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THE LEGAL PROTECTION OF PATENTS ON PHYTOPHARMACEUTICAL PRODUCTS IN INDONESIA: CASE STUDIES AND THEORETICAL PERSPECTIVES

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ABSTRACT
Indonesia has great potential in the development of biowealth-based phytopharmaceutical products, considering its rich natural wealth and traditional medicine traditions. This study uses theories of legal utilitarianism, distributive justice, and legal positivism to explore the challenges facing Indonesia, as well as opportunities for more inclusive and adaptive reforms. This analysis employs a normative juridical approach, focusing on the analysis of written laws, regulations, doctrines and legal interpretations related to patent protection for phytopharmaceutic products. This approach enables a thorough understanding of the patent legal framework in Indonesia and its practical implementation. The case study method is used to evaluate several patents registered with the Directorate General of Intellectual Property (DJKI). The results show that Indonesia is facing a number of complex legal challenges in the patent registration process, ranging from barriers to novelty criteria and inventive steps to lengthy administrative processes. In addition, Indonesia needs to strengthen its national patent system and intellectual property protection strategies to ensure that local communities benefit fairly from the use of their traditional knowledge. This research could investigate how these mechanisms influence innovation within local communities and their role in fostering sustainable practices.

INTRODUCTION

Indonesia has great potential in the development of biowealth-based phytopharmaceutical products, considering its rich natural wealth and traditional medicine traditions. However, legal protection against innovation in this sector is still a major challenge, especially in the context of patent law. Patent law regulations in Indonesia are regulated by Law Number 13 of 2016 concerning Patents, which is the legal basis for invention protection. Recently, Indonesia updated this regulation through Law Number 65 of 2024, which aims to accommodate the needs of the community and adjust to the development of international practices in the field of intellectual property. The update brings several emphasises, including local innovation policies that support the development of biodiversity-based inventions. Law Number 65 of 2024 underlines the importance of encouraging local innovation that is in line with national needs, especially in sectors that rely on genetic resources such as phytopharmaceuticals. This includes the development of products and processes that not only meet market needs, but also leverage local capabilities to increase the added value of Indonesia's biological resources.

Patent protection in Indonesia is based on three main criteria, namely novelty, inventive measures, and industrial application. However, in practice, phytopharmaceutical products often face

obstacles in meeting these criteria, especially in the aspect of novelty. Many phytopharmaceutical raw materials are based on traditional knowledge that has been widely known and recorded in prior art documents. This makes the claim of novelty difficult to prove, even though the formulation or processing process may contain innovations (Rausch et al., 2023). In addition, traditional knowledge that is not systematically documented also increases the risk of biopiracy, as foreign parties can easily claim these materials as their property in international patent filings (Patel, 2023). Law Number 65 of 2024 tries to answer this challenge by introducing a traditional knowledge documentation mechanism to protect local biodiversity. This is similar to the steps taken by India through the Traditional Knowledge Digital Library (TKDL), which has proven effective in preventing unauthorized patent claims by foreign parties. Unfortunately, this mechanism still needs to be strengthened in its implementation in Indonesia, including harmonization between national laws and international standards such as the TRIPS Agreement.

This study aims to provide an in-depth analysis of legal issues in the registration and patent protection of phytopharmaceutical products, by combining theoretical and empirical approaches. The results are expected to provide recommendations to strengthen legal protections that not only protect innovators but also ensure fair benefits for the wider community. That way, Indonesia can maximize the potential of its biodiversity to support national health and economy.

METHODS

This research employs a normative juridical approach, focusing on the analysis of written laws, regulations, doctrines, and legal interpretations related to patent protection for phytopharmaceutical products. This approach enables a thorough understanding of the patent legal framework in Indonesia and its practical implementation. Additionally, the study utilizes a case study method to evaluate several phytopharmaceutical patents registered with the Directorate General of Intellectual Property (DJKI). The case study aims to identify common legal issues encountered in the patent registration process, including administrative barriers and challenges in meeting novelty and inventive criteria. The selected phytopharmaceutical products comprise local biodiversity-based inventions that have either been successfully patented or failed to obtain patent protection, providing a comprehensive overview of the associated challenges and opportunities.

