 / 2004, it is reaffirmed that to control local varieties, it is given to the Regent or Mayor to act for and on behalf of the people in his area as owners of local varieties. This must be done in

order to strengthen the need for protecting the traditional knowledge of the community in agriculture.

5. In the Patent Law in Indonesia

Law No.13 / 2016 concerning Patents has emphasized that inventions relating to and / or originating from genetic resources and / or traditional knowledge, must clearly and correctly state the origin of the genetic resources and / or traditional knowledge in the description. Information on genetic resources and / or traditional knowledge as intended is stipulated by an official institution recognized by the government. The sharing of yields and / or access to the use of genetic resources and / or traditional knowledge is carried out in accordance with laws and regulations and international agreements in the field of genetic resources and traditional knowledge (Article 26 paragraph (1), (2), (3) of the Patent Law.).

This provision in the Patent Law is one way to protect the use of traditional public knowledge in pharmaceutical products in the era of technology 4.0. Where, the pharmaceutical industry which registers its products must clearly state the information as the source of origin of the product. Considering on the other hand, the traditional knowledge of the people obtained is directly registered in the IPR system because there is no element of novelty as required in patent registration. Thus the protection of traditional knowledge in the IPR system becomes constrained.

6. The need to protect traditional knowledge

There are two purposes for the protection of traditional knowledge, namely as bio-economics and moral rights. As a bio-economy, the use of traditional knowledge. In the midst of technological developments, the pharmaceutical industry is intensively using traditional knowledge in the health sector.¹⁴ The pharmaceutical industry contributes 50 percent of herbal-based medicines in the world.¹⁵ Sales of vinblastine as a medicine for Hodgkin disease and Vincristine as a leukemia drug were found in the Tapak Dara specimens found in Madagascar. This activity generates more than US \$ 200 million a year for Eli Lilly Corporation as a pharmaceutical producer from America.¹⁶ Sales of herbal medicinal products in Europe reached US \$ 1.6 billion to US \$ 3.3 billion in 1998, while in America it reached US \$ 6 billion in 1988. The use of traditional medicines in developing countries such as India reached 65 percent of the population of India, when in Africa it is up to 80 percent of the population of Africa.¹⁷ Therefore it is important, economically, to protect the use of traditional

knowledge of the community, including in the field of medicine for the welfare of society.

As a moral right, in the teachings of Natural Law, Socrates emphasized that moral power is the essence of law, because without morality, laws will lose their supremacy and independence. Therefore, fair and unfair will be measured through the value of morality.¹⁸ Thomas Aquinas also emphasized morality is a human being possessed because reason given by God is for do the good and avoid the bad.¹⁹ When, Grotius and Immanuel Kant is a proponent of the Rational Law of Nature which affirms that moral is based on the reasoning of human reason or mind, which can shows what is true and what is not. A good reasons and actions therein have a moral quality,²⁰ including the act of using the community's traditional knowledge in a responsible manner as a gift from God, as a truth and action that is useful and brings happiness to society.²¹ Therefore, in the development of pharmaceutical technology in the era of 4.0. The need for protection of traditional knowledge is getting higher considering that the higher the human intellect, the higher the level of morality for the use of traditional knowledge in society.

C. Conclusion

The protection of traditional knowledge amidst the development of pharmaceutical industry technology in the era of 4.0, really requires a harmonization of the regulatory system with the implementation and control of the government and community groups. Where, at the international level, it has paid respect to community rights, including traditional knowledge. In IPR legislation, it has also emphasized the obligation to mention the source of origin of the product to be patented. In addition, there is also a need for specific regulations governing traditional knowledge considering that this has very different characteristics from the innovative products in the IPR system.

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Because indigenous knowledge is similar to traditional knowledge, both in terms of distribution, scope and types.

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