

DISCLOSURE OF ORIGIN OF PLANT GENETIC RESOURCES: CHALLENGES FOR SUPPORTING FOOD SECURITY IN INDONESIA

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ABSTRACT

Protecting plant genetic resources is crucial because they are a key element in supporting food security for Indonesia's growing population. An important element in the protection of plant genetic resources is the disclosure of origin of genetic resources. In line with international standards and commitments, Indonesia has enacted a Patents Act that seeks to protect its plant genetic resources by requiring disclosure of origin. However it is one thing to enact legislation and quite a different thing to effectively implement the legislation to achieve its aims. This paper critically analyses the Indonesian Patent Act and highlights some key issues that undermine the effectiveness of the Act. The paper identifies the problems of implementing provisions of the Act at the normative and practical levels. At the normative, the Act lacks clarity with concepts undefined. This is compounded at the practical level by a lack of a regulatory framework and inadequate human resources. The paper suggests that given the importance of disclosure of origin in protecting plant genetic resources for Indonesia's food security, developing further legislative and institutional framework on disclosure of origin is an essential strategic solution for the country.

Keywords: Disclosure of origin; Benefit sharing; Plant genetic resources; Agriculture; Biopiracy; Food security.

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1. INTRODUCTION

Indonesia is a country rich in biodiversity. However, like most developing countries, it struggles to maintain effective ownership over its plant genetic resources (PGR). At the core of the problem for the country are two related issues: misappropriation, and lack of disclosure of origin of PGR. Misappropriation 'refers to access to and use of genetic resources without prior informed consent and/or mutually agreed terms pursuant to the national access legislation of the country providing the genetic resources and applicable international rules on access and benefit sharing.'(Nagoya, p1) Disclosure on the other hand is the obligation of the inventor to 'disclose' publicly relevant information about inputs from provider countries or the country of origin in the case of PGR.

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In recent times there has been public outcry in Indonesia mostly related to the grant of patents for inventions based on PGR and their subsequent commercial exploitation by foreign scientists or companies, without any recognition and sharing of benefits as stipulated in the Nagoya Protocol of 2010. To deal with the problem, in early 2017, the Indonesian Ministry of Research, Technology and Higher Education issued regulations to prevent suspected theft of genetic resources by foreign researchers disguising themselves as tourists. The most prominent incident was the Shiseido case in which the Japanese cosmetic Shiseido patented 11 different compounds of Indonesian traditional medicinal plants without authorisation. After a sustained campaign against the company for biopiracy, Shiseido withdrew its patent at the European Patent Office (Mehta, 2018).

The introduction of disclosure of origin (DO) into patent law has been a useful tool for developing countries including Indonesia. It helps countries to control and protect their PGR as it enhances transparency within the patent system and facilitates the monitoring of PGR utilization. However, the adoption of DO in patent law can be technically complex particularly for developing countries with inadequate human resources. More importantly, its incorporation raises fundamental concerns of balancing the demands of biotechnological development and patent law justification on one hand, and fairness, attribution, and recognition of public interests such as the sustainable use of genetic resources, or the conservation of biodiversity on the other hand.

To address the issue of DO and misappropriation, in 2016 Indonesia amended and enacted *the Indonesian Patents Act (IPA)* that deals specifically with PGR and other issues in patents. To date, the *IPA* remains the principal legislation on the issue of PGR in the country. However, the enactment of legislation is one thing; the effective implementation of the law and the policing of the legal framework is a different thing altogether. The objective of the article is to critically assess the effectiveness of the *IPA* in the country's effort to regulate DO. The article is divided into 4 parts. Part 1 examines the general scope and concept of DO. Using that as a background, Part 2 discusses Indonesia's biodiversity in context to explain the food security implications of misappropriation and the importance DO and the urgency to develop an appropriate legislative framework to regulate DO. Part 3 discusses the enactment and provision of the *IPA* in pursuance of Indonesia's international treaty obligations, and considers the main provisions the Act. Part 4 critically assesses the effectiveness of the *IPA*. Part 5 is devoted to the regulatory challenges associated with the Act. The article concludes with a brief discussion of recommendations to enhance the effectiveness of the implementation of the Act in Indonesia.

