

The Protection of Traditional Knowledge of Medicinal Herbs for Just Health and Welfare Access for the Traditional Communities: A Comparison between India and Indonesia

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Abstract

The purpose of this study is to identify a model in the protection of traditional knowledge (TK) of medicinal herbs by adopting a comprehensive protection instrument, comprising positive and defensive protection. Based on the regulation of TK in international conventions and the national laws, the best practice for the protection of TK of medicinal herbs is by implementing a sui generis regulation that stems from the principle of justice in fulfilling the traditional communities' rights over access to health and welfare.

Keywords: Protection, TK, Medicinal Herbs, Health, Welfare, Justice

Introduction

Currently, one important topic in regard to the progress of intellectual property (IP) rights is the protection of genetic resources and traditional knowledge (TK) of medicinal herbs. This protection is vital given that they are the sources of knowledge related to human lives that can be commercialized. The value of product sales that embraces TK in the form of genetic resources worth approximately 800 billion USD each year.^[1] This figure is according to the results of research by pharmaceutical products, wherein the annual market value of medicinal herbs traded in countries that joined the Organization for Economic Cooperation and Development (OECD)

reaches 800 billion USD.^[2] In addition, based on data by the Secretariat of the Convention on Biological Diversity (CBD), the profit made from the sales of medicinal herbs globally in 2000 amounted to 60 billion USD.^[3] In the same year, the trade value of medicinal herbs in Indonesia summed up to 1.5 trillion IDR, equivalent to 150 million USD.^[4] Without a doubt, these enormous values would require the necessary legal protections.

The demand rate of medicinal-herb-based products is closely related to the widespread usage level across nations and the economic aspects for improving people's economy. On the other hand, TK of medicinal herbs has been unrightfully misused by multiple companies, especially those from the developed countries in efforts to manufacture pharmaceutical, medicinal, and cosmetic products. As a result, the traditional communities in developing countries filed claims for the violations on TK. The filed lawsuit by the Council of Scientific and

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Industrial Research of India (CSIR) to revoke U.S. Patent No. 5.401.504 on behalf of University of Mississippi Medical Centre (1995) was regarding the use of turmeric in wound healing. According to Agarwal and Narain, turmeric powder is a traditional remedy passed down by their ancestors from the Ayurveda.^[2] Another one is the revocation lawsuit for U.S. Patent No. 4.946.681 and 5.124.349 on behalf of W. R. Grace & Co. regarding the extraction technique of the Neem tree and fruit for the production of Azadirachtin and the pesticide composition derived from the extract of Neem seeds and revocation of U.S. Patent No. 5.663.438 on behalf of Rice Tec., (1997) for rice lines and grains from Basmati.^[2] No less important, the patent case of Indonesian herbs and vegetations consisting of pulowaras (*Anethum foeniculum*), sintok (*Cinnamomum sintoc*), kayu rapat (*Parameria laevigata*), cubeb (*Piper cubeba*), pluchea (*Pluchea indica*), masoyi (*Massoia aromatica becc*), blackboard tree (*Alstonia scholaris*), and field milk thistle (*Sonchus aevensis*) by a Japanese cosmetic company, Shisedo, in which the patent was subsequently revoked based on the lawsuit filed by one of the Indonesian non-government organizations.^[2,5]

Based on these elaborations, TK of medicinal herbs is a part of nation's intellectual creativity products that must be protected from the act of misappropriation. Therefore, it is of the utmost importance to provide protection of TK of medicinal herbs for just and equitable access to health and welfare for the traditional communities.

Materials and Methods

This study employs the normative legal research method, which by definition is a know-how activity in legal studies for solving an examined legal issue.^[6] Legal research requires the ability to identify legal issues, conduct legal reasoning, analyze problems, and provide a solution to said problems. Morris L. Cohen and Kent C. Olson stated that: "Legal research is the process of finding the law that governs

activities in humans society".^[7] To find an answer to a problem, primary and secondary sources are used as expressed by Enid Campbell:^[8] "Law books may be divided into two broad categories: primary and secondary sources. The primary resources consist of authoritative records of the law made by the law-making authorities. The secondary sources comprise all of the publications that pertain to the law that are not themselves authoritative records of legal rules". Then, the entire collected law sources are analyzed normatively to obtain prescriptions according to the research problem.