RESULTS

Phytopharmaceutical products in Indonesia face a number of complex legal challenges, especially in the patent registration process, which is often a major barrier to the protection of innovation in this sector. The biggest obstacle is related to the novelty criterion, which is a fundamental requirement in the patent system as stipulated in Article 3 of Law Number 13 of 2016 concerning Patents. This criterion requires the invention to have an element of novelty in order to be patentable. However, most of the raw materials for phytopharmaceuticals come from traditional knowledge that has been documented in prior art, such as ethnopharmacological literature, written documents, or oral traditions that have been passed down from generation to generation (Tjandrawinata, 2020). Because this information is already considered "widely known," formulations based on natural ingredients often do not meet the criteria for novelty, despite the presence of an element of innovation in the process of developing the technology. For example, local plant-based formulations of traditional medicines, although they have been improved through innovations such as modern extraction methods or encapsulation technologies, are often denied registration because the main elements of their active ingredients are already documented in the scientific literature or traditional practices. This case shows the tension between modern innovation and traditional cultural heritage, which has not been fully accommodated by the current patent system. This challenge not only harms local innovators, but also hinders the global competitiveness of Indonesian phytopharmaceutical products. In addition, inventive steps are also a significant barrier.

In many cases, patent examiners often consider that innovations in extraction processes, stabilization of active ingredients, or reformulation of phytopharmaceuticals do not meet the standard of "inventive measures" because they are considered overly simplistic developments. In fact, these innovations can produce substantial practical benefits, such as increasing the bioavailability of active ingredients, extending shelf life, or reducing side effects. For example, nanoencapsulation technology applied to herbal extracts can significantly improve therapeutic efficacy through increased controlled release (Hanutami & Budiman, 2017). However, this lack of understanding of the value of technical

innovation often hampers patent recognition, suggesting that patent evaluation standards are not yet fully adaptive to the dynamics of the phytopharmaceutical sector. From an administrative point of view, the lengthy patent registration process and complex bureaucracy are also major obstacles, especially for small and medium enterprises (SMEs) that dominate the phytopharmaceutical sector in Indonesia. The high cost and time required to process patent applications creates significant obstacles. SMEs often do not have financial resources or access to adequate legal aid services, so they lose out to large companies that are better able to manage bureaucracy and costs (Cahyadi, 2015). As a result, innovation from high-potential SMEs often stalls before reaching the market.

At the international level, conflicts between national and international laws add another layer of complexity to the patent protection of phytopharmaceutical products. Especially in the context of the TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights), developing countries such as Indonesia face great challenges in balancing patent protection with justice for local communities. One of the issues that often arises is biopiracy, which is the exploitation of traditional knowledge by foreign parties without permission or fair compensation to the community of origin (Gulati, 2019). A prominent example is the patent case of turmeric (*Curcuma longa*) in the United States, where a patent claim over the use of turmeric for wound treatment was finally rejected after it was proven that the practice had been traditionally used for centuries in South Asia (Bhowmick et al., n.d.). This case emphasizes the importance of traditional knowledge documentation as a mechanism to prevent the exploitation of biological resources by foreign parties. Nevertheless, documentation alone is not enough to protect traditional knowledge. A more holistic approach is needed, such as strengthening the law on access and benefit sharing (ABS) that has been regulated in the Convention on Biological Diversity (CBD) (Kreiken & Arts, 2024). Indonesia needs to strengthen its national legal framework to ensure that local communities benefit fairly from the use of their traditional knowledge in phytopharmaceutical innovations. In addition, training and education programs for local innovators on appropriate intellectual property protection strategies, such as minor innovation patents or geographical indications, can be a solution to address these challenges. These legal and administrative challenges demonstrate the need for a comprehensive reform in the national patent system and intellectual property protection strategies in the phytopharmaceutical sector. This step is not only important to protect Indonesia's cultural heritage, but also to increase the competitiveness of phytopharmaceutical innovations in the global market.

Comparative Studies: India and China

Comparative studies from India and China can provide deeper insights into how they manage Access and Benefit Sharing (ABS) policies and document traditional knowledge to protect their biodiversity in a global context.

India With the Traditional Knowledge Digital Library (TKDL) System

India has been a global pioneer in protecting traditional knowledge through the Traditional Knowledge Digital Library (TKDL) initiative, a digital system that documents information on traditional medicine such as Ayurveda, Unani, Siddha, and other traditional health practices (Fredriksson, 2023). The TKDL is designed to prevent unauthorized patent claims on India's traditional knowledge and biowealth that have long been exploited without permission or compensation. By systematically documenting this knowledge, TKDL provides accessibility for patent examiners around the world, allowing them to verify patent claims by comparing information in the TKDL database (Fredriksson, 2023). This is an important step in protecting India's traditional resources from exploitation by foreign parties.