2. PART 1 DISCLOSURE OF ORIGIN: THE CONCEPT AND SCOPE

DO is central to the protection of PGR. As noted earlier, it is the obligation on the inventor to 'disclose' publicly relevant information about inputs from provider countries or sources of the origin in the case of PGR. The concept of DO was introduced and adopted formally by the Bonn Guidelines on the Convention on Biodiversity (CBD) in 2002. It was adopted as voluntary guidelines to address access to genetic resources including fair and equitable benefits sharing arising from use of genetic resources (UNEP, 2002, para 3). The Guidelines encourage user countries to take into account measures to promote DO of genetic resources and the origin of knowledge, innovations, and practices in IP applications (16.d.ii). They further provide that national IP offices may adopt appropriate requirements 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 invention concerns or utilize genetic resources in its development (UNEP, 2002, para 1, 2).

Generally, DO refers to a variety of requirements that have or may be adopted in IP applications, product approval and at other appropriate checkpoints, for the purpose of monitoring access to and utilization of genetic resources and traditional knowledge (UNEP, 2002, para 1, 2). DO entails the obligations included mainly in genetic resources access laws, to disclose the country of origin/source of genetic resources used in an invention, or to demonstrate the legality of access. (Medaglia, 2010). This obligation requires the evidence of the existence of prior informed consent (PIC) of the fair and equitable sharing of the benefits from access (or an access contract), and compliance with the legal requirements to access genetic resource or traditional knowledge established in national laws

DO was initially a concept applied in international environmental law; but its relevance and potential effectiveness have been applied more in patent law in modern times (Paraskevi, 2012). It is noteworthy that DO is already an accepted norm in international patent law practice and has now been adopted by a number of countries. The most critical role of DO in patent system is that it ensures transparency by allowing national authorities that grant access to PGR to track the use of these resources in patent applications.

The DO obligation serves as part of a process to systematise information that continuously ensures all relevant prior art information is available to patent examiners and the general public. This also helps examiners to determine whether the claimed invention is excluded from patentability under Article 27 paragraphs 2 and 3 of the Trade Related Aspect of Intellectual Property Rights (TRIPs) Agreement. DO requirements are also useful to challenge patent grants or disputes on inventorship or entitlement to a claimed invention, including infringement cases (Correa, 2005). DO obligations require inventors to disclosure of sources of genetic resources where such resources have been identified as inventive contributions (WIPO, 2004). Where PGR is so close to an invention that it is in fact intrinsic to it under the legal doctrine of 'inventive contribution', then it may be necessary to declare the PGR provider as a joint inventor.

DO should be required at the earliest stage of patent applications, and obligates applicants to disclose: (a)the source of genetic resources; (b)the country providing PGR; (c) genetic resources used in developing claimed inventions; (d)evidence of prior informed consent; (e) available documentary information regarding compliance with access and benefit-sharing requirements; (f)information known to the applicant regarding persons involved in the subject matter of the application and the country of origin of genetic resources (UNEP, 2002, para 4).

For developing countries such as Indonesia that are rich in biodiversity, the international regimes of DO provide an important avenue for protecting national sovereignty over PGR. Indeed, the importance of the international DO regime for developing countries is better understood in the context of Indonesia's biodiversity and the country's efforts to enact legislation to enforce DO and to promote food security.

3. THE INDONESIA'S BIODIVERSITY AND THE PROMOTION OF FOOD SECURITY

3.1. *PGR and Food Security for the Country*

Indonesia as a land blessed with abundant biodiversity is well documented (McGlynn & Stone, 2007). For the purposes of this article, we will only comment briefly to help establish the context. Indonesia has arguably the richest PGR in the world, and is also known as a megadiversity country because of the diversity range of its geographic area from the east to west, at sea and on land, and its many islands. The country is believed to have the world's richest marine biodiversity. It has 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% to the world's flora (FAO, 2012). Documented data on mangrove plant and species of sea grass has shown no less than 6,396 species (Deputy Minister of Environmental Degradation Control and Climate Change, 2014).

