

# Ensuring Disclosure of Origin of Genetic Resources in Patent Applications: Indonesia's efforts to Combat Biopiracy

*by Mas Rahmah*

---

**Submission date:** 18-Oct-2021 11:37AM (UTC+0800)

**Submission ID:** 1676696245

**File name:** JIPR\_25\_1-2\_40-56.pdf (95.48K)

**Word count:** 12750

**Character count:** 71562

## Ensuring Disclosure of Origin of Genetic Resources in Patent Applications: Indonesia's efforts to Combat Biopiracy

Mas Rahmah,<sup>1†</sup> Nurul Barizah<sup>1</sup> and Sam Blay<sup>2</sup>

<sup>1</sup>Department of Private Law, Law Faculty, Universitas Airlangga, Surabaya, Indonesia

<sup>2</sup>Department of Indonesian Studies, The University of Sydney, Sydney, Australia

*Received: 21 April 2018; accepted: 23 January 2020*

As a country of mega biodiversity, Indonesia is also vulnerable to biopiracy target. To prevent biopiracy, it is crucial to protect the country's genetic resources. In order to protect genetic resources and to prevent biopiracy, Indonesia has included the requirement of Disclosure of Origin (DO) in The Indonesian Patents Act, 2016 by imposing patent applicants to disclose the origins of genetic resources in Patent application. This paper critically analyses the Patents Act to highlight key issues that undermine the country's efforts to combat biopiracy. The principal findings are that there are significant problems with implementing DO provisions of the Act in the fight against bio piracy. The effectiveness of the legislation remains questionable and some important sections of the Act lack clarity. The purported regulatory framework under the Act to enforce DO and to help deal with biopiracy is ill defined and human resources are inadequate. The paper concludes that to combat biopiracy effectively Indonesia needs to review its legislative and institutional framework on DO and consider establishing a National Anti-Biopiracy Commission.

**Keywords:** Patents, Disclosure of Origin, Trade Related Aspects of Intellectual Property Rights, The Indonesian Patents Act, 2016, Indonesian Economy, Biodiversity, UPOV Convention, 1991, Indonesian Plant Variety Protection Act, 2000, Convention on Biological Diversity, genetic resources, biopiracy, UPOV Convention 1991, National Anti Biopiracy Commission of Peru

Genetic resources (GR) are important in critical areas of economic activity for food production, health, and poverty reduction. For the agriculture sector, GR are essential for agro biodiversity.<sup>1</sup> However, the legal control and ownership of GR remain a difficult and complex issue particularly for developing countries. The countries, including Indonesia, rich in biodiversity have long struggled to establish ownership and maintain sovereign control over their GR in order to protect them from biopiracy through misappropriation and unfair exploitation, particularly by foreign biotechnology-based industries from developed countries. The protection of GR is an integral element of a state's sovereignty over its natural resources. But GR is also at the heart of several bio-related patents. Developing countries consider the current international intellectual property (IP) regime that enshrines respect for patents as not serving their interests, and is sometimes incompatible with the conservation and sustainable use of genetic resources. The IP regime in relation to genetic resources particularly in Trade Related Aspects of

Intellectual Property Rights (TRIPS) is seen as largely favoring the interests of developed countries that generally seek access to GR in developing countries sometimes without adequate acknowledgment or compensation.<sup>2</sup>

The commercial exploitation of naturally occurring biochemical or genetic material, without paying fair compensation to the community from which it originates constitutes biopiracy.<sup>1</sup> To prevent biopiracy, patent applicants are required to disclose the origins of the GR in accordance with the laws of the source country. The DO ensures transparency within the patent system and facilitates the monitoring of genetic resources utilization. In 2016, Indonesia enacted the Indonesian Patents Act<sup>3</sup> that deals with GR and the enforcement of related law. However, the implementation of the Act to police and enforce DO in the Indonesian patents system has been far from effective. Indonesian policy and laws have lagged behind the practice and complexity of biopiracy and bioprospecting thus raising questions about the effectiveness of the current legal framework. The objective of the article is to critically assess the effectiveness of *The Patents Act* in the country's

<sup>†</sup>Corresponding author: Email: rahmah\_arifin@yahoo.com

effort to combat biopiracy. The paper is divided into seven parts. The first part provides the importance of protection of GR that includes Indonesian diversity, the importance of GR for Indonesian economy and necessitates an effective DO regime to protect GR. Part two analyzes sovereignty over natural resources to protect GR. Part three discusses the concepts of biopiracy and bio-prospecting. Part four overviews DO by analyzing the concept, the development, the function and the scope of DO. Further, the last part analyses the inclusion of DO in Indonesian Patents Act followed by the effectiveness of DO to combat biopiracy with critical challenges in part six. Finally in part seven, the paper discusses the main findings with recommendations.

### **The Protection of Genetic Resources**

#### **Indonesia's Mega Biodiversity**

As a tropical archipelago, Indonesia's territory comprises some 17,499 islands with a landmass of 2.01 million km<sup>2</sup>. Its maritime territory covers an area of about 5.8 million km<sup>2</sup> consisting of 3.25 million km<sup>2</sup> of territorial waters and 2.55 million km<sup>2</sup> of Exclusive Economic Zone. With a coastline of 80,791 km, and flanked by the Pacific and Indian oceans, Indonesia is home to some of the richest biodiversity in the world.<sup>5</sup> The country's documented species diversity comprises 1,500 species of algae, 80,000 fungal species, 595 species of lichens, 2,197 fern species, and 30,000-40,000 of spermatophyte species, accounting for 15.5% of the world flora. It is also home to 8,157 fauna species of mammal, bird, reptile, fish and 1,900 butterfly species accounting for 10% of the species on earth.<sup>6</sup>

#### **The Importance of GR for Indonesian Economy**

For centuries Indonesian communities have traditionally exploited genetic resources in plant species for their daily needs and crops' improvement through breeding and domestication. Since most Indonesians depend on the agricultural sector for subsistence and employment, the protection and conservation of the country's biodiversity and GR is critical to Indonesia's socio economic infrastructure. To put this in perspective, more than 100 species of plants are used as sources of carbohydrate; about 100 species of leguminous plants for protein and fat; about 450 species are harvested as fruit trees. About 1000 species are used as for ornamental plants, 250 species of vegetables for vitamin and mineral sources, 70 species are used for spices, and 40 species are used

for beverages; and more than 940 species are used as traditional medicinal plants.<sup>6</sup> The success of breeding and domestication depend heavily on GR diversity as the sources of genes. The proper management of GR especially plant genetic resources is very important for supporting breeding programs and other agricultural uses. The effective management of GR is also essential for supporting the proper utilization of plant genetic resources. It can help prevent biopiracy, ensure sustainability use of genetic resources, and accordingly support food security programs.

GR are essential for agriculture development and agro biodiversity. Agriculture in Indonesia is the main source of fulfilling domestic food consumption.<sup>7</sup> The demand of domestic consumers for agricultural products has been increasing over the years and its growth has largely been attributed to Indonesian per capita income growth.<sup>8</sup> It is undeniable that agriculture is a key factor to the Indonesian economy. The agricultural sector has lifted millions out of poverty and provided a platform for both rural and urban economic growth. For Indonesia, the protection of its GR and the need to combat biopiracy are therefore essential elements in its economic development strategy.

There is also an urgent need to ensure the security and development of GR to underpin Indonesian food security because of the vital contribution of GR (especially plants GR) for agro business. According to Article 1 of 1996 Rome Declaration on World Food Security,<sup>9</sup> food security exists when all people, at all times, have physical and economic access to sufficient safe and nutritious food that meets their dietary needs and food preferences for an active and healthy life. Similarly, The Indonesian Food Act of 2012 also defines food security as a situation where an individual at all times, has physical, social and economic access to sufficient, diversified, safe and nutritious food that meets his or her dietary needs necessary for an active and healthy life.<sup>10</sup> However, food security should not be seen in terms of the ability to access to food alone. Food security systems and strategies also involve interrelated subsystems that include production, process, distribution, and the consumption of food.<sup>11</sup> These in turn are determined by availability and the production of seeds and control over plant materials.<sup>12</sup>

#### **The Necessity of GR Protection**

The protection of GR in Indonesia is as complex as the vastness of its territory and its intricate mega

biodiversity. The problem for the country is how to balance the imperative of sovereign control of GR while still promoting and encouraging national and international research and development based on its rich biodiversity. The adoption of the Indonesian Patents Act with its provisions on DO was meant to address the balance between the competing demands of sovereignty over GR and the need to protect the national interest on the one hand, and the attraction of the country's mega biodiversity for international research and development and potential patent applicants for the benefit of mankind. To understand the issues with the Indonesian Patents Act it is first necessary to examine the concepts of biopiracy and bio prospecting that necessitate DO to protect the country's GR.

DO has become a critical issue in the modern era of biotechnology advancements where pharmaceutical and agricultural companies make extensive use of the patent system and rely on their research and development (R&D) based on naturally occurring materials or GR. They hunt and study GR, exploring opportunities to develop new products, techniques and applications. However, questions about fair and equitable access arise when no authorization for access to the resources, and no compensation is paid to local communities for their contribution in R&D activities, and when an invention developed from genetic resources is patented. For developing countries such as Indonesia that are rich in biodiversity, the international regime of DO provides an important avenue for protecting national sovereignty over GR.

