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Regulation on Access and Utilization of Biodiversity in India; Lesson Study for Indonesia

Nurul Barizah*
Department of International Law, Faculty of Law, Universitas Airlangga, Indonesia
Email:nurul.barizah@fh.unair.ac.id

Abstract

The correlation between intellectual property rights (IPR) protection and biodiversity conservation, particularly problems related to access and the use of biodiversity has inspired biodiversity rich country like India to provide national legal framework to address those problems. India has issued Biodiversity Act of 2002 in response to its commitment to implement the Convention on Biological Diversity (CBD) and the Nagoya Protocol. This Act was enacted not only to govern biodiversity, but also to prevent the practice of biopiracy. Although Indonesia is one of the richest countries on biodiversity, the legal framework to protect and manage the use of its biodiversity in accordance with CBD's principles is lack of sufficient. The objective of this research is to analyze the Indian law on regulating access to and the use of biodiversity derived from its territory, and whether such law capable of preventing biopiracy. This research focuses on three aspects of the law that are: access and benefit sharing rules, documentation of genetic resources for defensive protection, and India's experience in challenging patent rights granted through litigation. The most important part of this research is the lessons learned from India which can be implemented in Indonesia facing similar problem.

Keywords: Access and Benefit Sharing, Biopiracy, India, Indonesia

I. INTRODUCTION

The term 'biopiracy' is not legal term, but it has been used by many legal scholars to explain the use of genetic resources and related traditional knowledge (GRTK) by other parties without consent and compensation of the keepers and owners of those resources, and secure it through intellectual property rights (IPR) system, particularly through patent and plant varieties protection (PVP) (Conferto, 2004); (Liang, 2011). The practice of 'biopiracy' has been happening in many countries, particularly in biodiversity rich developing countries like India (Banarjee, 2018), and Indonesia. But, legal approaches and reaction for both countries to address that problem are different.

Both Indonesia and India are a party to a number of international laws, mainly the Trade Related Aspects of Intellectual Property (TRIPs) Agreement, the Convention on Biological Diversity (CBD), and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). But compared to Indonesia, India often plays a prominent role in the negotiation of the World Trade Organization (WTO) forums dealing with issues of IPR related genetic resources, and advocating for developing countries' interests. Interestingly, India is at the forefront in struggling against misappropriation of biodiversity through legal

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actions. India has initiated and pursued litigation against unauthorized exploitation of biodiversity, like in the cases of *Turmeric*, *Basmati* and *Neem Tree* and successfully turned them into the subject of international concern.

Besides that, after the ratification of those international agreements, India has enacted a new legislation known as Biodiversity Act of 2002. Despite some challenges on implementation (Varma, 2017); (Ghosh, 2017), this Act becomes an important legislation on biodiversity governance of this country. It was enacted mainly to comply with India's commitment under the CBD and ITPGRFA, and the need to introduce new principles of CBD that are 'access and 'benefit sharing' in fair and equitable ways as a consequence of recognizing the rights of local communities over traditional knowledge (TK) into national law of India. Then, this country has issued implementing rules in 2004. Subsequently, after India ratified the Nagoya Protocol in 2012, the National Guidelines on Access and Benefit Sharing (ABS) was enacted in 2014.

Indonesia also faces the problem of 'biopiracy', such as in the cases of Shiseido, Megalara Garuda (LIPI, 2012), and *Ornithoptera Goliath* - a butterfly species originated from Papua (Jong and Ompusunggu, 2017). Many practices of 'biopiracy' are related to the problem of foreigner's access permit by abusing traveler visa to enter into Indonesian territorial forests (Zulivan, 2007). Unfortunately, most of the cases are undocumented well compared to India. Literatures related to practice of 'biopiracy' usually found in national and local newspapers. Furthermore, Indonesia also does not have specific institutions responsible for addressing this problem of 'biopiracy'. Although this country has ratified all International multilateral treaties above, and obligated to sets up national law in accordance with principles enshrined in the CBD and Nagoya Protocol, the national legislation is still in the form of Bill.