Results and Discussion

1. Classifications and Characteristics of Traditional Knowledge

The 2001 WIPO Fact-Finding report states that: "TK in the narrow sense refers to knowledge as such, in particular the knowledge resulting from intellectual activity in a traditional context, and includes know-how, practices, skills, and innovations. Traditional knowledge can be found in a wide variety of contexts, including agricultural knowledge; scientific knowledge; technical knowledge; ecological knowledge; **medicinal knowledge, including related medicines and remedies**; and biodiversity-related knowledge".^[9]

Based on this basis, TK is established, derived from, developed, and practiced by the TK holders, which are a part of the heritage concept, classified as follows:^[10] 1) agricultural knowledge; 2) scientific knowledge; 3) technical knowledge; 4) ecological knowledge; 5) **medical knowledge, including related medicine and remedies**; 6) biodiversity-related knowledge; 7) expressions of folklore; 7) handicrafts; 8) design; 9) stories and artwork; 10) element of language; 10) movable cultural properties. According to Johanna Gibson in Zainul Daulay, the fundamental concept of TK is placed upon the fact that TK rests on tradition, which is "the ways that reflect the tradition of people, which are the ways by which knowledge is created, preserved, and spread".

[10] TK focuses on the use of knowledge, such as the knowledge of traditional technical skills, traditional environment, science, agriculture, or medicine—which includes the knowledge of medicinal herbs and medical techniques.^[10]

According to the aforementioned description, the characteristics of TK as mentioned by several international conventions:

Table 1

WIPO-IGCGRTKF Draft	2003 UNESCO Convention for The Safeguarding of The Intangible Cultural Heritage	1992 Convention on Biological Diversity
<ol style="list-style-type: none"> 1. generated, preserved, and transmitted in a traditional and intergenerational context; 2. distinctively associated with a traditional or indigenous community or people which preserves and transmits it between generations; 3. integral to the cultural identity of an indigenous or traditional community; 4. tangible and intangible. 	<ol style="list-style-type: none"> 1. is passed down between generations; 2. develops dynamically; 3. becomes an integral part of the community identity; 4. is the source of creativity; 5. intangible. 	<ol style="list-style-type: none"> 1. Knowledge, innovation, and practice of the traditional community; 2. Developed by the indigenous people and local communities across numerous generations; 3. A sustainable traditional lifestyle stemming from biodiversity.

2. Instruments for the Protection of Traditional Knowledge of Medicinal Herbs

According to the WIPO-IGCGRTKF Glossary, protection “refers to the protection of traditional knowledge and traditional cultural expressions against some form of unauthorized use by third parties”.^[11] Instruments for the protection of TK of medicinal herbs in this study include positive and defensive protection. As stated in the WIPO-IGCGRTKF draft, positive protection “...grants IP rights in the TK and TCEs. These rights may be used to prevent unauthorized or inappropriate uses by third parties. It may also enable active exploitation of TK and TCEs by the originating community itself, for example, to build up its own handicraft enterprises”.^[12]

Positive protection involves the creation of law by granting exclusive rights over TK to prevent its exploitation of unauthorized or inappropriate uses by third parties. The reason why it is named as such is that there are new legal provisions that act as positive law through implementations.^[13] The implementation here means both the ratification of international conventions and the legislative process within the national legal system.

On the other hand, there is defensive protection. As stated in the WIPO-IGCGRTKF draft, defensive protection “does not grant IP rights over the subject matter of TK but aims to stop such rights from being acquired by third parties”.^[14, 15] Defensive protection is a strategy to ensure that no illegitimate claims are filed over TK, which may be achieved by making an inventory and documentation. This defensive protection

can also mean “preservation” and “safekeeping” as the manifestation of comprehensive protection over TK, described in the WIPO-IGCGRTKF draft as such:^[16] “... non-IP laws and programs dealing with the safeguarding and promotion of living heritage can play a useful role in complementing laws dealing with IP protection”. These efforts aim to guarantee that TK does not cease to exist in the traditional communities’ everyday life, but instead, endures and be carried out.