One of TKDL's key successes is its ability to prevent more than 200 invalid international patent claims. For example, TKDL helped overturn patent claims over the use of neem (*Azadirachta indica*) as a natural pesticide, turmeric (*Curcuma longa*) for wound treatment, and basmati rice, all of which are part of traditional Indian knowledge (Kumar & Sharma, 2024). In the case of turmeric, for example, a patent filed in the United States was denied after information in the TKDL showed that the use of turmeric for wound healing has been a common practice for centuries in India (Udgaonkar, 2002).

The success of TKDL is inseparable from the close collaboration between the Indian government, research institutions, and local communities. The Government of India, through the Council of Scientific and Industrial Research (CSIR), plays a central role in establishing and managing TKDL (Fredriksson, 2023). The data collected came from a variety of sources, including ancient manuscripts, traditional

medical texts, and interviews with local practitioners. The information is then translated into several languages, including English, German, Japanese, and French, to ensure that patent examiners in different countries can understand the context of that traditional knowledge. This detailed documentation makes TKDL a powerful tool in protecting India's cultural heritage from biopiracy (Kumar & Sharma, 2024).

The TKDL system is also designed to ensure that the economic benefits of using traditional knowledge can be returned to local communities. One example is the implementation of Access and Benefit Sharing (ABS) in accordance with the Convention on Biological Diversity (CBD). In this way, communities that are sources of knowledge gain recognition and financial benefits from the commercial exploitation of their knowledge (Barizah, 2021). For example, pharmaceutical manufacturers that utilize traditional formulations must contribute in the form of royalties or other compensation to the communities of origin. In addition, TKDL has encouraged transparency in the protection of traditional knowledge through the use of digital technology and big data. The TKDL database is designed to be easily accessible to patent examiners in member countries of the World Intellectual Property Organization (WIPO), which makes the process of evaluating patent claims more efficient and accurate (Deshpande, 2021). It also puts pressure on other countries to adopt a similar approach in protecting their traditional knowledge, making TKDL a global model.

However, despite showing significant success, the system still faces challenges. One of them is limited access for the general public. TKDL is only accessible to accredited patent examiners, while the scientific community or the wider public does not have direct access permission. This raises concerns about the lack of involvement of academics and traditional practitioners in managing recorded information. In addition, the integration of traditional knowledge with modern innovations often gives rise to conflicts between individual intellectual property rights and the collective rights of local communities (Fredriksson, 2023).

The success of TKDL also opens up opportunities for other developing countries to follow similar steps. This system proves that well-organized documentation can not only prevent the exploitation of traditional knowledge, but can also promote the sustainable use of biological wealth. By integrating modern technologies such as artificial intelligence and data analysis, TKDL can expand further to support innovation in the traditional knowledge-based medical and pharmaceutical sectors. On a global scale, TKDL is an important instrument in reducing conflicts related to biopiracy and increasing international recognition of the importance of protecting cultural heritage. Initiatives such as TKDL also encourage the international community to update policies related to intellectual property protection to be more inclusive of traditional knowledge. The system has shown how technology and cross-sector collaboration can be used to protect the rights of local communities while encouraging sustainable innovation (Fredriksson, 2023). Thus, TKDL not only serves as a protection mechanism but also as a successful example of a traditional knowledge protection model based on digital technology, which can be replicated by other countries to protect their biological wealth.

China: Traditional Chinese Medicine (TCM) dan Patent System

China adopts an innovative and effective approach in protecting traditional knowledge through the integration of Traditional Chinese Medicine (TCM) into the national patent legal system. This system allows traditional knowledge to be the basis for modern patentable innovations, provided the invention meets legal requirements, such as having elements of novelty, inventive measures, and industrial applications. This creates a legal framework that is adaptive to technological developments, while providing legal protection for traditional formulation-based innovations that have been enhanced with modern technology (Song et al., 2024). The Chinese government has taken proactive steps in documenting, researching, and standardizing TCM through various national research institutions, such as the China Academy of Chinese Medical Sciences (CACMS) and the National Administration of Traditional Chinese Medicine (NATCM) (J. Wang et al., 2016). These initiatives include the digitization of traditional recipes, the development of modern research methods, and the preparation of international quality standards for TCM products. With these steps, innovators can more easily patent new formulations, including products based on modern technologies such as supercritical extraction or nanoencapsulation, which improve the efficacy of active ingredients in TCM formulations (Zhou et al., 2024).

One example of remarkable success in integrating TCM into modern innovation is the discovery and patenting of artemisinin, an antimalarial drug extracted from the traditional Qinghao plant (*Artemisia annua*). The discovery, led by TCM scientist Tu Youyou, is based on in-depth research into

ancient medical texts that record Qinghao's use to treat fever. Using modern extraction methods, Tu Youyou's team successfully isolated the active compound artemisininin, which has high efficacy in treating malaria without causing drug resistance like previous therapies (Su & Miller, 2015). This success made a major contribution to global health and was internationally recognized with the Nobel Prize in Physiology or Medicine in 2015. Artemisinin is a symbol of how the integration of traditional knowledge and modern technology can result in wide-impact innovations. In addition, artemisinin-related patents also provide significant economic value to China, reinforcing the country's position as a leader in TCM-based innovation (Zheng et al., 2020).