To address the problem of access, Indonesia uses the Act Number 11 of 2019 on National System on Science and Technology in which some Articles of the Act regulates license for foreign institutions and foreigners before conducting research Indonesia. Earlier, Indonesia has enacted Government regulation Number 41 of 2006 on License for Foreigner to Conduct Research in Indonesia. Thus the legal approach that has been used by Indonesia in dealing with practice of 'biopiracy' is through administrative law instrument only, namely license permit. Accordingly, it is significantly important to study on how India addresses the practice of 'biopiracy' through the enactment of specific law on biodiversity and their implementing rules in response to the Nagoya Protocol. To provide a complete picture of the law, it is also important to explore implementation problems that might arise so that Indonesia can learn from it.

From the above background, the purpose of this research is to analyze law and rules on access and utilization of biodiversity in India, and whether this law capable of preventing 'biopiracy' and providing sharing of benefit in equitable ways as mandated by the CBD and Nagoya Protocol. However, this research focuses on three aspects of the law, that are, firstly, the access and benefit sharing rules, the documentation of biodiversity including genetic resources as a defensive protection and the India's experience in the litigation process for

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challenging patent right granted overseas.

II. METHOD

The type of this research is normative legal research by mainly using primary and secondary legal resources. Primarily legal resources for this research consists of international law, such as conventions, treaties, protocols, and national law, like legislations, regulations, and rules relevant to this research. While, secondary legal materials consists of books on law related to the topic of this research, journal articles and many other references that can be scientifically justified. This research uses several approaches to address the problem arise that are; statute, conceptual and comparative approaches. Statute approach is significantly important to analyze existing laws, legislations, rules and bill related to the problems. This statute approach is also needed to find out philosophical considerations why the law was issued and *ratio legis* why a rule of law was enacted, and to analyze consistency among existing laws and regulations related to this research problem. Conceptual approach is also needed to understand several legal concepts, theories and thought to answer the problem, such as concept of access, equitable benefit sharing, and others. Then, comparative approach is required to compare Indian legal framework with Indonesia's prevailing laws. All the above legal materials and resources then analyzed by using such approaches above.

III. RESULTS AND DISCUSSIONS

III.1. Rules on Access and Benefit Sharing under the Indian Biodiversity Act

Access and Benefit Sharing for the use of biodiversity in India are mainly regulated under the Indian Biological Diversity Act (entered into force in 2002). In general, the Act addresses several issues related to the management of biodiversity which has considerable current concern, particularly in relation to the issue of 'biopiracy'. This Act reflects the Indian government's strong reaction to 'biopiracy' and desire to avoid direct confrontation with the WTO obligations related to plant genetic resources (Biber-Klemm and Cottier, eds, 2006).

According to the Preamble, the Act has three main purposes. Firstly, to regulate access to genetic resources and related knowledge by foreigners and other legal entities; Secondly, to secure equitable benefit sharing derived from the use of these resources with local people as the conservers of genetic resources and the holders of knowledge and information relating to the utilization of such resources, and lastly, to protect biodiversity related knowledge of local communities. For these purposes, the Act ordered (3) institutions; the National Biodiversity Authority (NBA); State Biodiversity Boards (SBB) and Biodiversity Management Committee (BMC). NBA is the body responsible for managing the implementation of the Act and issuing guidelines for access to genetic resources and regulating fair benefit sharing from their use (section 18). The NBA is also empowered to advise the Central Government on matters related to biodiversity conservation and sustainable use, and fair benefit sharing (section 18 (3)). The SBB and BMC have roles to promote conservation, sustainable use and documentation of biodiversity at both national and local levels. They will be consulted in

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facilitating access (section 41) but, ultimate decisions will lie with the NBA (Devi and Padmavati, 2016).