4. The Protection of Traditional Knowledge of Medicinal Herbs within National Laws

a. India

India governs the protection of TK in The Biological Diversity Act No. 18 of 2002 (Act No. 18/2002), enacted in 2003. The exercise of this Act is further regulated in the executive regulation through the Ministry of Environment and Forests Notification and contained in “the Gazette of India Extraordinary”, on 15 July 2004. This Act is a form of positive protection of TK, explicitly mentioned as such: “An act to provide for the conservation of biological diversity, sustainable use of its components and fair and equitable sharing of the benefits arising out of the use of biological resources, knowledge and for matters connected therewith or incidental thereto”.^[17]

Furthermore, India provides protection of TK in the scope of biodiversity, expressly put in Article 2 (b) Act No. 18/ 2002 that “The Central Government shall endeavour to respect and protect the knowledge of local people relating to biological diversity”. Based on this stipulation, India places biodiversity as a resource that must be protected by the government due to having high economic value. Therefore, the country imposes regulations concerning the access to benefit sharing, using terms such as “benefit claimers”, defined as “... the conservers of biological resources, their by-products, creators and holders of knowledge and information relating to the use of such biological resources, innovations and practices associated with such use and application”.^[18]

On a related note, the distribution of benefits gained from TK becomes the authority of the National Biodiversity Authority, by whom the amount of money payable to the TK holder—individual or group—is determined, thereby ensuring that the traditional communities receive the benefits of the TK belonged to them as a form of access to equitable health as regulated in Article 21 section (3): “Where any amount of money is ordered by way of benefit sharing, the National Biodiversity Authority may direct the amount to be deposited in the National Biodiversity Fund: Provided that where biological resource or knowledge was a result of access from specific individual or group of individuals or organisations, the National Biodiversity Authority may direct that the amount shall be paid directly to such individual or group of individuals or organisations in accordance with the terms of any agreement and in such manner as it deems fit”. In addition, the National Biodiversity Authority can take steps in delivering the agreed sum of money directly to the traditional communities through the local governments. In the event that the individual or individual groups of the traditional communities cannot be identified or found, then the payment is reserved in the National Biodiversity Fund as regulated in Article 20 (8) Ministry of Environment and Forestry Notification 2004.

India’s experience represents the general tendency of developing countries in managing genetic natural resources and TK legacies. The country’s strategic measure in regard to defensive protection is to set up the Traditional Knowledge Digital Library (TKDL), an electronic database of TK in the field of medicinal herbs. The purpose of which is to prevent any registration of a patent for TK. The existing database will allow patent offices across the globe to search and examine every common usage and, thus, preventing any grants of wrong patent based on the knowledge in the public domain^[19, 20] Additionally, India has also made revisions on its Patent Law that has put into effect since 1970 with The Patent (Amendment) Act No. 15 of 2005. India’s Patent Law provides positive

protection of its traditional communities' TK through the Law's implementation within the national legal system of India.

b. Indonesia

In regulating the protection of TK of medicinal herbs for just and equitable access to health and welfare for the traditional communities, Ronald Dworkin's principle of justice serves as the basis, which revolves around the provision of facilities, infrastructure, and access for the people based on an equal opportunity, regardless of the genetic luck that results in "the different talents" and "the different ambitions".^[21] In Dworkin's criteria, a just law should 'take rights seriously'. He argues that this is fundamental start as a demand to the government to provide equal respect and concern to the people, to which he further added, "anyone who professes to take rights seriously, and who praises our Government for respecting them, must have some sense of what that point is. He must accept, at the minimum, one or both of two important ideas. The first is the vague but powerful idea of human dignity...".^[22] This line of thinking is pivotal in the regulation of TK, i.e., a legislative process consistent with said principle will produce a just law to realize the protection of TK.