Indonesia's PGR is mostly utilized to support livelihoods, especially for food, health and energy, and basic industrial materials that ultimately aim to meet human necessities. PGR are primary sources to provide food to communities by being exploited for daily needs and crop improvement for food consumption. According to the Deputy Minister of Environmental Degradation Control and Climate Change (2014), to meet the need for food consumption, more than 100 species are used as sources of carbohydrate, while 100 species of leguminous plants are used for protein and fat. About 450 species of fruit trees, 1000 species of ornamental plants and 250 species of vegetables are used for vitamin and mineral sources. NO less than 70 species are used for spices, 40 species for beverages, and more than 940 species of medicinal plants are used for traditional medicine or herbs

Food supply depends heavily on the PGR as the sources of genes; therefore, food security programs rely on the sustainable use of PGR. The well established management of PGR will certainly increase the contribution of sustainable uses of PGR for food availability and diversification in order to provide enough food for domestic consumption.

Agro business is the main source of meeting domestic food consumption needs of Indonesia. The demand for agricultural products has been increasing over the years and its growth has largely been attributed to Indonesia's per capita income growth (Rahmah, 2017a). Agricultural sector is also an important source of income and has lifted millions out of poverty and provided a platform for both rural and urban economic growth in the country (Rahmah, 2017b).

Access to food is a food security indicator because according to Article 1 of 1996 Rome Declaration on World Food Security, 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, Article 1.4 of Indonesian Food Law of 2012 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. However, food security should not be seen as the ability to access to food only. Food security is a comprehensive concept. It also relates to interrelated subsystems that include production, processing, distribution, access, and consumption

of food (Subejo & Padmaningrum, 2013). The subsystems and strategy should in turn be supported by agriculture productivity, diversity and availability of agricultural products that are essential to meet the food needs of the Indonesia's growing population and for national food security. They can be measured by a number of factors related to the production of seeds and control over PGR. Accordingly, the protection of PGR is an essential element in food security because PGR serve as the raw materials for plant breeders and farmers to create new crop varieties. PGR are is the foundation for modern agro ecosystems.

3.2. *The Role of Disclosure of Origin for Food security in the Indonesian Context*

More than 70 % of the global food supply is dependent on a small number of edible plant resources comprising mainly wheat, maize, rice, and potato, which are fundamental to food security (Bhattacharya, 2014). Patenting these plants varieties poses a potential threat to food security for many countries because it encourages monopoly control over PGR by seed multinational enterprises.

For Indonesia with a population of 264 million that is mostly dependent on its PGR for suatianable food production, patenting and monopolies by multinationals of its PGR poses a clear threat to its food security, and ultimately to its sovereignty as a state. The threat to food security through patenting of PGR by multinationals lays in the potential for the foreign patent holders to dictate seed prices with local farmers unable to buy seeds at affordable rates. The ripple effect of such a situation is that traditional farmers will be forced to use portions of their harvest to plant in the next growing season thus reducing the volume of production available for domestic food consumption. Futhermore, Indonesian farmers' rights to choose the desired varieties/crops will become limited. Even if farmers are able to afford the seeds, the right to use the purchased seeds could be significantly limited by the terms and consitions under which the patent holder sells the seeds. This may prohibit farmers from saving or reusing seeds from the patented sources or recultivate the seed (Hamilton, 2014),

In addition, Indonesian local varieties may not be able to compete with new comers of superior varieties and GM crops. GM crops can proliferate and suppress local vegetation that may harm the sustainability of local varieties. This can undermine food security because it ca eventually immobilize the locally adapted, inexpensive traditional crop varieties (Bhattacharya, et al, 2013).

Given the current GM application in farming fields that are primarily herbicide-tolerant and/or insect-resistant, the cultivation of an insect-resistant crop will lead to a reduced use of insecticides, which is positive for the environment. However, the protective substance such as lectin can also be directly or indirectly destructive to useful insects or other non-harmful and beneficial organisms, which is negative for biodiversity (VIB, 2016). In addition, GM seeds will create superweeds or superbugs that, over time, become resistant to herbicides and pesticides since some research suggests that weeds and bugs could possibly evolve into resistant organisms (Kurft, 2001). Moreover, the uncertain effects of GM products may horify domestic consumers, based on the public perception that GM products pose a hidden health risk to humans. The health risk of GM product on food safety is an integral element in food security.

For Indonesia, the importantace of DO is not just in facilitating fair and equitable access of PGR with subsequent uses. It is a matter of protecting food security and national sovereign rights that

require a legislative framework. In spite of the importance of DO to the country, DO is relatively new in Indonesia. The country adopted its first comprehensive DO related legislation in 2016.