One of the measures to prevent the problem of 'biopiracy', the Act stipulates very strict access requirements based on the principle of prior approval from the NBA (section 3-4). Section 3 (2) states that all persons and legal entities except Indian citizens who obtain any biological resource and or knowledge associated with it for either commercial or non-commercial activities, including transfer and exchange of research results, with the exception of collaborative research, and must have prior approval from the NBA. Interestingly, according to the explanation of section 4, the meaning of 'transfer' does not include publication of research papers or dissemination of knowledge in any seminar or workshop, if such publication is as per the guidelines issued by the Central Government.

Collaborative research is subject to different conditions specified in sub-section (3) that require compliance with the policy guidelines approved and issued by the Central Government (section 5). To obtain approval from the NBA, an application with a fee shall be made by any person intending to obtain biological resources (section 19). The NBA will decide to grant or reject the application after consultation with an expert committee. This approval shall not include approval to transfer any biological resources or related knowledge. There is a separate process to apply for permission to transfer (section 20). When the NBA decides to grant approval for either access or transfer of biological resources, the terms and conditions will be specified including any imposition of charges and the royalty. Furthermore, when granting approval, the NBA will ensure fair benefit sharing from the use of accessed biological resources in conformity with MATs and conditions between the person applying for such access, local bodies concerned and the benefit claimers (section 21).

Then section 21 (3) specified that the money derived from benefit sharing will be deposited in the National Biodiversity Fund. However, in a case where biological resources are the result of access from specific individuals or organizations, the amount of benefit sharing will be directly given to such individuals or organizations in line with any existing agreement.

Significantly, as stipulated under section 7, the Act prohibits any citizen of India or any legal entities registered in India to take biological resources for the purpose of commercialization, including bio-surveys and bio-utilization without prior notification to the concerned SBB. But, local people who take the resources and communities, which include growers and cultivators of biodiversity together with indigenous medicine practitioners like *vaids* and *hakims,* are not required to comply with this provision. The main function of the SBB is to restrict certain activities which have potential to violate the conservation objectives (section 24).

In the context of IPR, the Act stipulates a very rigorous provision. Section 6 requires that any person applying for any kind of IPR, in or outside India, for any invention derived from any research or information on biological resources obtained from India, must obtain prior approval from the NBA. If a person applies for a patent, approval from the NBA may be

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obtained after the patent is accepted but before the sealing of patent by the patent authority concerned. Similar conditions apply to the approval of access and transfer, when the NBA is granting approval for applying for IPR, they may oblige a benefit sharing fee or royalty or both, or impose conditions which may include financial benefit sharing arising from the commercial use of such right. Applicants for PVP are excluded from the provisions under Article 6 above. The NBA is also entitled to take any necessary measure to oppose the grant of any IPR in any country outside India on any biological resources or related knowledge derived from India (section 18 (4)).

With respect to the fund, the Act stipulates that the National Biodiversity Fund shall be used; (1) to channel benefits to the benefit claimers; (2) to conserve biological resources, and to develop the area in which the biological resources and related knowledge have been accessed; and (3) to support social and economic development of such areas (section 27). The State Biodiversity Fund also, shall be used for (1) conservation and management of heritage sites; (2) rehabilitation and compensation of the people economically affected by the development of heritage sites; (3) biological resources conservation; and (4) the promotion of social and economic development of such areas (section 32).

The Act requires the Central Government to respect and protect traditional knowledge related to biodiversity through several measures recommended by the NBA (section 36). These measures include providing a *sui generis* system of IP protection and registration of such knowledge at local, state, and national levels. Surprisingly, the Act does not provide recognition to biodiversity related community's IPR. It may be more appropriate to protect such rights under a *sui generis* system like PVP or farmers' rights rather than under the patent system which is unable to provide a fairer balancing of interests.

There are also several difficulties in the practice of the benefit sharing mechanism proposed by India, particularly with the involvement of many stakeholders. This is because the legal framework of benefit sharing pursuant to the Act is designed to regulate foreign stakeholders only, and does not provide sufficient provision for benefit sharing by local and Indian national stakeholders. In addition, this well –designed mechanism becomes controversial in practice and may even hinder the sustainable use of such resources when they become commercially feasible, due to the problem of over exploitation (UNEP and WIPO, 2000).