### **The Principle of Sovereignty over Natural Resources to Protect GR**

#### **Genetic Resources and the Sovereignty over Natural Resources**

Prior to the CBD, genetic resources were regarded as a common good and part of the common heritage of mankind. The international customary law notion that genetic resources were *res nullius* led to the impression that genetic resources were "(...) something over which everybody and, at the same time, nobody had rights".<sup>13</sup> Under this notion, everybody and nobody specifically have the right to access and use genetic resources. The state (of origins') right could only be understood within the context of everybody's right.<sup>14</sup> That meant that States in whose territories the genetic resources found have

the right to use the genetic resources, but not to regulate any genetic resources related to activities of other States in their territories.

The first international agreement to recognize states' sovereign rights with respect to plant genetic resources was the FAO International Undertaking on Plant Genetic Resources, as clarified by Resolution 3/91, which endorsed the concept that "nations have sovereign rights over their plant genetic resources."<sup>15</sup> This principle means that a state has the power and jurisdiction to establish how the resources and assets (tangible and intangible) existing in its territory are distributed, used and eventually subject to property rights. However, the FAO undertaking limits such rights by allowing access to samples of plant genetic resources only for specified purposes (scientific research, plant breeding or conservation). The undertaking clearly excludes access with the aim to reproduce the materials for commercial purposes, such as for propagating seeds.<sup>16</sup>

The CBD went a step further by establishing rules of a binding nature, applied to resources held in their natural habitats. The FAO also adopted the International Code of Conduct for Plant Germplasm Collection and Transfer<sup>17</sup> that included rules on the granting of collectors' permits and on the responsibilities of collectors, sponsors, curators and users of plant germplasm. Progressively, the CBD brought about more significant changes when Article 15 not only recognized the sovereign rights of states over their natural resources, but also their authority to determine access to genetic resources and benefit sharing subject to their national legislations. While the *res nullius doctrine* did not clearly delineate the rights of states over genetic resources, the CBD came to advocate a right states never had before: the sovereign right over genetic resources in their jurisdiction and determining the related rules of access and other conditions (Article. 15.1). Under the CBD, not only were states obliged to respect the need for their biogenetic resources to be made available for humankind, but they were also required to respect the right of a significant other class of stakeholders such as indigenous peoples cultivating or breeding the genetic resources. It must however be noted that under the terms of the CBD the right to protect genetic resources is not meant to be a tool against access since it is contrary to the CBD objectives to illegitimately restrict access to genetic resources.<sup>18</sup>

As a CBD party, Indonesia is required under the CBD framework to enact laws domestically in order to give effect to the principles and commitments in the CBD including provision related to access and benefit sharing. Based on the right to regulate, genetic resources are managed and controlled by Indonesia as sovereign custodian. According to Article 15.2 of the CBD, Indonesia has the sovereign right to regulate access to genetic resources in its territories and is encouraged to tailor measures that facilitate access and sustainable use of genetic resources, as well as promote benefit sharing from utilized genetic resources (Article 15.7). This requires appropriate legislative, administrative and policy measures (Article 15.7). Genetic resources users in turn are obliged to compensate suppliers for appropriation of these resources and to share benefits from utilized resources either in monetary or non-monetary form. They are also required to provide DO of the genetic resources based on the Bonn Guidelines and Nagoya Protocol.

#### **GR and Indonesia's Sovereignty over Natural Resources**

The sovereignty of Indonesia over its natural resources is acknowledged under Article 33.3 of Indonesian Constitution 1945 which states that the land, the waters and the natural resources within Indonesia shall be under the powers of the State and shall be utilized for the greatest benefit and social welfare of the Indonesian people. With specific references to plant genetic resources, the country's sovereignty has been recognized under the Indonesian Plant Variety Protection Act of 2000 which provides that local plant varieties owned by the community shall be under the control of the State (Article 7.1). Such control of the State referred to in paragraph Article 7.1 shall be implemented by the Government (Article 7.2). The government is responsible for giving denomination to the local varieties (Article 7.3). Provisions relating to the denomination of the variety, registration, and the use of local variety as well as the agency that is given the implementation task shall be further regulated by the Government (Article 7.4).

Sovereignty over genetic resources is further reflected in the 2017 Ministerial Regulation released by the Research and Technology and Higher Education Ministry. The regulation aims to prevent biopiracy. It stipulates that the government will no longer provide recommendations for foreign

researchers to conduct research in less-explored regions prone to natural resources theft such as Papua and Maluku islands.<sup>19</sup> While the regulation does not impose a total ban on research in those areas, it makes it more difficult for foreign scientists to obtain a permit for research there. Indonesia allows local researchers first to conduct research in areas where new species of flora and fauna have been found.

The 2017 ministerial regulation was a response to the threat of biopiracy in Indonesia. It also aims to fight a more subtle form of biopiracy that occurs through unfair research cooperation agreements between local and foreign scientists. The government's free-visa policy for 169 countries - aimed at boosting foreign tourist arrivals in Indonesia - has made it easier for foreigners to access Indonesian local genetic resources under the guise of tourism. There are concerns that foreign 'tourists' are prospecting, developing and exploiting local genetic resources without obtaining consent or relevant permits from authorities or providing fair compensation to Indonesia as stipulated in the Nagoya Protocol.<sup>20</sup> All these factors necessitate a rigorous and coherent patent governance system that incorporates a well policed regime of DO in Indonesia as a necessary anti biopiracy strategy.

#### **Biopiracy and Bio prospecting of GR**

##### **Biopiracy**

One of the functions of DO is to eliminate biopiracy. The term biopiracy is used to describe misappropriation of indigenous people's knowledge and biocultural resources, especially through the use of IP schemes.<sup>21</sup> The term implies negative connotations. Accordingly some prefer the neutral phrase "appropriation without benefit sharing".<sup>22</sup>

Although there are no authoritative definitions for the term of biopiracy, it is generally defined as unauthorized use of biological resources or traditional knowledge, unequal shares of benefits, or patenting without respect to substantive patent law criteria. Graham Dutfield defines biopiracy as "theft, misappropriation of, or unfair free riding" or "unauthorized and uncompensated collection [of GR] for commercial ends."<sup>23</sup> Vandana Siva refers to biopiracy as the use of IP systems to legitimize the exclusive ownership and control over biological resources and biological products that have been used over centuries in non-industrialized countries.<sup>24</sup> Biopiracy includes elements such as the acquiring of

<sup>21</sup> exclusive monopoly control through use of intellectual property and in particular patenting, and the lack of prior informed consent for the transaction.<sup>25</sup> Biopiracy is essentially the patenting of (often spurious) inventions based on biological resources and/or traditional knowledge that are extracted without adequate authorization and benefit sharing from other (usually developing countries), indigenous or local communities.<sup>26</sup>

Common patterns of biopiracy cases reflect commodification accompanied by patenting of promising genetic resources from the developing world. The world's first case against biopiracy was a patent taken out by *WR Grace and Co* in the well-known Neem Tree of India (*EPO Patent 436257 B1*), which was famously revoked in 2000 after community opposition on the grounds of lack of novelty and inventive steps.<sup>27</sup> Another famous case was a USA patent held by University of Mississippi (*US Pat No. 5401, 504*) for turmeric powder which was a well-known wound-healing medicine in India, and which was successfully revoked on the ground that the plant used was common knowledge in India.<sup>2</sup> In Indonesia, the Shiseido case became a famous biopiracy incident in which the Japanese cosmetic Shiseido patented 11 different compounds of Indonesian traditional medicinal plants or "Jamu", and after launching a campaign against the claim, Shiseido withdrew its patent at the European Patent Office.<sup>27</sup>

Cases of biopiracy are most commonly associated with the granting of a patent over some product or derivative from genetic resources and/or traditional knowledge. Incidents of biopiracy and genetic resources misappropriation have been triggered by the strengthening of IP systems in developed countries and the expansion of IP protection to biological materials and their derivatives.<sup>28</sup> The rise of an aggressive biotechnology industry using genetic resources in developed countries has also played a role in contributing the rise of biopiracy phenomenon.<sup>29</sup>

#### **Bio prospecting**

In the early 1990s bio prospecting became a political talking point when less developed countries perceived injustice because the benefits from those inventions were not passed on to them. The origins of the term bio prospecting are associated with the 1993 book *Biodiversity Prospecting* by Reid *et al.*, where it

<sup>33</sup> was defined as the exploration of biodiversity for commercially valuable genetic and biochemical resources.<sup>30</sup> The term bio prospecting has come to be used to positively portray the collection of biological specimens for scientific research and/or commercialization, in contrast to biopiracy.<sup>31</sup> Bio prospecting is defined as where parties from more economically developed countries travel to less developed countries with high biodiversity, and seek natural source materials from which to develop drugs and other inventions. Bio prospecting involves searching for, collecting, and deriving genetic materials from biodiversity samples that can be used in commercialized pharmaceutical, agricultural, industrial, or chemical processing end products.<sup>32</sup>

To address bio prospecting and biopiracy, the World Intellectual Property Organization (WIPO) and CBD, proposed mandatory a requirement to disclose - in relevant patent applications - the source of genetic resources used in the invention, and the source countries that would have the right to some share of the profit from the invention. This provided the foundations to implement DO in a legally binding and universal manner by facilitating a global and compulsory system of disclosure and access and benefit sharing (ABS) as a level playing field for commercial exploitation of patents derived from genetic resources under Article 15(7) of the CBD.