4. LEGISLATION TO REGULATE DO: INDONESIAN PATENTS ACT 2016 (IPA)

In 2002, the Bonn Guidelines of CBD formally adopted DO framework to address access to genetic resources and fair and equitable benefit sharing deriving from utilization. Given Indonesia ratified the CBD incorporated it into Law No. 5 in 1994, there is an obligation to adopt a DO framework as mandated by CBD and Bonn Guidelines. Thus, the IPA adopted DO for patent applications. The framework introduced under the IPA does not only deal with information about origin, but also about compliance with national access laws, including effective fair and equitable benefit sharing.

The IPA 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 PGR, 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. The preamble of 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 the 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 PGR and the issue of disclosure, the Act says very little. Of the 173 Articles of the Act only one Article is devoted directly to PGR and the issue of disclosure in spite of the great significance of the issue of disclosure to Indonesia’s food security and indeed national sovereignty as discussed earlier. Article 26 of stipulates that :

- (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.*

Indonesia’s obliged under the CBD framework is to enact laws domestically in order to give effect to the principles and objectives/commitments in the Convention, 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. To achieve these commitments, under Article 15.2 of the CBD, Indonesia has the sovereign right to regulate access to genetic resources in its territories and to tailor measures (legislative, administrative and policy measures)

that facilitate access and sustainable use, including promote benefit sharing from utilized genetic resources (Article 15.7).

The IPA is complimented by other pieces of legislation. The sovereignty over genetic resources is recognized by Article 33.3 of Indonesian Constitution 1945. This article stipulates that land, waters and the natural resources shall be under the powers of the State, and shall be utilised to the greatest benefit of the Indonesian people and social welfare. For PGR, Indonesian Plant Variety Protection Act 2000 acknowledges that local plant varieties owned by the community shall be under the control of the State (Article 7.1) and implemented by the Government (Article 7.2), including responsible for giving a denomination to the local varieties (Article 7.3). In the research area, the 2017 ministerial regulation of Research and Technology, and Higher Education recently issued a regulation to control the utilization of local genetic resources and prevent misappropriation of them.

The enactment of the IPA is 2016 was a step in the right direction as it provides a good basis for Indonesia to develop an appropriate framework to protect PGR and to enhance for security for the nation. However the effectiveness of any protection regime depends on the national legislative and administrative framework, adequate human resource capabilities, an understanding of the complexities of scientific research and disclosure protocols. More importantly, without clear guidelines and adequate resourcing the protection framework is bound to be ineffective as we set out to demonstrate in the sections below.

5. THE IPA: A CRITICAL ANALYSIS

5.1. *The Issue of Substance and Procedure*

By its very nature, DO may be a substantive or procedural requirement. This is an important issue that is left unclear in the IPA given its very limited provisions on the matter. A procedural requirement means that DO will be reviewed at stages of the application for completeness and for formal compliance with specified procedures. Substantive requirements will be required for validity or legality of protection. For plant varieties, it seems possible to include DO as non-formal substantive requirement since according to Article 5 of International Convention for the Protection of New Varieties of Plants (UPOV Convention), the substantive requirements to grant a plant variety right may be established by requiring new, distinct, uniform sample. UPOV Convention affirms that plant variety protection shall not be subject to different or further conditions provided by national formalities. Thus it does not seem possible to make DO a substantive/additional condition for protection. Similarly, Indonesia has strictly specified the substantive requirements for plant variety protection in other regulations. Although Indonesia has not ratified UPOV Convention, Article 2.1 of *Indonesia Plant Variety Protection Act* has identical requirements for protection. This act doesn't require DO as substantive/additional condition for plant protection.

For patent applications, substantive requirements must be met in order to obtain patent rights, while failure to comply with DO requirements could result in the cancelation of the patent application, a refusal to process applications, patent revocation, transferring patent in joint ownership, or criminal sanctions. Most countries have adopted the substantive requirements for patent protection required by Article 27.1 of TRIPs, stipulating that patents 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. Similarly, Indonesia has adopted Article 27.1 of TRIPS for substantive patentability based on criteria of new, inventive steps, and capable of industrial (Article 3 of IPA). According to Article 3 of IPA, DO obligations will not be considered as a substantive requirement. It is difficult to include DO as substantive requirement because DO is an 'accessory' and only related to the invention colaterally unlike novelty, non-obviousness, or industrially applicable patentability requirement (Carvalho, 2000).