III.2. Documentation of Biodiversity under the Indian Biodiversity Act

Another way to prevent the practice of 'biopiracy' is through documentation of biodiversity related to TK (Tripathi, 2017). This Biodiversity Act regulates documentation of biodiversity, which could be useful to check potential 'biopiracy' and to assist the local BMC to provide evidence in the case of challenging the IPR granted in foreign jurisdictions (Verma, 2005). India is also setting up a traditional knowledge digital library (TKDL) (Nakazora, 2015). But, some rich traditional knowledge village communities reject the concept of patent monopoly over their natural resources and because of that they keep their knowledge secret. For example, in the documentation of all natural resources and

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knowledge related to these resources in *Pattuvan* Village of Kerala (one of the States in India with the richest level of biodiversity), the Village undertook to register all natural resources and related TK. The register was accompanied by the people' Biodiversity Declaration asserting that no monopoly claims on life forms will be accepted by local people. This documentation is also subject to conditions that it is not for commercial exploitation of local knowledge, and the register was kept as a secret, and information sharing was only permitted in exceptional circumstances (Verma, 2005).

Despite the practical difficulties of documenting such knowledge, this approach is not without controversy. There are concerns that TKDL could be used as tool that facilitates 'biopiracy' on the basis that a little improvement on an original traditional medicine can easily be regarded as a novel product that was not previously known. In the 'dry eyes' case for example, the case of a patent granted on the ailment 'dry eyes'. In the Indian literature, 'dry eyes' control has been spelled out through the use of leaves of Aloe Vera (leaves of Kumari plant in Indian Language). The process of the remedy is to take few leaves of Aloe Vera, wash these in clean water and then crush the leaves. Put some drops of solution that is extracted from the leaves into the eyes and the' dry eyes' problem is cured. The patent application has been granted to the USPTO follow the same principle or similar process, the only different is that the clean water has been replaced with chlorinated water. And of course, the technical terms and languages also used to make it look like a new product (South Centre, 2002).

The TKDL Task Force study also found that there were a significant number of medicinal plants that have been the subject of patent granted by the USPTO but can be categorized as traditional (Kidd, 2012). The TKDL Task Force itself was astounded to learn that of the 4, 896 references on 90 medicinal plants in the USPTO database, 80 per cent of the references pertained to just seven medicinal plants of Indian origin. In other words, nearly 4,000 patents or patent applications are based on the medicinal properties of plants that were already known. The task Force studied the patents and found that 360 of the 762 patents on medicinal plants that were granted by USPTO could be easily categorized as traditional (South Centre, 2002). Therefore, these patents are not novel and potentially invalid.

Furthermore, the function of documentation is limited to simply acknowledging local people's knowledge, but does not clearly specify that the conserver, creator and holder of such natural resources and related knowledge are the owners of these resources. This condition may in a sense be contrary to the possible interests of knowledge holders or indigenous people (Krisna, 2019). This may imply that benefit sharing as an attempt to make a bargain offered by the owner of such resources and knowledge would not be achieved. It seems that this documentation sacrifices local communities and farmers' rights and denies their rights over their knowledge and innovations.

This experience of India has shown that the TKDL supported by World Intellectual Property Organization (WIPO) and UNCTAD is obviously not the single answer to the problem of 'biopiracy' because of the inherent weaknesses of this system (Sharma, 2017).

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III.3. Litigation Against Unauthorized Patent Granted Overseas; India's Experience

The Indian Council of Scientific and Industrial Research (CISR) has a long extending experience in challenging patent right granted in other countries on the basis that the claimed invention was part of the public domain of India, such as in the cases of *Turmeric, Basmati*, and *Neem Tree*. In the Turmeric case, two researchers from the University of Mississippi Medical Center, the US, applied for a patent on the use of *Turmeric* at the USPTO (US patent No. 5, 401,504). While it is well-recognized that Turmeric is one of the most basic ingredients of Indian food. It is also known to have antiseptic properties. *Turmeric* has long been used as a traditional medicine in India for 'treatment of various sprains and inflammatory conditions'. The patent was then re-examined and as a result, all the claims cancelled (Cullet, et. al, 2006).