One of the main advantages of the patent system in China is its speed and efficiency. The Chinese government, through institutions such as the China National Intellectual Property Administration (CNIPA), has designed a faster patent registration process than many other countries. This provides a competitive advantage for the TCM-based pharmaceutical industry, allowing innovators to launch new products to market more quickly (Huang et al., 2024). For example, the process of filing and evaluating patents in China can be completed in less than two years, much faster than the average time in the United States or Europe, which often takes more than three years (Lin et al., 2021). This pace not only improves TCM's global competitiveness, but also drives increased investment in research and development (R&D). With fast and efficient patent protection, pharmaceutical companies in China are more encouraged to develop new TCM-based innovations. Additionally, the patent system in China provides flexibility to accommodate patents on processes, methods, and formulations, which are often an important part of TCM-based innovation (Xia, 2023a).

The success of TCM in the patent system is inseparable from the support of government policies that focus on sustainability and global expansion. The Chinese government has included TCM as an integral part of the National Five-Year Plan, which includes strategies to increase international recognition of TCM. One of these strategies is to encourage the standardization of TCM products through collaboration with the World Health Organization (WHO) and Pharmacopoeia International. This step aims to ensure that TCM products meet international quality standards so that they can be accepted in the global market (W. Y. Wang et al., 2021). In addition, the government is also encouraging the integration of TCM into the global healthcare system, including research collaborations with other countries to develop new therapies based on traditional formulations. For example, China has established partnerships with countries in Southeast Asia and Africa for artemisinin-based malaria research, expanding the influence of TCM in global health efforts (Zhang et al., 2023).

Although the TCM patent system in China has shown many successes, challenges remain. One of them is the conflict between the protection of individual intellectual property rights and the collectivity of traditional knowledge. Many TCM formulations are based on ancient recipes that have been used for centuries, thus raising ethical questions about who is entitled to the economic benefits of the patent (Xia, 2023b). In addition, there is still a gap in international recognition of TCM, especially in Western countries, where TCM products often face strict regulatory barriers. However, with more and more scientific evidence supporting the efficacy of TCM, as well as the ever-growing innovation in pharmaceutical technology, the future prospects of TCM under China's patent system remain bright. The combination of policy support, patent system efficiency, and increased international recognition makes TCM a model that is not only relevant to China, but can also be adopted by other countries in protecting and developing their traditional knowledge. China has shown how Traditional Chinese Medicine (TCM) can be protected and developed through integration into the adaptive national patent system. From the discovery of artemisinin to the development of a rapid and efficient patent system, this approach not only protects cultural heritage, but also encourages innovation based on modern technology. By continuing to encourage global documentation, research, and collaboration, TCM can be a model for other countries in managing traditional knowledge to create sustainable health and economic benefits.

Implications and Recommendations for Indonesia

Indonesia, as a country with abundant biological wealth and traditional knowledge, has great potential to develop traditional knowledge-based products such as herbal medicine and phytopharmaceuticals. However, to maximize this potential, integrated strategic steps are needed to protect and utilize this wealth. The successes of India and China can be an important inspiration in building an adaptive and sustainable framework.

Establishment of Documentation Systems such as TKDL

Indonesia can learn from India's success in establishing the Traditional Knowledge Digital Library (TKDL), which has proven to be an effective tool to prevent the exploitation of traditional knowledge by foreign parties. A similar documentation system can be developed in Indonesia to record detailed information on various traditional medicines, including herbal medicine, phytopharmaceuticals, and other local herbs. This information needs to be drawn from written sources, ancient manuscripts, and oral traditions that have been passed down from generation to generation, by involving local communities as the main owners of such knowledge (Tjandrawinata, 2020). This system not only protects traditional knowledge but also provides access to patent examiners around the world to verify patent claims involving Indonesia's biodiversity. For example, information about traditional plants such as temulawak, sambiloto, and moringa leaves can be included in this database to prevent biopiracy. With a strong documentation system, Indonesia can strengthen its position in the protection of traditional-based intellectual property (Wiradirja, 2013).