#### **Disclosure of Origin**

##### **The Concept of Disclosure of Origin**

In general terms, DO refers to the obligation, included mainly in genetic resources access laws, to disclose the country of origin or source of genetic resources used in an invention, or to demonstrate the legality of access to the resources.<sup>32</sup> This obligation may also include evidence of the existence of prior informed consent, the fair and equitable sharing of the benefits, and compliance with national law regarding access to the genetic resource or traditional knowledge.<sup>32</sup> DO is thus a critical element in intellectual property applications, product approval and the monitoring access to and utilization of genetic resources and traditional knowledge.<sup>33</sup>

##### **The Development of DO**

<sup>30</sup> DO was introduced formally at the sixth Conference of Parties (COP) to the Convention on Biological Diversity (CBD) in 2002. The COP adopted the Bonn Guidelines as voluntary guidelines

to address access to genetic resources and fair and equitable benefit sharing arising from use of genetic resources.<sup>34</sup> The Bonn Guidelines encourage national governments to oblige patent applicants to disclose the country of origin of genetic resources and the origin of traditional knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles (traditional knowledge), when the subject matter of the application concerns or makes use of genetic resources in its development.<sup>35</sup> The Guidelines also provide that user countries should take into account measures to promote disclosure of the origin of genetic resources and the origin of knowledge, innovations, and practices in IP applications (16.d.ii).

The aim of disclosure is to help track compliance with prior informed consent and the mutually agreed upon conditions on which access to genetic resources was granted. Furthermore, at the VII Conference of the Parties, in CBD Decision VII/ 19, aspects related to disclosure of the origin of genetic resources in IP applications were identified, including aspects related to the certificate of origin or source/legal provenance. CBD Decision VII/19 advocated for (a) model provisions on proposed disclosure requirements; (b) practical options for IP rights application procedures with regard to the triggers of disclosure requirements; (c) options for incentive measures for applicants; (d) identification of the implications for the functioning of disclosure requirements (e) IP-related issues raised by proposed international certificate of origin/source/legal provenance.<sup>36</sup>

DO may include information of: (a) genetic resources used in developing claimed inventions; (b) the country of origin of such genetic resources; (c) associated traditional knowledge used in such development; (d) the source of such associated genetic resources and traditional knowledge; and (e) evidence of prior informed consent.<sup>37</sup>

The rationale for DO is to prevent misappropriation of genetic resources, and ensure compliance with prior informed consent and benefit sharing obligations. DO has not only been justified within the patent system, but also outside patent regime. The introduction of DO in patent systems aims to improve examination and to determine inventorship.<sup>38</sup> On the other hand, the obligation of DO outside the patent system aims at ensuring compliance with prior informed consent (PIC) requirements and to promote effective benefit sharing arrangements.<sup>39</sup> The

arguments justifying the DO within the patent system has been put as follows:

*"a legally binding obligation to disclose the source and country of origin of biological resources and/or traditional knowledge used in inventions will guide the patent examiners in ensuring that all relevant prior art information is available to the patent examiners. Disclosure will also be relevant in helping patent examiners determine whether the claimed invention constitutes an invention that is excluded from patentability under Article 27 Paragraphs 2 and 3 of the TRIPS Agreement. Further, disclosure would serve as part of a process to systematize available information of biological resources and traditional knowledge that will continuously build the prior art information available to patent examiners and the general public. In addition to matters relating to prior art, patentability and exclusions to patentability, the disclosure requirements will also be useful in cases relating to challenges to patent grants or disputes on inventorship or entitlement to a claimed invention as well as infringement cases. It has already been shown in the TRIPS Council that patent challenges involve a great cost in terms of time and resources, and are not a suitable option for developing countries. Patent grant challenges, cases on inventorship or entitlement as well as infringement cases form an important component of processes that ensure patent quality. In this regard, it is noteworthy that disclosure requirements of various types are already an accepted norm in international patent law practice".<sup>39</sup>*

#### **The Function and Scope of Disclosure of Origin in Patent Law**

The DO was initially associated with international environmental law; but in modern times but its relevance is generally associated with patent law.<sup>17</sup> Correa notes that DO enhances the substantive examination of patent applications that are based on genetic materials and knowledge of their resources. The disclosure may facilitate the determination of prior art by providing useful information to the examiner. The information supplied may also help to identify possible cases of misappropriation of biological materials and facilitate actions to challenge the validity of wrongly granted patents.<sup>40</sup> In essence, disclosure 'functions to help ensure that inventions that meet the criteria of novelty, inventive step and industrial application are granted exclusive rights, and to exclude from patentability those that do not meet these criteria, as well as to make technical information

available to ABS law, by requiring inventors to include and make public relevant information about important inputs obtained from provider countries.<sup>41</sup>

Disclosure ensures the transparency by allowing national authorities that grant access to genetic resources to track the use of these resources in patent applications and deeds. Disclosure is at the core of the policy rationale and the practical operation of the patent system. Disclosure illustrating technical and legal information, often to exacting standards, is central to the operation of the patent system because the grant of a patent and the effective exercise of patent rights, are based on the principle of adequate disclosure. The patent system involves making publicly available a detail of legal, administrative and technological information, in an accessible format. The disclosure in patent applications is used as a resource for those monitoring the use of genetic resources in inventions, including where the nature of genetic resources derived from and a matter of existing practice, disclose significant information concerning genetic resources.

DO obligation ensures that all relevant prior art information is available to patent examiners, and enables examiners to determine whether the claimed invention is excluded from patentability under Article 27(2) and (3) of the TRIPS Agreement. DO obligations require inventors to disclose sources of genetic resources where such resources have been identified as inventive contributions. While naturally occurring GR are clearly not inventions, traditional knowledge that triggers the research leading to the patenting associated with GR may well qualify as an 'inventive contribution' that needs to be declared. According to one authority on United Kingdom, "the generation of the idea or avenue for research, that is the formulation of the problem to be addressed, has also been treated as inventive".<sup>42</sup> The extent to which traditional knowledge may constitute invention contribution however depends on national legislation. WIPO notes:

*"Where the inventive activity of a patent applicant uses the (traditional knowledge) (TK) as a lead or a hint, and the TK is not part of the inventive process as such, then TK holders or TK providers may not be considered a co-inventor as such. Outcomes in this area and the distinctions between inventive and non-inventive contribution may also vary according to the way general principles are applied in respective national legal systems. Potentially, what is considered*

*an inventive contribution in one jurisdiction may not be considered as such in another jurisdiction, meaning that the obligation to identify each inventor could in some borderline cases differ in different countries – cases in which TK provided a directly relevant lead or constituted the first step of the inventive process could figure among such borderline cases. This eventuality is illustrated by Rule 4.6 (c) of the Regulations under the PCT, which provides for the possible need for a request filed with an international application to "indicate different persons as inventors where, in this respect, the requirements of the national laws of the designated States are not the same".<sup>43</sup>*

### **Incorporation of DO within the Indonesian Patent System**

#### **Regulation of DO in the Indonesian Patent Act 2016**

As noted earlier, DO was formally introduced in the sixth Conference of Parties (COP) to the CBD and adopted in the Bonn Guidelines in 2002.<sup>44</sup> Indonesia ratified the United Nations Convention on Biological Diversity (UNCBD), and enacted its own Act No. 5 of 1994. Not only was the Convention ratified to achieve its three main objectives, namely (i) the conservation of biological diversity, (ii) sustainable use of components; and (iii) fair and equitable sharing of benefits arising from use of genetic resources, but also it is in line with Indonesia's national food security interest and general economic development as discussed earlier in this paper.

While the DO framework adopted in the CBD and Bonn Guidelines are not mandatory, Indonesia considered it prudent to legislate for a patents regime that incorporates DO. Thus, The Indonesian Patent Act, 2016 adopted DO for patent applications. The framework introduced under The Indonesian Patent Act, 2016 does not only deal with information about origin, but also compliance with national access laws, including effective fair and equitable benefit sharing. The Indonesian Patent Act, 2016 replaced Law No. 14 of 2001 on Patents and was meant to bring clarity to the issue of Patents. Relevantly on the issue of GR, the Act provides an obligation to specify the origin of genetic resources and or traditional knowledge in the descriptions of those inventions derived from either source: (i) to avoid any potential contesting claims by other countries; and (ii) to support access benefit sharing for Indonesia.