The absence of clarity in the IPA on DO as a substantive requirement for patent, or alternatively establish procedural DO requirement has created ambiguity. The ambiguous provisions emerge in Article 3 and Article 54 of IPA because although the main substantive requirement of patent is established under Article 3, Article 54 also integrates DO regulated by Article 26 as one of substantive requirements for granting a patent. There is confusion under the Act 'blending' the substantive and prosedural requirements for patent application.

5.2. DO under the IPA: Voluntary or Mandatory ?

Aside from substantive and procedural character of DO, it is not clear if requirement to disclose the origin of genetic resources is voluntary or mandatory, directly and indirectly. Voluntary or permissive basis of DO indicates that non compliance of such requirement will have no legal consequences. Compared to a mandatory requirement, voluntary DO is the least burdensome because non-compliance of such disclosure requirement does not attract any legal consequences such as disqualification of the patent application from being accepted, granted, or subsequently enforced (Dutfield, 2005).

The direct nature of DO suggests that the requirement is mandatory and enforceable through a loss of patent rights, while the indirect requirement of DO denotes that the requirement is mandatory but enforceable only through means other than the patent system (Gollin, 2005). The mandatory obligation of DO helps to develop a more transparent patent system by improving patent examination to be more coherent..

With a mandatory DO, the failure to disclose would result in non-acceptance of a patent application or the rejection; or if granted, it would not be enforceable or it could be revoked with possible criminal sanctions. In the case of a false of DO, the annulment or cancellation of right or penal, administrative or civil sanctions will be applied. The sanctions are necessary to ensure effective compliance. The sanctions regime also helps ensure greater certainty as to the validity of granted rights/privileges, or the entitlement to own or retain benefits from the patent.

As noted earlier, the IPA obligates DO under Article 26. Under Article 58(1) the 'Minister shall approve the application, if based on the result of the examination, the invention for which a patent has been requested complies with the provisions of Article 54'. Article 54 on the other hand provides that 'substantive examination' must be carried out in relation to DO under Article 26. Under Article 132, (1) an application may be rejected if patents derived from genetic resources and / or traditional knowledge does not meet the provision. By implication DO under Article 26 is mandatory. Non-compliance with its provisions could result in a rejection of the patent application. What is awkward about these provisions is that one has to read through several provisions to arrive at the conclusion as to whether Article 26 DO is mandatory or not. It would have been better

drafting if Article 26 had clearly stated the implication of non-compliance in view of the important of DO for Indonesia. As indicated earlier, the IPA seems very protective of patent applicants, and appears too soft on the issue of food security for Indonesia.

5.3. *The Regulatory Deficit in the Indonesian DO Regime*

There is a shortage of regulation on DO that leads to uncertainty and uncoordinated practice of DO in Indonesian patent law. It is difficult to deal with DO since the concept is alien to Indonesian patent law. Although Indonesia has regulated DO obligations under Article 26 of IPA since 2016, this is a relatively short legislative history. The country lacks an adequate framework of policies and regulations to implement Article 26 effectively. Article 29 of IPA mandates that further provisions concerning the terms and procedures for filing the patent application, including the patent requirements such as DO and benefit shall be regulated by Ministerial Regulation. Since Ministerial Regulations have not been created yet, it is still not clear what procedural, institutional and legal consequences related to DO apply in Indonesian Patent Law. Important details such as the requirements for disclosure, information content, the timing, format, standards, mechanism, authorized institution, the consequences and sanctions and enforcement are still unclear. There is also no clarity on how the applicant must identify where the material is obtained, the person or organisation providing it, any genetic resources used, etc. In addition, there is no regulation about the obligation of a patent applicant to compulsorily enter into an access and benefit sharing agreement with the appropriate rights-holder or provide prior informed consent (PIC) first before lodging patent application. Furthermore, it is lack of clarity about the normative definition of the sort of the genetic resources involved, the meaning of origin, the origin of a resource, ownership, local community, etc. The lack of clarity over such terminologies and definitions lead to greater legal uncertainty and legal loopholes.