Harmonization of National and International Law

Harmonization between national laws and international standards is urgently needed to ensure the competitiveness of Indonesian products in the global market. In this context, Indonesia needs to align national regulations, such as Law Number 65 of 2024, with the provisions of the TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights). This can be done by strengthening the implementation of Access and Benefit Sharing (ABS) as stipulated in the Convention on Biological Diversity (CBD) (Sulistianingsih & Ilyasa, 2022). With this harmonization, Indonesia can reduce the potential for international legal conflicts, such as biopiracy cases that often occur in the biowealth of developing countries. In addition, Indonesia also needs to encourage international recognition of geographical indications for traditional knowledge-based products, such as herbal medicine or essential oils, which can increase the added value of products in the global market.

Integration of Traditional Knowledge with Modern Technology

China has shown how the integration of traditional knowledge with modern technology can drive globally recognized innovation. An example is the discovery of artemisinin resulting from research on Artemisia annua, which combines modern extraction methods with a traditional knowledge base. Indonesia can adopt a similar approach to increase the added value of local phytopharmaceutical products (Su & Miller, 2015). Technology-based innovations, such as supercritical extraction, nanoencapsulation, and controlled release technology, can be applied to traditional Indonesian raw materials to improve the bioavailability, stability, and efficacy of products. With this system, traditional products not only meet patent criteria such as novelty and inventive measures, but can also compete in the global market (Wiradirja, 2013). For example, the development of temulawak extract with nano-encapsulation technology can produce more effective anti-inflammatory products (Rachmawati et al., 2015).

Bureaucratic Reform and Support for SMEs

The patent registration process in Indonesia currently still faces challenges in the form of long time and high costs, which are often obstacles for small and medium enterprises (SMEs) that dominate the phytopharmaceutical sector. Bureaucratic reform is needed to speed up the patent registration process and reduce the burden of costs, especially for local innovators who do not have access to adequate resources (Harahap et al., 2024). The government can also provide subsidies or tax incentives for SMEs that contribute to the development of traditional knowledge-based products. In addition, training and education programs are needed to increase the capacity of local innovators in understanding and utilizing the intellectual property protection system. An intellectual property legal aid center may also be established to provide support to innovators in the patent registration process.

Collaboration with Research Institutions and Local Communities

Support from governments, collaboration with research institutions, and the participation of local communities are essential in developing inclusive and sustainable traditional knowledge protection systems. The government can collaborate with universities and research centers to develop traditional methods of standardization and certification of knowledge-based products. Meanwhile, local communities must be actively involved in the documentation and product development process. This is

important to ensure that the economic benefits of the innovation can be returned to the community of origin, such as through a royalty system or profit sharing (Esmail et al., 2023). This kind of collaboration can also increase public trust in the government and the intellectual property protection system.

Increasing Phytopharmacasia's Competitiveness in the Global Market

With the strategic steps mentioned above, Indonesia has a great opportunity to increase the competitiveness of phytopharmaceutical products in the global market. Structured documentation, harmonization of regulations, and innovation based on modern technology can help position traditional Indonesian products as internationally recognized high-value products. In addition, with bureaucratic reform and support for SMEs, Indonesia's phytopharmaceutical sector can develop more rapidly and contribute to national economic growth.

The success of India and China in protecting their traditional knowledge provides valuable lessons for Indonesia. By establishing documentation systems such as TKDL, harmonization of national and international regulations, and integration of modern technologies, Indonesia can effectively protect its biodiversity and traditional knowledge. Bureaucratic reforms and support for SMEs are also needed to ensure that traditional-based innovations are widely accessible and developed. Through this approach, Indonesia can protect national biodiversity, promote sustainable innovation, and increase competitiveness in the global market (Harahap et al., 2024).

Discussion

The patent legal system in Indonesia plays an important role in protecting traditional knowledge-based innovations, such as phytopharmaceutical products. However, its effectiveness is often questioned due to various obstacles that hinder legal protection of the nation's biological and traditional wealth. This analysis uses theories of legal utilitarianism, distributive justice, and legal positivism to explore the challenges facing Indonesia, as well as opportunities for more inclusive and adaptive reforms.