In the preamble, The Act acknowledges that patents are granted as intellectual property by the state



to inventors and that patents have ‘a strategic role in supporting the development of the nation and promote the general welfare’. Interestingly enough the preamble also states that ‘technological development in various fields has been so rapid that it is necessary to increase the *protection of inventors and patent holders*. What is interesting about this statement in the preamble is that the focus appears to be on the ‘protection of inventors and patent holders’ without reference to Indonesian interests as a host or source state. On GR and the issue of disclosure, the Act says very little. Indeed only Article 26 directly mentions GR and DO directly:

(1) *If the Invention relates to and / or originates from genetic resources and or traditional knowledge, it have to be mentioned clearly and correctly the origin of genetic resources and / or knowledge traditional in the description.*

(2) *Information on genetic resources and / or traditional knowledge as referred to in Paragraph (1) shall be established by an authorized institution recognized by the government.*

(3) *Distribution of results and / or access to utilization of genetic resources and / or traditional knowledge as referred to in paragraph (1) shall be carried out in accordance with the laws and regulations international treaties in the field of genetic resources and traditional knowledge.*

There are other sections of the Act that relate indirectly to GR. For instance under Article 93:

(1) *The Minister may grant a compulsory license for the manufacture of pharmaceutical products patented in Indonesia for the treatment of human disease.*

(2) *The Minister may grant a compulsory license for the import of the procurement of pharmaceutical products patented in Indonesia but have not been able to be produced in Indonesia for the treatment of human disease.*

(3) *The Minister may grant a compulsory license for export of pharmaceutical products patented and manufactured in Indonesia for treating human disease by demand from developing countries or underdeveloped countries*

However the effectiveness of this provision will depend on whether the inventor patented the product in Indonesian. As a party to the CBD has to enact laws to give effect to mainly in relation to: (a) the conservation of biological diversity, (b) sustainable use of its components, and (c) fair and equitable

sharing of benefits arising from use of genetic resources. Under the Convention, Indonesia has the sovereign right to regulate access to genetic resources in its territories and to adopt measures to regulate access and sustainable use and benefit sharing of genetic resources found within its territory (Article 15.7). The Indonesian Patent Act, 2016 is thus consistent with the rights and obligations of Indonesia under the CBD. Other laws such as Article 33.3 of the Indonesian Constitution and Articles 7.1, 7.2 and 7.3 of the Indonesian Plant Variety Protection Act 2000 also complement The Indonesian Patent Act, 2016. In addition, the 2017 Ministerial Regulation of Research and Technology, and Higher Education issued a regulation to control the utilization of local genetic resources and prevent misappropriation.

#### Model of Imposing Disclosure of Origin

DO for genetic resources can be mandatory or voluntary, direct and indirect. Disclosure of origin requirements could be direct (mandatory and enforceable through a loss of patent rights), indirect (mandatory but enforceable only through means other than the patent system), and voluntary or on permissive basis.<sup>45</sup> According to Graham Dutfield, voluntary DO is the least burdensome. It encourages the disclosure of genetic resources to an invention being patented without any penalties. Given the voluntary nature, noncompliance with such disclosure requirements gives rise to no legal consequences since it would not disqualify the patent application from being accepted, being granted, or being subsequently enforced. On the other hand, with mandatory DO, the burden of compliance is placed on patent applicants, and the failure to disclose or dishonest disclosure will could lead to the rejection of the patent application or if granted it would not be enforceable, or it can be revoked with possible criminal sanctions.<sup>46</sup> The role of the provider country is to monitor compliance and take legal action in cases of non-compliance.

The DO can also be substantive or procedural in nature. The DO is procedural where it is reviewed at stages of IP application process for completeness and for formal compliance with specified procedures. It is substantive if compliance is required in determining validity or legality of the application. In the case of plant varieties, The International Union for the Protection of New Varieties of Plants (UPOV Convention 1991) UPOV does not consider DO as a requirement or an additional condition for plant

varieties protection because based on Article 5, the UPOV has established specific requirements to grant a plant breeder right where the variety is new, distinct, uniform and stable.<sup>47</sup> The UPOV stipulates that plant breeders' rights shall not be subject to different or further conditions, provided by national formalities.

Although Indonesia has not ratified the UPOV Convention, similar criteria for protection of plant varieties have been stipulated based on the 'new, distinct, uniform and stable' elements (Article 2.1 of Indonesian Plant Variety Protection Act). In addition, according to Article 30.1 of Indonesian Plant Variety Protection Act, substantive inspection is to be conducted by the examiner who shall investigate whether a variety is new, distinct, uniform and stable. While the Act appears silent on disclosure, the examiner is allowed to demand information related to genetic resources because Article 33.2 of Indonesian Plant Variety Protection Act stipulates that in conducting the inspection, the PVP office may request information from other institutions from within the country or abroad.

In the case of patent applications, substantive requirements must be met in order to obtain a grant of a patent of IP rights, while failure to comply with requirements on DO may have severe consequences such as cancellation of IPR, refusal to process applications, revocation of patents, or placing IP in joint ownership or possible criminal sanctions. The Indonesian legislation is ambiguous with respect to DO requirements. In fact, unlike 'novelty' or 'non-obviousness' as patentability requirements that concern the substance, i.e., the very essence of an inventive activity, DO seems to be merely an accessory, which relates to the invention collaterally under the Act. Similarly, the Act stipulates the patentability of invention based on the criteria of 'new or inventive steps' related to the industry (Article 3 of The Indonesian Patent Act, 2016). DO obligation is not made a part of substantive patentability requirements under Article 3 of The Indonesian Patent Act, 2016.

In order to enforce the compliance with DO requirement, there are options for sanctions against noncompliance including patent invalidity, unenforceability of a patent, transfer of patent right, imposition of benefit sharing arrangements, criminal sanctions, or rejecting patent processing. Indonesia has stipulated legal consequences for failure of compliance of DO requirement under Article 58.1<sup>48</sup>

of The Indonesian Patent Act, 2016. This provision affirms the interconnection of the obligation to provide DO with the legal consequences that failure to satisfy any of these requirements will result in the rejection of a patent application. In addition, under Article 62 Paragraph (10) of The Indonesian Patent Act, 2016, the failure to satisfy DO requirements also affects the judgement of application withdrawal. Furthermore, Article 132 (1) provide legal consequences by terminating the patent validity based on a court decision if the terms of patents derived from genetic resources and or traditional knowledge do not satisfy the provisions of DO as referred to Article 26. Under Articles 67 and 68 of The Indonesian Patent Act, 2016, applicants can file an objection to a rejection of patent application with the Appeal Committee of the Directorate General of Intellectual Property<sup>49</sup> as a post-grant administrative challenge proceeding. Alternatively, a judicial action can also be brought as substantive review of a decision on invalidity based on Article 130 of the Act.

Since DO under the Indonesian Patent Act 2016 may be reviewed for substantive requirements, it is also essential to establish mandatory DO requirements in order to prevent misappropriation of genetic resources, to prevent misuse of IP system, and to promote compliance with CBD access and benefit-sharing requirements, reflecting the interconnection of the CBD regime with the IP regime. Mandatory DO requirements may be useful in improving substantive examinations and in assuring the integrity of determinations under conventional IP legal requirements, in providing greater certainty as to the validity of granted rights or privileges, and in reducing the need for revocation of improperly granted IP. Such disclosure assists in identifying conditions and facilitating corrective actions where IP is wrongfully granted, or where access to genetic resources has been obtained without prior informed consent and equitable benefit-sharing. The DO is also necessary to prevent misappropriation of commercial benefits that are inappropriately obtained as consequence of applying, owning or transferring IP.

### **Effectiveness and Challenges of Disclosure of Origin to Address Biopiracy**

#### **Effective to Address Biopiracy**

Indonesia being rich in genetic resources has been always been an easy target for seed and biotechnology multinational enterprises engaging in agribusiness for

the purpose of bio-piracy. The obligation of DO may contribute to address a major concern of developing countries about the biopiracy of genetic resources and traditional knowledge (TK),<sup>55</sup> especially in patent. DO paves the way for monitoring the respect of the rules on utilization, commercialization of genetic resources, including access and benefit-sharing, where such rules are in place. Disclosure may stop biopiracy or the misappropriation of genetic resources, or granting of “bad patents.”<sup>50</sup> Bad patents concern ideas that are only of minimal variations on existing knowledge or hardly new. According to Correa, without further improvement, there has been extensive documentation of patent being sought over plant genetic resources “as they are”. There were many incidents of bad patents such as *US Pat No. 5,304,718* on quinoa granted to researchers of the Colorado State University, *US Plant Pat No. 5,751* on Ayahuasca - a sacred and medicinal plant of the Amazonia, and on products based on plant materials and knowledge developed and used by local/indigenous communities such as the cases of the Neem Tree, Kava, Barbasco, Endod and Turmeric, among others.<sup>51</sup>

The misappropriation of GR and the forgone benefits derived from their utilization continues to elicit serious misgivings among the biodiversity rich countries, including in Indonesia. A series of cases of misappropriation of genetic resources have solidified the tensions between CBD objective of promoting the fair and equitable benefit sharing and the types of incentives established by IP rules under TRIPS. According to Article 8 (j) of the CBD, there is a commitment to respect, preserve and maintain genetic resources and traditional knowledge. In relation to inventions directly based on genetic resources or traditional knowledge, there is an obligation for patent applicants to disclose and declare the specific source of such resources, if knowledge, innovations and practices of traditional knowledge and genetic resource are used on the invention. However, the realization of these CBD objectives has faced tremendous challenges. The CBD objective has proven difficult to implement in an effective manner since the use of genetic resources is increasingly linked with international trade. Genetic resources users such as individuals, researchers and firms that develop innovative applications based on such resources, often are located outside the country of origin of these resources, thus it is arduous to implement the obligation of DO including benefit sharing.