About the consequences for non-compliance of DO, there are several options to 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 transferred either partially or completely to ensure fair benefit sharing, or the requirement that any benefits received be repaid, etc. or involve the application of provisions on unfair competition (Oldham & Burton, 2010).

The existing provisions IPA provide three legal consequences against non compliance of DO i.e the rejection of a patent application (Article 58.1), judgment of application withdrawal (Article 62 paragraph (10) and termination of the patent validity based on court decision (Article 132 paragraph (1)b of IPA). Indonesia could complement these measures with other consequences for non compliance of DO requirements by including criminal/penal liabilities, administrative sanctions, suspension of application processing, revocation or annulment of rights, or patent rights transfer either partially or completely, or repayment of any received benefits, or the application of provisions on unfair competition.

5.4. *Practical Challenges*

There are some practical problems with the implementation of the DO regime in Indonesia: Along with incomplete DO regulatory framework, Indonesia has not yet established a DO mechanism and also lacks institutional capacity and expertise to implement DO, including insufficient

monitoring for PGR utilization. The effective degree of co-ordination between authorities, including institutional arrangements is still also questionable.

In addition, it is also more problematic to access to PGR because the procedure to obtain access itself is complex and unclear. In addition, since a workable system for DO will rely to a large degree on good faith, the requirement will not be effective and need to allow flexibility for the various situations in which disclosure could not be made. This flexibility could be misused by malicious applicants. Moreover, PGR users are often located outside Indonesia, and ironically, the users (pharmaceutical, biotechnological and agricultural companies) who usually utilize PGR for their products/patents, have not put in place corresponding regulations to ensure DO and its requirements.

There is also a concern that the measures of DO may lead to a complex, bureaucratic and inefficient system. The feasibility both with respect to the ability of patent applicants to comply and patent offices to check compliance is also questionable. None of Indonesian institutions is experienced enough to provide any insights on a workable DO regime for the country because of the narrow scope of measures and no notification system has been established to enhance transparency of the patent system.

DO brings an additional burden to patent applicants and examiners since. Any effective DO regime is likely lead to increased workload on the patent office, although it is still unclear the role of patent examiners, whether they only file the information received, or also check its veracity, or must cooperate with other institutions to check. The Patent office has not yet executed any DO measures because of lack of clarity of the legislation and limited experience.

Since Indonesia has no a long history of managing DO, the DO obligation may decrease the number of patent applications and increase disputes. Given patents should be seen as a tool to encourage innovation rather than an enforcement, extensive DO requirement has the potential to be destructive on the patent system, and a deterrent to R&D activities. Thus, Indonesia should develop an efficient system of DO in order to balance the need to increase innovations, and to protect PGR in the place national interests.

Another practical problem with the implementation of the DO regime in Indonesia is the cost of implementing and establishing a system to enforce compliance and monitoring. DO will be costly in Indonesia because of the need to adopt further legislation, establish institutions, train staff, develop appropriate system/mechanism, etc. The cost of these measures need to be assessed whether these might in fact outweigh any possible benefits. Unfortunately, any benefits do seem to outweigh DO costs. DO is unlikely to result in significant benefits distribution to Indonesia. Article 26(3) of IPA stipulates that distribution of benefit derived from genetic resources use shall be carried out in accordance with the laws and regulations. However, Indonesia lacks experience in arranging and developing an effective distribution mechanism. Thus, it is a challenge to distribute equitable benefits, including the distribution methods on how the benefits will go to local communities and to owners. It is difficult to establish ownership of PGR, and not easy to determine to whom benefits should be shared because numerous PGR are found in more than one geographical area and may be shared by a number of communities.

It is also difficult to identify the link between genetic resources and an invention meaningfully since current Indonesia legislation vaguely defines this. The concept of genetic resources is usually defined very broadly, to include "any material, of plant, or animal, or any other origin containing functional units of heredity" (Forester, 2012). It is unclear how to define the sort of resources involved, whether disclosure is required for the use of a product if it was several generations away from the original PGR, or for a synthetic compound derived from lead compounds discovered in nature, or whether resources should be tracked through research processes and commercial exchange. This could create problems for the Indonesian Patent Office.