Legal Utilitarianism: Optimization of Social Benefits

The theory of legal utilitarianism developed by Jeremy Bentham focuses on the goal of law to provide the greatest benefit to society (Pratiwi et al., 2022). In the context of patents, effective protection of phytopharmacasia-based innovations can provide a wide range of benefits, such as encouraging investment in research, improving public access to health products, and creating jobs. Natural ingredient-based products such as herbal medicine and phytopharmaceuticals have great potential to improve people's welfare through the provision of more affordable and locally-based treatment alternatives (Tjandrawinata, 2020). However, in practice, the patent system in Indonesia often benefits large companies that have access to resources and the ability to understand complex legal processes. Meanwhile, indigenous communities, which are the main source of traditional knowledge, often do not reap the economic benefits of their biodiversity-based innovations. This inequality raises ethical questions about how the benefits of patent protection can be distributed more equitably. To overcome this problem, a redistribution policy is needed through an Access and Benefit Sharing (ABS) mechanism, as stipulated in the Convention on Biological Diversity (Meyer & Naicker, 2023). For example, indigenous communities that have in-depth knowledge of plants such as temulawak, moringa leaves, or sambiloto are often the subject of exploitation without fair reward (Irawan, 2012). Redistribution of benefits in the form of royalties or direct profit sharing can ensure that the economic benefits of patents are also felt by the community of origin, while encouraging the sustainability of traditional-based innovation (Hoffmann, 2016).

Distributive Justice: Equitable Distribution of Benefits

The distributive justice theory introduced by John Rawls emphasizes the importance of equitable distribution of benefits in society (Fattah, 2013). In the context of phytopharmaceutical patent law, distributive justice is relevant to ensure that the economic benefits of patents are not only enjoyed by large corporations but also by parties that make significant contributions to innovation, such as indigenous communities and SMEs. This redistribution of benefits can be done through patent royalty mechanisms or collective recognition of traditional knowledge. In addition, the government can encourage the development of geographical indications for traditional knowledge-based products such as herbal medicine or essential oils. Geographical indications not only provide legal protection but also

increase the added value of products in the global market (Agustina & Yahya, 2022). However, this redistribution of benefits requires a supporting legal framework. For example, India has successfully developed the Traditional Knowledge Digital Library (TKDL), which records detailed information about traditional knowledge in a format that can be accessed by patent examiners around the world. This system prevents unauthorized patent filings of natural materials based on traditional knowledge and ensures that the economic benefits of such innovations remain in the hands of the origin community (Fredriksson, 2023). Indonesia can adopt a similar approach to protect its biodiversity and traditional knowledge.

Legal Positivism: A Systematic and Effective Legal Framework

The theory of legal positivism, as formulated by H.L.A. Hart, highlights the importance of written law that is clear, systematic, and can be applied consistently (Rusydi, 2021). In the Indonesian context, Law No. 13 of 2016 and Law No. 65 of 2024 concerning Patents have provided a legal framework to protect traditional knowledge-based innovations. However, its implementation often faces challenges, including a lack of harmonization between national regulations and international obligations such as the TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights). In addition, the capacity of institutions in Indonesia to support local innovators is still limited. Many small innovators and indigenous communities do not understand patent legal procedures or do not have access to adequate legal services. This makes them vulnerable to exploitation and loss of rights to their innovations (Adinugraha, 2022). Bureaucratic reform is needed to simplify patent registration procedures, reduce costs, and increase the capacity of local innovators through training and education (Limanto et al., 2024).

CONCLUSION

Patent law in Indonesia faces significant challenges in protecting phytopharmaceutical products, including barriers related to novelty criteria, lengthy administrative processes, and insufficient documentation of traditional knowledge, which heightens the risk of biopiracy. To address these issues, integrating theories of legal utilitarianism, distributive justice, and legal positivism could lead to a more inclusive patent system tailored to biodiversity-based products. Recommended policy reforms include developing documentation systems like Traditional Knowledge Digital Libraries (TKDL), harmonizing national and international laws, and implementing economic benefit redistribution mechanisms such as royalties and profit-sharing. These measures aim to enhance legal protection, promote sustainable innovation, and ensure equitable economic benefits. Future research could evaluate the effectiveness of these reforms through case studies and stakeholder interviews, focusing on their impact on preventing biopiracy, fostering innovation, and understanding perceptions of patent law in relation to biodiversity conservation and economic equity.

REFERENCES

Adinugraha, H. H. (2022). *EKONOMI KREATIF: Konsep, Peluang, dan Strategi Pengembangan*. Scientist Publishing.

Agustina, G. A. P. E., & Yahya, T. (2022). Perlindungan Hukum Terhadap Produk Indikasi Geografis dalam Perspektif Peraturan Perundang-Undangan. *Hangoluan Law Review*, *1*(2), 204–213.

Barizah, N. (2021). Access and Benefit Sharing of Biodiversity for Empowering Local Communities; Case Studies in Selected Countries. *Review of International Geographical Education Online*, *11*(4). https://doi.org/10.33403/rigeo.800636

Bhowmick, A., Roy, S. D., & De, M. (n.d.). A BRIEF REVIEW ON THE TURMERIC PATENT CASE WITH ITS IMPLICATIONS ON THE DOCUMENTATION ON THE DOCUMENTATION OF TRADITIONAL KNOWLEDGE. *NDC E-BIOS*, *1*.