Benefit sharing and DO have reciprocal relationships in which benefit sharing cannot occur if patent-holders do not disclose the geographical origins of the biological resources that they used for their inventions. Many biopiracy cases have persisted because of an information problem that exists at the patent application level. In patent applications, those engaging in biopiracy often do not identify the geographical origins of genetic resources materials, and when patent offices approve the applications, these patent-holders could enjoy the fruits of their products for a long period without encountering a challenge.

DO at the patent application stage is essential because it gives prompt notice to those who want to challenge the patent by examining requirements of patentability. According to Article 27.1 of TRIPS, key criteria for obtaining a patent shall be available for any inventions, whether products or processes, in all fields of technology provided that they are new, involve an inventive step and are capable of industrial application.

Article 3.1 of The Indonesian Patent Act, 2016 has also adopted similar criteria by stipulating that a patent shall be granted to an invention, which is novel, involves an inventive step and is susceptible of industrial application. According to Article 5.1. of The Indonesian Patent Act, 2016, an invention shall be considered novel, if at the date of filing of the application, the invention is not the same with any previous technological disclosure. Moreover, an invention shall be deemed to involve an inventive step if the invention does not constitute something that is obvious to a person skilled in the art (Article 7.1. of the Act). The evaluation of whether or not an invention constitutes something that is obvious must be made taking into account the state of the art at the time the application is filed or which has existed at the time the first application was filed, in case the application is filed on the basis of a Priority Right (Article 7.2. of the Act). Furthermore, an invention shall be considered susceptible of industrial application if it can be implemented in the industrial as described in the application (Article 8 of the Act).

In cases of biopiracy, complainants have often challenged the lack of real novelty frequently due to existing art in the form of common/traditional knowledge or documented prior use. In Indonesia, the consideration of novelty is based on the criteria as to whether at the date of filing, the invention is not the

same with any previous “technological disclosure”. Article 5.2. of the Indonesian Patent Act 2016 further stipulates that technological disclosure as referred to is one which has been announced in Indonesia or outside Indonesia by writing, by a verbal description or by a demonstration, or in other ways, which enable a skilled person to implement the invention before the Filing Date, or the Priority Date.

In Indonesia, DO is relatively new; therefore the effectiveness of this measure remains unproven, and needs other measures that can be just as valuable in preventing biopiracy. In addition, DO can only deal with a small part of the problem of genetic resource misappropriation, and so a range of other measures is also needed. The implementation of a workable DO regime with prior informed consent, ABS legislation and other measures such as certificates of origin, systems to track genetic resources, or monitoring and controlling system within sectoral fields, will be the effective way of preventing biopiracy.

### **Challenges of Disclosure of Origin**

#### **Regulatory Challenge: Lack of Clarity**

Although Indonesia has imposed an obligation of DO and benefit sharing under Article 26 The Indonesian Patent Act, 2016, further provisions are needed to enforce the regulation since Article 29 of the Act mandates that further provisions concerning the terms and procedures for filing the patent application, including the patent requirements such as DO and benefit sharing shall be regulated by a Ministerial Regulation. Since the Ministerial Regulation has not been adopted yet, the scope of procedural, institutional and legal consequences relating to non-compliance of DO remains unclear. Indonesia has not yet specified many details, including the circumstances leading to the requirements for disclosure, content of information, the timing, format and level of detail required, and the consequences of a failure to disclose. There is also no clarity regarding how applicants must identify where the material is obtained, the person or organization providing it, any genetic resources used, etc. In addition, there is no regulation about the obligation of patent applicant to enter into an agreement of access and benefit sharing with the appropriate rights-holder or provide prior informed consent first before lodging a patent application.

Article 3 and Article 54 of The Indonesian Patent Act, 2016 confusingly scramble the substantive and

procedural requirements by incorporating DO into the measures of substantive assessment of patent application. The substantive requirement of patent has been set under Article 3, however, Article 54 also shuffles other requirements (including the DO regulated under Article 26) as one of substantive requirements for granting patent.

The next regulatory problem is about unclear definition of the genetic resources involved: whether genetic resources disclosure required for the use of a product is several generations away from the original genetic resource, or a synthetic compound derived from lead compounds discovered in nature. The lack of clarity over terminology and definitions in this regard creates greater legal uncertainty and legal loopholes.

With respect to the consequences for non-compliance of DO measures, there are several options open to Indonesia. The options include civil or penal liabilities, administrative sanctions, suspension of application processing, revocation or annulment of rights when the submitted information required in DO is insufficient or false, or the requirement that patent rights should be jointly owned or transferred either partially or completely.<sup>52</sup> Indonesia can adopt any of these options. However The Indonesian Patent Act, 2016 only narrowly provides that failure to satisfy any of the DO requirements will result in administrative consequences such as the rejection of a patent application (based on Article 58.1), or lead to application withdrawal (Article 62 Paragraph (10) or terminating the patent validity (Article 132 (1)(b)). In addition, it is also unclear what is meant by termination of patent rights under Article 132 (1)(b). In specific terms, it is not clear whether the revocation or annulment of patent rights is the result of when the submitted information required in DO is insufficient or false.

Indonesia should consider other measures for non-compliance of DO requirements by including not only administrative penalties (rejection and withdrawal of patent application) and legal sanctions (terminating of patent rights), but also civil or penal liabilities, suspension or pending of application processing, clear revocation or annulment of rights, or transfer of patent rights partially or completely, or repayment of any benefits received. It is also necessary to develop other measures outside the patent system such as unfair competition, environmental law, consumer protection, etc. In other words, Indonesia still needs to provide

opportunities to rectify disclosure failures and remedies tailored to the scope and nature of the failures.

#### **Poor Definition of ‘Origin’**

‘Genetic resources’ is defined very broadly, to include “any biological material which contains genes and/or metabolic material that may be derived from genes. They fall within the scope of the Nagoya Protocol whenever they are used for research or product development”.<sup>53</sup> This definition offers little practical guidance. It is not clear whether the ‘origin’ refers to the resource’s country of origin or to its source, *i.e.* the country from which the resource is received. It is also not clear whether the concept of origin refers to the country that contributes or provides the resource’s geographic origin, or to combination of different options, such as the disclosure of the source together with, if known, the resource’s country of origin. It is often difficult to determine the origin of a resource, in cases in which a resource comes from an *ex situ* collection e.g. a botanic garden and was collected many years ago. The Indonesian Patent Act, 2016 needs to provide clarity on this issue since it is central to disclosure.

#### **The Absence of Clear Access and Benefits Sharing Regulation**

Access and benefits sharing (ABS) are at the heart of disclosure and the prohibition of biopiracy. Indonesia has no clearly defined ABS regulation in spite of adopting the Indonesian Patent Act, 2016. A comprehensive ABS regulation is an essential element to DO. A good ABS regulatory framework can provide prior informed consent to get access to genetic resources. Effective DO will help to promote ABS and prior informed consent in Indonesia because such information would allow the government to check whether the access legislation had been complied with and if prior informed consent had been obtained.

#### **Inadequate Human and Other Resources Capacity**

DO protocols as envisaged under The Indonesian Patent Act, 2016 are relatively new to Indonesia. The reality is that the state lacks the requisite human resources capacity to police or manage an effective DO regime. The government and its institutional agencies lack experience in arranging and developing DO and benefit sharing mechanisms. Accordingly, fair and equitable sharing of benefits arising out of the use of genetic resources have proven difficult to

implement in an effective manner, as the use of genetic resources is increasingly linked with international trade which sometimes requires high levels of expertise in negotiations and drafting of necessary regulations.

Indonesian bureaucratic procedures are inefficient and slow at the best of times. It is a fair assumption that the interdiction of DO is likely to impose additional burden to patent system with increased workload on patent examiners. In any event, The Indonesian Patent Act, 2016 and related regulation do not articulate clearly what the role of the patent examiners should be in respect of DO. It is not clear whether they will only file the information received or also check its veracity; or they must cooperate with other institutions. Therefore, some argue that it is wrong in principal to try to deal with DO and ABS issues within the patent system, since these are alien to patent law in Indonesia.

Another problem is the cost of implementing DO and ABS regulation, including the cost of establishing systems to monitor and enforce compliance. This can be considerable, particularly in Indonesia where budget, expertise and institutional capacity are often limited. It cannot be denied that development of DO and ABS system will be costly in Indonesia because of the need to introduce new further legislation, establish monitoring institutions, train staff, develop appropriate system, etc. In fact Indonesia still lacks institutional capacity and the expertise to implement the necessary legislation. The capacity to monitor patent applications and the use of genetic resources is also insufficient. The effective degree of co-ordination between authorities as well as new institutional arrangements is still also questionable.

As indicated earlier Indonesia lacks the human resources capacity to monitor or police DO effectively. However even if misappropriation is detected, it is doubtful that Indonesia has the economic and financial capacity to invalidate patents particularly in foreign jurisdictions, considering the long and costly process involved, and the need to study the measures of other user countries. Some non-governmental organizations (NGO) have helped in tracking bad patents over genetic resources, however it is uncertain the extent to which they may continue to do so. In addition, if a fallaciously granted patent is found, who will be eligible to initiate invalidation procedures with given the costs involved in any potential litigation?