Similarly, in the case of *Basmati*, RiceTec, a Texas Company, received a patent for 'novel rice lines and to plants and grains of these lines and to a method for breeding these lines' in 1994 (Kumar, 2019). Basmati is along grained rice with more than 400 varieties, traditionally grown in both India and Pakistan. RiceTec's original patent claim consisted of twenty claims which mostly described the starch index, the burst index, the production per acre, the length of the seed, the height of the plant, and the method of selecting a rice plant based on the starch index, burst index, etc. Then, the CISR of India challenged the patent on the basis that the rice characteristics claimed were already in use in India. The CISR also submitted 'prior art' as evidence. After re-examination process, the United States Patent and Trademark Office (USPTO) limited the number of claims granted to RiceTec, in which only allow some claims, while all physical characteristic claims were rejected. However, the RiceTec, still has a patent and can still call its rice '*Basmati'*. This is because the US Federal Trade Commission considered the term '*basmati*' as generic and therefore, anybody can use it (Ghosh, 2003); (Kohls, 2007).

Furthermore, a number of *neem* tree related -patents were filed in the US and Europe. A patent, granted to Robert Larson (The US nationality) and in 1988, sold to W.R, Grace (US patent 5, 124,349) was the most controversial issue. The claim of the patent covers a method of creating a stabilized *azadirachtin* solution itself. Patent claims for novel insecticide of antifungal product and process used to obtain the *neem* oil were also filed in the EPO Patent 0436 257.While *Neem Tree* is an indigenous plant of India. Its oil has been used as a medicine to cure a number of ailments for hundreds of years. The residue, after oil has been extracted from the *Neem* seeds, can be used as an effective pesticide. Consequently, in 2000, the Indian NGOs and the Government then challenged this patent. The Opposition Division of the EPO revoked the patent because the claims did not satisfy the requirement of novelty in view of their prior art in India. In the context of conservation, it is important to note that after the patent was granted, the *Neem* trees have been exploited on a big scale as W.R Grace began processing twenty ton of *Neem* tree per day. This led to the skyrocketing price of *neem* trees in India from 300 rupees per ton to 3500 rupees per ton, resulting in this resource becoming unaffordable for local farmers in India to purchase (Aoki, 1998).

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However, there are many cases that have not received significant publication, for example, '*phyllanthus niruri'* (commonly known as *Bhadharti* in Sanskrit and *Jaramla* in Hindi) for the cure of jaundice or viral hepatitis. The use of *Phyllanthus niruri* for treatment of jaundice has been an ancient and well –recorded innovation in the Indian system of medicine. But, the Fox Chase Cancer Centre of Philadelphia has applied to the EPO for its use in curing viral hepatitis B (Verma, 2005).

III.4. Lesson Study for Indonesia

As mentioned earlier, that Indonesia has ratified CBD in 1994, twenty five years ago, and Nagoya Protocol in 2013, seven years ago, but the national legislation as mandated by both international laws is still the form of bill. Although Indonesia faces the practice of 'biopiracy', but specific legislation has not yet been issued.

To address the problem of unlawful access to Indonesian territorial forests by abusing of visitor visa granted to foreigners, the Indonesian Government uses the Act Number 11 of 2019, a new Act on National System on Science and Technology and Government Regulation No 41 of 2006 which specifically regulates foreign entities and individuals who will conduct research in Indonesia. Both new Act and Regulation clearly mentions that all foreigners cannot bring samples, specimens, research material in any form overseas without Material Transfer Agreement (MTA). Under the new Act, the requirements for access and to conduct research seems uneasy to be fulfilled by foreigners, because it requires the output of the research shall have benefit to Indonesia, technology transfer, and benefit sharing in proportional way as specified in the agreement (Article 76). However, implementing rules on benefit sharing has not been issued yet.