Cahyadi, I. (2015). Tantangan Internasionalisasi Ukm Di Indonesia Dalam Menghadapi Masyarakat Ekonomi Asean. *Kajian*, *20*(02).

Deshpande, G. (2021). Traditional Knowledge and TWAIL. *Indonesian Journal of International Law*, *19*(3).

Esmail, N., McPherson, J. M., Abulu, L., Amend, T., Amit, R., Bhatia, S., Bikaba, D., Brichieri-Colombi, T. A., Brown, J., Buschman, V., Fabinyi, M., Farhadinia, M., Ghayoumi, R., Hay-Edie, T., Horigue, V., Jungblut, V., Jupiter, S., Keane, A., Macdonald, D. W., … Wintle, B. (2023). What's on the horizon for

community-based conservation? Emerging threats and opportunities. *Trends in Ecology and Evolution*, *38*(7). https://doi.org/10.1016/j.tree.2023.02.008

Fattah, D. (2013). Teori Keadilan Menurut John Rawl. *Jurnal TAPIs*, *9*(2).

Fredriksson, M. (2023). India's Traditional Knowledge Digital Library and the Politics of Patent Classifications. *Law and Critique*, *34*(1). https://doi.org/10.1007/s10978-021-09299-7

Gulati, R. (2019). BIOPIRACY, A BIOLOGICAL THEFT? *International Journal of Legal Studies (IJOLS)*, *5*(1). https://doi.org/10.5604/01.3001.0013.3244

Hanutami, B. N. P., & Budiman, A. (2017). Review Artikel: Penggunaan Teknologi Nano pada Formulasi Obat Herbal. *Farmaka*, *15*(2).

Harahap, N. A., Gaol, I. N. L., Sari, S., & Lubis, P. K. D. (2024). Tantangan Pendaftaran Hak Kekayaan Intelektual bagi UMKM sebagai Pelaku Ekonomi Kreatif Di Kecamatan pancing, Medan, Sumatera Utara. *EduTech: Jurnal Ilmu Pendidikan Dan Ilmu Sosial*, *10*(1), 90–95.

Hoffmann, W. A. (2016). Benefit-Sharing. In *Encyclopedia of Global Bioethics* (pp. 246–256). Springer International Publishing. https://doi.org/10.1007/978-3-319-09483-0_38

Huang, C., Cao, C., & Coreynen, W. (2024). Stronger and more just? Recent reforms of China's intellectual property rights system and their implications. *Asia Pacific Journal of Innovation and Entrepreneurship*, *18*(3). https://doi.org/10.1108/apjie-04-2023-0081

Irawan, C. (2012). *Politik hukum hak kekayaan intelektual Indonesia: Kritik terhadap WTO/TRIPs Agreement dan upaya membangun hukum kekayaan intelektual demi kepentingan nasional*. CV. Mandar Maju.

Kreiken, B. E., & Arts, B. J. M. (2024). Disruptive data: How access and benefit-sharing discourses structured ideas and decisions during the Convention on Biological Diversity negotiations over digital sequence information from 2016 to 2022. *Global Environmental Change*, *87*, 102892. https://doi.org/10.1016/j.gloenvcha.2024.102892

Kumar, P., & Sharma, A. (2024). Impact of TKDL on Patent Applications in the Field of Bio-resources and the Associated TK. *Journal of Intellectual Property Rights (JIPR)*, *29*(2), 133–140.

Limanto, C. J., Eugenia, F., & Tedjokusumo, D. D. (2024). Tantangan dalam Perlindungan Hukum Desain Industri di Indonesia: Perbandingan Hukum dengan Amerika Serikat, Uni Eropa, dan Jepang. *Iuris Studia: Jurnal Kajian Hukum*, *5*(2), 473–483.

Lin, J., Wu, H. M., & Wu, H. (2021). Could government lead the way? Evaluation of China's patent subsidy policy on patent quality. *China Economic Review*, *69*. https://doi.org/10.1016/j.chieco.2021.101663

Meyer, C., & Naicker, K. (2023). Collective intellectual property of Indigenous peoples and local communities: Exploring power asymmetries in the rooibos geographical indication and industry-wide benefit-sharing agreement. *Research Policy*, *52*(9). https://doi.org/10.1016/j.respol.2023.104851

Patel, A. (2023). Traditional Knowledge, Sustainability, and International Intellectual Property Law: Biopiracy in Patent-Intensive Industries. In *Sustainable Boardrooms. Responsible Leadership and Sustainable Management* (pp. 115–140). Springer Singapore. https://doi.org/10.1007/978-981-99-4837-6_7