**Challenges with Ensuring Community Benefits**

Article 26 (3) of The Indonesian Patent Act, 2016 stipulates that benefit sharing and access to utilization of genetic resources shall be carried out in accordance with the laws and regulations and international treaties in the field of genetic resources. There is no doubt that local communities are legitimate stakeholders in local genetic resources and are entitled to benefits sharing from any inventions based on their local resources. Indonesia does not have any systematic policy or procedure for determining ownership of resources. It is not clear with whom benefits should be shared because many genetic resources are found in more than one geographical origin in the country, and may have to be shared by a number of communities or peoples. In its current state, the notion of ensuring community benefits envisaged in The Indonesian Patent Act, 2016 only remains on paper and needs clarity.

**Lack of Clarity on Institutional Agencies**

Under Article 26 (2) of The Indonesian Patent Act, 2016, the information on genetic resources as referred to in DO shall be established by an authorized institution recognized by the government. Given that the applicants are likely to have to show they were authorized by a relevant national institution to access the resource before they obtained it, it is unclear who the relevant national bodies will be and what constitutes such authorization. It is unclear and often difficult to determine who is the authorized institution or legal authority to establish conditions and mechanism provided in DO requirements and ABS. It is also unclear which institutions are competent to authorize the source to provide access and to determine the legality of the conditions established for access and equitable benefit-sharing, including provisions for approval and for defining misappropriation.

**Lack of Clarity on Links between Genetic Resource and Invention**

A further problem is the difficulty to identify the link between genetic resource and an invention that would trigger disclosure since current Indonesia legislation only vaguely defines this. Indonesia has not determined how the link between an invention and genetic resource can be meaningfully related, how closely the invention must be to such resources, whether the invention makes use of biological material involving components of biodiversity. It is

also unclear how to define the sort of genetic resources involved, whether disclosure is required for the use of a product if it was several generations away from the original genetic resources.

From a technical point of view, many questions still remain to be answered. For instance, it is not clear if standardized terminology and certain specific content should be used, what sort of information should be submitted, or how the information should be presented. It is also questionable whether the mere disclosure of information will be adequate to comply with the DO requirements, or should the application be accompanied by a declaration or proof of origin from the applicants, or by some form of authorizing evidence to prove compliance with access laws, such as a copy of the access contract or other required documents.

**Issue of Timing**

The time for presenting the DO is also unclear. The regulations do not indicate when the information be examined and by whom, or when access to genetic resources should be considered to have been duly authorized. It is not easy to determine the exact time of required disclosure because of the complexity and length of the research process.

Although DO is mandatory in Indonesia, there is no checking or monitoring system for patent applications such as monitoring resource use or preventing resource misappropriation. In addition, no notification system has been established in Indonesia. This means that little progress has been made in enhancing the transparency of the patent system. The feasibility of DO both with respect to the ability of patent applicants to comply and of patent offices to check compliance, particularly with requirements to meet the prior informed consent and ABS legislation is also questionable. To date DO together with prior informed consent and ABS requirement have been seen as a burden, either for applicants or patent offices. Lack of clarity of the legislation has meant that the patent office has not yet utilized this measure and these limited experiences underline the need for a well-established legislation.

**Findings and Suggested Solutions****Prioritizing an Effective Regulatory Framework**

With its mega biodiversity Indonesia is vulnerable to biopiracy. What is evident from the current Indonesian policies and regulations is that the country's regulatory framework to protect its GR does

not adequately deal with the prevention of biopiracy. If Indonesia is to combat biopiracy, then it must create further regulation to effectively implement the provisions on DO and the related issues since DO alone will not be able to solve misappropriation of genetic resources and cannot be regarded as the only panacea. To achieve an effective DO system, it is necessary to regulate procedural, institutional and other infrastructural measures such as the standards, procedures, further requirements, mechanism, monitoring and evaluating system, institution that authorizes to the implementation, remedies, etc. Further regulation should specify details of circumstances for disclosure, information content, the timing, format and level of detail required, including obligation of patent applicants to compulsorily provide PIC and enter into an access and benefit sharing agreement with the appropriate rights-holder first before applying for patents.

It is important to develop a strong and user-friendly legislation with a two-tiered system of approval for access to genetic resources. A two-tiered system could be established with: (a) non-restrictive licensing for non-commercial research, (b) a restrictive policy for commercial users of resources. In addition, codes of conduct for both industry and researchers would be a useful step, including a system for establishing bonafide research organizations that will collaborate with those wishing to utilize resources within Indonesia.

#### **Rethinking the Enforcement of DO Requirements**

In its current form, the DO regime lacks 'teeth'. Noncompliance with DO does not attract severe sanctions. Failure to disclose could result in not granting a patent or withdrawing a patent. It is not enough to dissuade a patent applicant from nondisclosure. To ensure DO compliance, Indonesia should develop rigorous enforcement mechanisms by considering civil liabilities, administrative sanctions, suspension of application processing, revocation or annulment of rights, transfer of patent rights either partially or completely, or repayment of benefits received, etc. Sanctions should not be established under patent system only, but effective, proportionate and dissuasive sanctions should be envisaged outside the field of patent law such as application of provisions on unfair competition penalties imposed on the non-compliant patent applicants/holders. To be more effective, Indonesia could also adopt the model of criminal sanctions applied in Article 81 of the

Patent Law of Switzerland which regulates that patent applicants could face additional criminal sanctions for lack of disclosure or false statements.<sup>54</sup>

#### **Standardization of Procedures**

In order to become effective, the way that the relevant information will be submitted to the patent offices must be standardized. This should be organized in a non-bureaucratic and cost-efficient manner. Recommendations on standardized model of DO could include: (a) the applicants should declare the country of origin or, if unknown, the source of the specific GR to which the inventor has had physical access which is still known; (b) the invention must be directly based on or derived from the specific GR; (c) the incentive for compliance and penalties for noncompliance; (d) simple notification procedure by the patent offices when they receive a declaration and it will be adequate to identify in particular the Clearing House Mechanism as the central body to which the patent offices should send the available information. In this sense, the high level of coordination between patent office and Clearing House Mechanism could be a useful avenue for notification and should be as simple as possible in order to avoid any unnecessary administrative burden for patent offices. The exchange of information should also be managed in a cost-effective way and without unnecessary additional charges imposed on patent applicants.

#### **Improvements in Stages of the DO Regime**

In a general context, to prevent GR misappropriation and support food security, Indonesia needs to improve various strategies of its DO regime to address: (a) the importance and value of GR through mainstreaming issues at every institutional and community level; (b) human resources capacity, including political, regulatory, and budgeting support from various stakeholders in the implementation of GR management; (c) inventory, identification, and publication of GR potential and value; (d) GR management impacts and benefits for various parties, especially the general public.

#### **National Anti Biopiracy Commission**

As noted earlier Indonesia's mega biodiversity is vulnerable to biopiracy because of the country's liberal visa system that encourages tourism which in enables and embolden 'biopirating tourists'. The situation is exacerbated by the absence of an effective

regulatory framework and supporting institutions. Given the importance of protecting GR in the national economy and the national food security strategy, it is essential to establish a national body charged with dealing with biopiracy. Such a National Anti-Biopiracy Commission could be established on a similar basis as the National Anti Biopiracy Commission of Peru which has successfully led Peru's effort in enforcing anti biopiracy regulations. Established in 2004 The Commission has the following functions:

- a) Establish and maintain a register of biological resources and traditional knowledge.
- b) Provide protection against acts of bio piracy.
- c) Identify and follow up patent applications made or patents granted abroad that relate to Peruvian biological resources or collective knowledge of the indigenous peoples of Peru.
- d) Conduct technical evaluations of the above-mentioned applications and patent grants.
- e) Issue reports on the cases studied.
- f) Lodge objections or institute actions for annulment concerning the above-mentioned patent applications or patent grants.
- g) Establish information channels with the main intellectual property offices around the world.
- h) Draw up proposals for the defense of Peru's interests in different forums.<sup>55</sup>

The Indonesian Patent Act, 2016 in its current form does not provide the structured operational framework for any agency similar to the Commission in Peru. The Peruvian experience provides an important example for Indonesia in combating biopiracy.

#### **Spreading the Benefits and Building Capacity**

Indonesia must also establish effective mechanism for the restitution of the rights of communities and the model of benefit sharing for appropriation of genetic resources. Since benefit sharing is not limited to monetary sharing, Indonesia needs to seek the appropriate non-monetary form of benefits for the stakeholder communities. Benefits could be shared in other ways, for example, through training and capacity building since to ensure the effective implementation of ABS procedures and legislation, capacity building is needed within patent offices, customs and immigration, ABS institutions and more widely within many government and environmental institutions. Given that governmental authorities are relatively unfamiliar with the IP system, it is essential

to develop IP understanding especially through training on issues related to IP including DO.

This capacity building for human and technical resources of the environmental and IP authorities is crucial in order to review IP applications, identify the cases in which DO is mandatory, develop IP and genetic resources databases, compile and disseminate, as appropriate, information that can be useful for destroying the novelty of patent applications presented in other countries related to genetic resources, improve coordination with domestic and foreign IP and environmental offices. It is also important to exchange experience through internships, workshops, colloquium, etc. with countries that have established similar requirements and developed a significant practical experience that support the implementation of this instrument in Indonesia.