Indonesia grants positive protection of medicinal herb TK, by enacting international conventions that have been ratified into national law through the Law No. 5 of 1994 on the Ratification of United Nations Convention on Biological Diversity, Law No. 11 of 2013 on the Ratification of Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity, Presidential Regulation of the Republic of Indonesia No. 78 of 2007 on the Ratification of the 2003 Convention for the Safeguarding of the Intangible Cultural Heritage. Moreover, the Law No. 13 of 2016 on Patent explicitly states that "Indonesia is a country with genetic resources and traditional knowledge oftentimes utilized by domestic and foreign investors to produce

new inventions. Therefore, this Law contains regulations regarding clear and honest mentions about the materials used for the invention should it pertain to and/or is derived from the genetic resources and/or TK in its description". However, as part of positive protection, the most ideal protection of TK is through a sui generis system. Currently, Indonesia has a Draft of Traditional Knowledge and Traditional Cultural Expression (TKTCE) Law as an effort to provide sui generis protection. The context of TK protection for the traditional community's access to health and welfare should encompass a number of essential points, which are:

1. General Scope of Subject Protection

Article 4 (1) notes that "The Scope of Traditional Knowledge comprises technical knowledge in the traditional context, traditional skills, innovations in the traditional context, traditional practices, traditional education, and knowledge inherited from generation to generation that underlies a lifestyle, including **Traditional Knowledge regarding genetic resources, traditional medicines**, and other intellectual properties". This article accommodates TK of medicinal herbs within a wide scope.

2. Beneficiaries of Protection

Article 3 of Draft of TKTCE Law mentions that "the country holds sovereignty to governs the regulation of TKTCE for the utmost prosperity and welfare of the people". This means that the regulation of TK is more appropriate to be passed on to the country for the utmost prosperity and welfare of the people that ultimately addresses the traditional community, in line with Article 11 of Draft of TKTCE Law—governing that "every citizen, whether they are individual, community, or business entity, has the right to make use of TKTCE to be used as and converted into raw materials for creative economy".

3. Fair and Equitable Benefit-Sharing

Access benefit sharing (*ABS*) is crucial for the

welfare of traditional communities, both in the form of monetary and non-monetary compensation. As monetary compensation, ABS can be provided through cash payment or continuous stipend, whereas non-monetary compensation is a model long practiced in Indonesia that has enriched Indonesian TK, in which the new products or works that are made based on it must be “returned” or available to those who have preserved the relevant TK.

Regarding ABS, the Draft of TKTCE Law dictates:

- 1) The caretaker communities receive benefits from the use of TKTCE;
- 2) Should the use of TKTCE be unknown to the caretaker communities, the government and/or local government acts as the caretaker for the benefit of the Indonesian people.

Furthermore, the Draft of TKTCE Law, Article 17 (1) stipulates that:

- 1) The distribution of benefits referred to in Article 14 section (4), is accomplished according to the agreements made between the User and the beneficiaries.
- 2) The agreement in section (1) is contained in written form unless otherwise specified contingent on the customary law.

A designated legal instrument is necessary to protect the traditional communities from the use of TK by third parties, especially in circumstances related to misappropriation. For that reason, provisions regarding obligations of “adequate disclosure (or disclosure of origin requirement)” are closely associated with ABS and Material Transfer Agreement (MTA).^[2] As a result, the distribution of economic and other benefits calls for provisions that lay down several preconditions, which are:^[2] *first*, establishing the stages to attain commercial benefit distribution through participation, partnership, and public-private sector collaboration. *Second*, determining the MTA standard that imposes

the resource beneficiary that commercializes products received from the multilateral system to pay according to the agreed mechanism—with equitable and fair benefit distribution—unless the products is readily available without limitations for subsequent research and advancements. This may serve as the basis of improvements for ABS provisions for TK within the Draft of TKTCE Law.

Conclusion

The protection of TK of medicinal herbs can be attained comprehensively using positive and defensive protection. Positive protection is implemented by ratifying international conventions in the field of IP and non-IP law in national law thus becoming a positive law. Defensive protection comprises the preservation and safeguarding by making inventory and documentation, compiled in a centralized database so that strategic measures can be made to prevent misappropriation of TK of medicinal herbs. These protection instruments are built on the principle of justice to fulfill the rights of traditional communities over access to health and welfare.

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