Pratiwi, E., Negoro, T., & Haykal, H. (2022). Teori Utilitarianisme Jeremy Bentham: Tujuan Hukum Atau Metode Pengujian Produk Hukum? *Jurnal Konstitusi*, *19*(2). https://doi.org/10.31078/jk1922

Rachmawati, H., Budiputra, D. K., & Mauludin, R. (2015). Curcumin nanoemulsion for transdermal application: Formulation and evaluation. *Drug Development and Industrial Pharmacy*, *41*(4). https://doi.org/10.3109/03639045.2014.884127

Rausch, H., Schröder, S., Friedemann, T., Cameron, S., Kuchta, K., & Konrad, M. (2023). History and Present of European Traditional Herbal Medicine (Phytotherapy). In *History, Present and Prospect of World Traditional Medicine: In 2 Volumes* (Vol. 2). World Scientific. https://doi.org/10.1142/9789811282171_0003

Rusydi, M. (2021). HUKUM DAN MORAL: MENGULIK ULANG PERDEBATAN POSITIVISME HUKUM DAN TEORI HUKUM KODRAT H.L.A HART & LON F. FULLER. *AL WASATH Jurnal Ilmu Hukum*, *2*(1). https://doi.org/10.47776/alwasath.v2i1.134

Song, Z., Chen, G., & Chen, C. Y.-C. (2024). AI empowering traditional Chinese medicine? *Chemical Science*, *15*(41), 16844–16886.

Su, X. Z., & Miller, L. H. (2015). The discovery of artemisinin and the Nobel Prize in Physiology or Medicine. *Science China. Life Sciences*, *58*(11). https://doi.org/10.1007/s11427-015-4948-7

Sulistianingsih, D., & Ilyasa, R. M. A. (2022). THE IMPACT OF TRIPS AGREEMENT ON THE DEVELOPMENT OF INTELLECTUAL PROPERTY LAWS IN INDONESIA. *Indonesia Private Law Review*, *3*(2). https://doi.org/10.25041/iplr.v3i2.2579

Tjandrawinata, R. (2020). Konsep Obat Modern Asli Indonesia (OMAI) Dalam Penggunaannya di Fasilitas Kesehatan Formal. *Jurnal Perspective*, *33*(2). https://doi.org/10.6084/m9.figshare.12367331

Udgaonkar, S. (2002). The recording of traditional knowledge: Will it prevent "bio-piracy"? *Current Science*, *82*(4).

Wang, J., Guo, Y., & Li, G. L. (2016). Current Status of Standardization of Traditional Chinese Medicine in China. *Evidence-Based Complementary and Alternative Medicine*, *2016*. https://doi.org/10.1155/2016/9123103

Wang, W. Y., Zhou, H., Wang, Y. F., Sang, B. S., & Liu, L. (2021). Current Policies and Measures on the Development of Traditional Chinese Medicine in China. *Pharmacological Research*, *163*. https://doi.org/10.1016/j.phrs.2020.105187

Wiradirja, I. R. (2013). Konsep Perlindungan Pengetahuan Tradisional Berdasarkan Asas Keadilan Melalui Sui Generis Intellectual Property System. *Jurnal Hukum Ius Quia Iustum*, *2*(20), 163–185.

Xia, N. (2023a). Intellectual property protection for traditional medical knowledge in China's context: A round peg in a square hole? *Medical Law Review*, *31*(3). https://doi.org/10.1093/medlaw/fwad006

Xia, N. (2023b). The domestic struggle for traditional medical knowledge rights. *Developing World Bioethics*, *23*(1). https://doi.org/10.1111/dewb.12354

Zhang, Q., Wu, C., Ai, X., Huang, M., Zheng, B., Li, Y., Zhang, S., Yao, L., Wang, J., & Tang, Y. (2023). Study on the synergistic development of TCM service trade within the GBA. *Journal of Holistic Integrative Pharmacy*, *4*(3). https://doi.org/10.1016/j.jhip.2023.12.002

Zheng, W. rong, Li, E. chang, Peng, S., & Wang, X. shang. (2020). Tu Youyou winning the Nobel Prize: Ethical research on the value and safety of traditional Chinese medicine. *Bioethics*, *34*(2). https://doi.org/10.1111/bioe.12456

Zhou, E., Shen, Q., & Hou, Y. (2024). Integrating artificial intelligence into the modernization of traditional Chinese medicine industry: a review. *Frontiers in Pharmacology*, *15*. https://doi.org/10.3389/fphar.2024.1181183