Within civil society, public understanding and awareness of the IP system should be enhanced, especially among local communities by developing expertise among such communities to negotiate ABS agreements. The government should also prioritize the training of communities in negotiating skills and legal education, to help them to establish fair access agreements. There is also a need for further awareness raising and education about DO, prior informed consent and benefit sharing obligations among small firms and sectors of the research community.

#### **Conclusion**

Indonesia is a land blessed with significant biodiversity that attracts biopiracy in the absence of a strong and effective DO enforcement mechanism. In general, DO plays an important role in protecting plant genetic resources. It helps in (a) identifying scientific or commercial use; (b) identifying rights holders; (c) identifying the existence of prior art; (e) facilitating the monitoring and enforcement of rights; (f) preventing illegal and/or unauthorized use; (g) preventing the grant of wrong patents; and (h) promoting equitable benefit sharing. The adoption of The Indonesian Patent Act, 2016 was a step in the right direction in enforcing DO and stopping biopiracy and achieving these objectives of DO. However DO remain a relatively new concept for Indonesia. The country has little practical experience in implementing and enforcing DO legislation. In its current form, The Indonesian Patent Act, 2016 lacks coherence and clarity in several areas. That makes it hard for the country to combat biopiracy



meaningfully. The Indonesian Patent Act, 2016, therefore needs improvement.

As part of the improvements needed to enforce DO and combat biopiracy effectively, Indonesia should consider the establishment of a National Anti Biopiracy Commission. The commission could provide a coordinating platform and oversee the effective implementation of The Indonesian Patent Act, 2016 provisions on DO. More importantly it could also provide an incubating channel for building capacity in policing biopiracy. While The Indonesian Patent Act, 2016 is clearly a step in the right direction, it does not appear to have a well-defined destination or objective in terms of combating biopiracy. A National Anti-Biopiracy Commission can provide clearer objectives and ensure a more effective fight against biopiracy.

Indeed the protection of GR is a cross cutting national issue for the country given its relevance to agribusiness, food security and the general economy. An effective DO system must therefore necessarily involve coordination between state agencies from the environment to agriculture and economic planning and community stakeholders who may be traditional knowledge holders. The objective in strengthening the DO system is not to deter researchers, inventors and investors, but to enhance transparency, and to discourage misappropriation of GR.

#### References

- 1 Harword *et al.*, Plant genetic resources for food and agriculture: Opportunities and challenges emerging from the science and information technology revolution, *New Phytologist*, 217 (4) (2018), 1407-14019.
- 2 The general attitude of developing countries to intellectual property and the TRIPS Agreement, The detailed report by Nathan Associates Inc. submitted to USAid: *Intellectual Property and Developing Countries: An Overview* (2003), <https://www.hsd.org/?view&did=446296> (accessed on 12 December 2019).
- 3 There are several definitions of and theories on biopiracy. Robinson D F, *Confronting Biopiracy: Challenges, Cases and International Debates* (Earthscan), 2010; Ikechi M, *Global Biopiracy: Patents, Plants, and Indigenous Knowledge* (UBC Press), 2006; Vandana S, *Biopiracy: The Plunder of Nature and Knowledge* (South End Press), 1997.
- 4 European Patent Office, ASEAN: Amendment of the Indonesian Patent Law <https://www.epo.org/searching-for-patents/helpful-resources/asian/asia-updates/2017/20170217.html> (accessed on 27 December 2019).
- 5 Comments of Deputy Minister of Environmental, Degradation Control and Climate Change. *The Fifth National Report to the Convention on Biological Diversity*, Ministry of Environment and Forestry, Jakarta (2014).
- 6 FAO, *Country Report on The State of Plant Genetic Resources for Food and Agriculture: Indonesia*, <http://www.fao.org/docrep/013/i1500e/Indonesia.pdf> (accessed on 11 January 2020).
- 7 Rahmah M, The Protection of Agricultural Products under Geographical Indication: An Alternative Tool for Agricultural Development in Indonesia, *Journal of Intellectual Property Rights*, 22 (March 2017) 90-103.
- 8 Rahmah M, Promoting Geographical Indications for Agricultural Products in Indonesia, in Taubman A, *et al.*, *WIPO-WTO Colloquium Papers: 2017 Asian Edition, Research Papers From The 2017 Regional WIPO-WTO Colloquium For IP Teachers And Scholars In Asia*, (WIPO-WTO), 2017.
- 9 FAO, *Rome Declaration on World Food Security*, <http://www.fao.org/3/w3613e/w3613e00.htm> (accessed on 11 January 2020).
- 10 Article 1.4 of Indonesian Food Act of 2012.
- 11 Subejo P D, Tackling Food Security Problem in Indonesia, *Jakarta Pos*, 26 November 2013.
- 12 Correa C *et al.*, TRIPS-Related Patent Flexibilities and Food Security: Options for Developing Countries, Policy Guide, *QUNO-ICTSD*, (2012).
- 13 Mgbeoji I, *Global Biopiracy: Patents, Plants and Indigenous Knowledge*, (UBC Press), 2006.
- 14 Feng W, Appropriation without benefit-sharing: Origin-of resource disclosure requirements and enforcement under TRIPS and the Nagoya Protocol, *Chicago Journal of International Law*, 18 (1) (2012) 248-286.
- 15 Duffield G, Thinking Aloud on Disclosure of Origin, *QUNO Occasional Paper 18*, Quaker International Affairs Program and Quaker United Nations Office (QUNO), (October 2005).
- 16 Shiva V, *Biopiracy: The Plunder of Nature and Knowledge* (South End Press), 1997.
- 17 Correa C, Sovereign and property rights over plant genetic resource, *Agriculture and Human Values*, 12 (4) (September 1995) 58-79.
- 18 Robinson D, *Confronting Biopiracy: Challenges, Cases, and International Debates*, (Routledge), 2010.
- 19 Ugas R, Policy development in the organic movement, *Leisa Magazine*, 21 (4) (2005), <http://ileia.fourdigits.nl/magazines/global/practice-and-policy/policy-development-in-the-organic-movement>.
- 20 Ganguli P, *Intellectual Property Rights: Unleashing The Knowledge*, (Tata McGraw Hill), (2001).
- 21 Metha H, *Indonesia Strengthens Laws Against Biopirates*, New Patent Law introduces several new provisions to protect local genetic resources and rewards for inventors, <https://www.businesstimes.com.sg/opinion/indonesia-strengthens-laws-against-biopirates> (accessed on 10 December 2019).
- 22 Dwyer L, Biopiracy, trade, and sustainable development, *Colorado Journal of International Environmental Law and Policy*, 19 (2008) 226-27.
- 23 Conforto D, Traditional and modern-day biopiracy: Redefining the biopiracy debate, *Journal of Environmental Law and Litigation*, 19 (2) (2004) 358-397.
- 24 Robinson D, *Confronting Biopiracy: Challenges, Cases, and International Debates*, (Routledge), 2010, 12.
- 25 Robinson D, *Confronting Biopiracy: Challenges, Cases, and International Debates*, (Routledge), 2010, 11.