Under the CBD, the Parties to the Convention has to establish national law which consistent with the principles stipulated under the Convention, such as access and benefit sharing in equitable ways, but Indonesia is regulate access only, this country still does not consider the significant to regulates benefit sharing resulting from access. This is probably the answer for the reason why there are no benefit sharing agreements that have been concluded between local communities and the users of biodiversity and related knowledge. This is also showed that regulation on access only is still unable to solve the problem. It is therefore, the provisions on access shall be accompanied by the provisions on benefit sharing arrangement in equitable way.

In the context of documentation of biodiversity and knowledge related to it, as suggested by the WIPO, Indonesia have been developing database for documentation of genetic resources, TK, and traditional expression with the purpose for protecting biodiversity from 'biopiracy' and national economic development (BRPSDI, 2018). The Ministry of Agriculture, through Plant Varieties Protection Office sets up database for agricultural genetic resources for the purpose not only for preventing 'biopiracy', but also for preventing genetic extinction, and management of such resources in certain localities. While, the Indonesia Institute of Science also manages national biodiversity database. The data

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collected from different resources, such as from reports and other institutions, and because of that, the quality of data collected by those institutions are varied, some derived from unverified field data and others derived from a scientifically data collection (Nakano, et.al. eds, 2012). The data exchange derived from research project and collaboration also transferred to Indonesian Institute of Science (Kamau, et.al, eds, 2015).

From those perspectives, Indonesia needs to learn from India on how to govern its richness of biodiversity by enactment of a specific and comprehensive national legislation as mandated by the CBD and Nagoya Protocol. A mere access permit rules for foreigner entities and individuals are insufficient to address the practice of 'biopiracy' in this country. Indonesia shall also appoint special agency responsible for not only protecting biodiversity nationally, but also preventing of unlawfully use and exploitation of biodiversity by using IPR system. An institution which has a capacity to challenge a patent right granted to a part of Indonesia's genetic resources and the public domain by unauthorized person, like the authority given to the Indian Council of Scientific and Industrial Research (CISR) is also needed by Indonesian Institute of Science. In addition, the documentation of genetic resources in the form of database as a defensive protection that have been developed by Indonesia also needs to take into consideration the experience of India. As such documentation has a potential to facilitate 'biopiracy'.

IV. CONCLUSION AND SUGGESTION

The conclusions from this research are as follows:

1. It is important for biodiversity rich country to implement principles of CBD and Nagoya Protocol on providing national law on access and benefit sharing from the use of biodiversity. This national law is not only for biodiversity governance but also to prevent the practice of 'biopiracy'. Despite several challenges in its implementation, the provisions under the Indian Biodiversity Act able to prevent such unlawful practices.

2. One of the challenges in implementation of such law is the provision on documentation of biodiversity related TK in the form of TKDL. This is regarded as defensive protection, however, the experience of India showed that this approach has inherent weaknesses. Despite the practical difficulties of documenting such knowledge, this approach could be used as tool to facilitate 'biopiracy'. This documentation tends to sacrifice local communities and denies their rights over their knowledge and innovations.

3. National Agency, like the Indian CISR which has responsibility to challenge unauthorized patent granted overseas through litigation are needed. Such Agency is a crucially important not only to prevent unlawful patent granted overseas because of using part of biodiversity and related TK derived from national territory, but also to show that country has a sovereign right over biological resources in its territory in accordance with CBD's Principle. It is also to show that the law is capable of being enforced well.

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Based on the above conclusions, this research suggests that Indonesia needs to learn from India on how to govern its richness of biodiversity by enactment of a specific and comprehensive national legislation and its implementing rules as mandated by the CBD and Nagoya Protocol. The Indian Biodiversity Act and its implementing rules are not without weaknesses, but it has much strength to regulate access and benefit sharing, conserve biodiversity, and prevent 'biopiracy'. Indonesia can adopt some substantive provisions which can be well implemented. It is time for Indonesia to take serious legal approach to prevent the practices of 'biopiracy' before our biodiversity runs out.

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