- 26 Hamilton C, *Biodiversity, Biopiracy and benefits: What Allegations of Biopiracy tell us about Intellectual Property*, (Blackwell Publishing), cited in Sayan Bhattacharya, Bioprospecting, biopiracy and food security in India: The emerging sides of neo liberalism, *International Letters of Social and Humanistic Sciences*, 23 (2014) 49-56.
- 27 Medaglia J C, The Disclosure of Origin Requirement in Central America: Legal Texts, Practical Experience and Implementation Challenges, *Issue Paper No. 3*, (June 2010).
- 28 UNEP/CBD/COP/6/20, Para 3 and Annex, <http://www.biodiv.org/doc/decisions/COP-06-dec-en.pdf>.
- 29 UNEP/CBD/COP/6/20, Decision VI-24.C. and Paras 1, 2, <http://www.biodiv.org/doc/decisions/COP-06-dec-en.pdf>.
- 30 CBD, COP 7 Decision VII/19, Access and Benefit Sharing as related to Genetic Resources (Article 15) <https://www.cbd.int/decision/cop/?id=7756> (accessed on 12 January 2020).
- 31 UNEP/CBD/COP/6/20, Decision VI-24. C, Para. 4, UNEP/CBD/COP/6/20.
- 32 Correa C, The Politics and Practicalities of a Disclosure of Origin Obligation, *Occasional Paper 16*, Quaker United Nations Office, (January 2005).
- 33 Submission of Brazil, India, Pakistan, Peru, Thailand, and Venezuela, *IP/C/W/429*, (September 21), 2004.
- 34 Paraskevi K, Disclosure of Origin in Patent Law: How to Enforce it Best?, *MIPLC Master Thesis*, (2012), <http://www.miplc.de/research/>, SSRN: <http://ssrn.com/abstract=2407321>.
- 35 Correa C M, Establishing a disclosure of origin obligation in the TRIPS Agreement, *Occasional Paper 12*, Quaker United Nations Office, (August 2003).
- 36 UNCTAD, Disclosure of Origin/Source and Legal Provenance, [https://unctad.org/en/PublicationChapters/diaepcb2014d3\\_ch3\\_en.pdf](https://unctad.org/en/PublicationChapters/diaepcb2014d3_ch3_en.pdf) (accessed on 10 January 2020).
- 37 *Staeng's Patent* [1996] RPC 183.
- 38 WIPO, Technical study on patents disclosure requirements related to genetic resources and traditional knowledge, [https://www.wipo.int/edocs/pubdocs/en/tk/786/wipo\\_pub\\_78.pdf](https://www.wipo.int/edocs/pubdocs/en/tk/786/wipo_pub_78.pdf) (accessed on 28 December 2019).
- 39 Kamau E C, Sovereignty over genetic resources: Right to regulate access in a balance, the case of Kenya, *Revista Internacional de Direito e Cidadania*, 2 (2009) 73-88.
- 40 FAO, Resolution 8/83: International Undertaking On Plant Genetic Resources. [http://www.fao.org/wiews-archive/docs/Resolution\\_8\\_83.pdf](http://www.fao.org/wiews-archive/docs/Resolution_8_83.pdf) (accessed on 11 January 2020).
- 41 FAO, International code of conduct for plant germplasm collecting and transfer <http://www.fao.org/3/x5586e/x5586e0k.htm> (assessed on 12 January 2020).
- 42 Mugabe J *et al.* (ed.), *Access to genetic resources*, (ACTS Press), 1997.
- 43 Nicholas H, Indonesia steps up fight against biopiracy, <https://www.thejakartapost.com/news/2017/03/20/ri-steps-up-fight-against-biopiracy.html> (accessed on 11 January 2020).
- 44 Ompusunggu M, Indonesia steps up fight against biopiracy, *The Jakarta Post*, (20 March), 2017, <http://www.thejakartapost.com/news/2017/03/20/ri-steps-up-fight-against-biopiracy.html> (accessed on 11 January 2020).
- 45 <https://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf> (accessed on 11 January 2020).
- 46 Dutfield G, Thinking aloud on disclosure of origin, *QUNO Occasional Paper 18*, Quaker International Affairs Program and Quaker United Nation Office (QUNO), October 2005.
- 47 Article 5.1 of UPOV Convention 1991.
- 48 Article 58.1 states that Minister shall approve the application, if based on the result of the substantive examination, the invention which is filed for a Patent complies with the provisions referred to in Article 54.
- 49 The Directorate General of Intellectual Property is the national IP office which has the authority to administer and develop Indonesian IP system. The DGIP is government institution operating under the Ministry of Law and Human Rights.
- 50 Morinville P, *Bad Patents: Are they Just Another Big Tech False Narrative?* <https://www.ipwatchdog.com/2019/03/29/bad-patents-are-just-another-big-tech-false-narrative/id=107819/>.
- 51 Medaglia J C, The disclosure of origin requirement in Central America: Legal texts, practical experience and implementation challenges, *Issue Paper No. 3*, (June 2010).
- 52 Oldham P D & Burton G, Defusing Disclosure in Patent Applications, (20 October 2010), <https://ssrn.com/abstract=1694899> or <http://dx.doi.org/10.2139/ssrn.1694899> (accessed on 27 December 2019).
- 53 Biodiversity.fi., What are genetic resources? <https://www.biodiversity.fi/geneticresources/genetic-resources/what-are-genetic-resources> (accessed on 11 January 2019).
- 54 Lexology, Patents in Switzerland, <https://www.lexology.com/library/detail.aspx?g=793c0e66-67b2-4fb7-83d7-cf2af79b2d5> (accessed on 27 December 2019).
- 55 Brinckmann J, Peruvian Maca and allegations of biopiracy, *HerbalGram, American Botanical Council*, 75 (2007) 44-53.

# Ensuring Disclosure of Origin of Genetic Resources in Patent Applications: Indonesia's efforts to Combat Biopiracy

## ORIGINALITY REPORT

8%

SIMILARITY INDEX

7%

INTERNET SOURCES

4%

PUBLICATIONS

0%

STUDENT PAPERS

## PRIMARY SOURCES

1	<a href="http://www.genecampaign.org">www.genecampaign.org</a> Internet Source	1%
2	<a href="http://asean.chm-cbd.net">asean.chm-cbd.net</a> Internet Source	<1%
3	<a href="http://media.ffii.org">media.ffii.org</a> Internet Source	<1%
4	<a href="http://press-files.anu.edu.au">press-files.anu.edu.au</a> Internet Source	<1%
5	<a href="http://docs.wto.org">docs.wto.org</a> Internet Source	<1%
6	<a href="http://www.mdpi.com">www.mdpi.com</a> Internet Source	<1%
7	<a href="http://www.timeshighereducation.com">www.timeshighereducation.com</a> Internet Source	<1%
8	<a href="http://i-lib.ugm.ac.id">i-lib.ugm.ac.id</a> Internet Source	<1%
9	Alebe Linhares Mesquita. "The dialogue between the intellectual property provisions	<1%

in preferential trade agreements and the Brazilian legal framework", Universidade de Sao Paulo, Agencia USP de Gestao da Informacao Academica (AGUIA), 2018

Publication

10

Morten Walløe Tvedt. "Patent law and bioprospecting in Antarctica", Polar Record, 2010

Publication

<1 %

11

[law.fsc.gov.tw](http://law.fsc.gov.tw)

Internet Source

<1 %

12

[www.jpo.go.jp](http://www.jpo.go.jp)

Internet Source

<1 %

13

Edward Buzigi, Stephen Onakuse. "Food price volatility and socio-inequalities in household food insecurity during coronavirus disease-2019 lockdown in Nansana municipality, Wakiso district Uganda", Research Square, 2020

Publication

<1 %

14

[www.ijser.org](http://www.ijser.org)

Internet Source

<1 %

15

[www.nou.edu.ng](http://www.nou.edu.ng)

Internet Source

<1 %

16

[ia803400.us.archive.org](http://ia803400.us.archive.org)

Internet Source

<1 %

17	<a href="http://www.kipo.ke.wipo.net">www.kipo.ke.wipo.net</a> Internet Source	<1 %
18	<a href="http://www.kmfri.co.ke">www.kmfri.co.ke</a> Internet Source	<1 %
19	Alan L., Nigel Gericke. "Chapter 15 Bioprospecting: Creating a Value for Biodiversity", IntechOpen, 2011 Publication	<1 %
20	<a href="http://krishi.icar.gov.in">krishi.icar.gov.in</a> Internet Source	<1 %
21	<a href="http://uncst.go.ug">uncst.go.ug</a> Internet Source	<1 %
22	<a href="http://ciat-library.ciat.cgiar.org:8080">ciat-library.ciat.cgiar.org:8080</a> Internet Source	<1 %
23	<a href="http://network.bepress.com">network.bepress.com</a> Internet Source	<1 %
24	<a href="http://webthesis.biblio.polito.it">webthesis.biblio.polito.it</a> Internet Source	<1 %
25	<a href="http://www.southeastasia-iprhelppdesk.eu">www.southeastasia-iprhelppdesk.eu</a> Internet Source	<1 %
26	<a href="http://www.wisnu.or.id">www.wisnu.or.id</a> Internet Source	<1 %
27	<a href="http://d3n8a8pro7vhmx.cloudfront.net">d3n8a8pro7vhmx.cloudfront.net</a> Internet Source	<1 %

28	<a href="https://open.library.ubc.ca">open.library.ubc.ca</a> Internet Source	<1 %
29	<a href="https://shodhganga.inflibnet.ac.in">shodhganga.inflibnet.ac.in</a> Internet Source	<1 %
30	<a href="https://www.bgci.org">www.bgci.org</a> Internet Source	<1 %
31	Ignasius D.A. Sutapa, Apip, M. Fakhrudin, Herry Yogaswara. "Implementation of ecohydrology to support sustainable water resources management in tropical region, Indonesia", <i>Ecohydrology &amp; Hydrobiology</i> , 2021 Publication	<1 %
32	<a href="https://www.lexology.com">www.lexology.com</a> Internet Source	<1 %
33	<a href="https://www.npb.co.za">www.npb.co.za</a> Internet Source	<1 %
34	<a href="https://www.globalpatentfiling.com">www.globalpatentfiling.com</a> Internet Source	<1 %
35	<a href="https://www.nlsenlaw.org">www.nlsenlaw.org</a> Internet Source	<1 %
36	<a href="https://www.pnuma.org">www.pnuma.org</a> Internet Source	<1 %

---

Exclude quotes      Off

Exclude matches      < 10 words

Exclude bibliography      On

# Ensuring Disclosure of Origin of Genetic Resources in Patent Applications: Indonesia's efforts to Combat Biopiracy

GRADEMARK REPORT

FINAL GRADE

**/0**

GENERAL COMMENTS

**Instructor**

PAGE 1

PAGE 2

PAGE 3

PAGE 4

PAGE 5

PAGE 6

PAGE 7

PAGE 8

PAGE 9

PAGE 10

PAGE 11

PAGE 12

PAGE 13

PAGE 14

PAGE 15

PAGE 16

PAGE 17