From a technical point of view, many questions remain to be unanswered such as the content of the obligation, and how information should be presented and standardised. It is questionable whether mere disclosure of information will be adequate to comply with the requirement, or should be accompanied by a declaration/prove of origin from the applicants, or by some form of authorizing evidence to prove compliance with access regulations, such as a copy of the access contract or other required documents. It is also difficult to determine the exact time of required disclosure because of the complexity of length chains of research process. The timing of presenting DO is unclear: when access to genetic resources or knowledge should be considered to have been duly authorised, and when will the information be examined, and by whom. According to Article 26(2) of IPA, the genetic resources information referred to in DO shall be provided by an authorized institution recognized by the government. The applicants must show that they were authorised by a relevant institutions to access resources. However, there is an institutional problem because it is unclear to determine the relevant authorized institution or competent authority to establish further conditions and mechanism of DO, including providing an approval or reference for certificates of legal provenance. It is not clear whether any person or entity meets requirements under laws and will possess such authority, or government will choose certain institutions for carrying out DO arrangement and what constitutes such authorisation.

6. SOLUTIONS

As noted earlier, it is not enough to pass legislation that incorporate DO. To be effective, a good DO regime needs a supportive regulatory infrastructure. This is what Indonesia lacks. In order to address the regulatory deficit, Indonesia must prioritize to create further regulations and the related provisions to effectively implement DO. It is necessary to regulate in detail the scope of obligations in order to facilitate its implementation and ensure legal certainty. Premised on the lack of clarity and certainty that constitute obstacles in order to put DO into practice, it is indispensable to determine clearly the legal texts and terminologies of DO so that they can better be interpreted. 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 authorize 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 patent.

It is important to develop a strong and user friendly legislation with a two-tiered system of approval for access of 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 are regarded as a useful step, including a system for establishing bonafide research organisations that will collaborate with those wishing to utilize resources within Indonesia.

In order to make DO more workable, Indonesia should develop meaningful enforcement mechanisms by considering civil liabilities, administrative sanctions, suspension of application processing, revocation or annulment of rights, transfer of patent right 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 imposed on the patent applicants/holders. To be more effective, Indonesia could also adopt the model of criminal sanctions applied in Art 81 a Patent Law of Switzerland that states that patent applicants could face some additional criminal sanctions for a lack of disclosure or false statements (Medaglia, 2010). It is necessary also to determine the character and the level of sanctions, in accordance with Indonesia legal practices and general principles of law. In addition, subsequent efforts to monitor, track and report on DO implementation and compliance by a national body in accordance with standards of accountability and good governance will be useful (Oldham & Burton, 2010).

In order to become effective, the way that the relevant information will be submitted to the patent offices must be standardised. This could be organised in a non-bureaucratic and cost-efficient manner. Recommendations of standardised model of DO could include: (a) the applicants should declare the country of origin or, if unknown, the source of the specific PGR 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 PGR; (c) the incentive for compliance and penalties for noncompliance; (d) simple notification procedure should be introduced and followed 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 the patent office and the clearing House mechanism is needed and the notification should be as simple as possible in order to not lead to an 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.

Indonesia could learn some useful lesson from countries with similar biodiversity attributes as in Latin America. For instance in the case of Costa Rica The competent body that grants access in the first place is the Technical Office (TO) of the National Biodiversity Commission (CONAGEBIO) within the Ministry of Environment, Energy and Telecommunications (MEET). CONAGEBIO is entrusted with preparing access and benefit-sharing policies, and can revoke the rulings of the TO on access issues (Medaglia, 2010). The law 'regulates the terms of access permits, including their limitations and characteristics; the information required in a permit application; the authorisation of agreements with individuals seeking access to genetic and biochemical components by the Technical Office; and the possibility of agreements with universities and other duly registered centres' (Medaglia, 2010, p.18). Panama has similarly established the Genetic Resources Access Unit or Department (Unidad de Acceso al Recurso Genético -UNARGEN) whose functions, 'the responsibility of processing all of the biological and

genetic resource access applications (commercial, industrial and non-commercial).’ (Medaglia, 2010, 22).

Indeed all members so the Andean Community have similar specialist institutions (Medaglia, 2010). The establishment of such specialist institutions can also pave the way for Indonesia to develop the human resources capabilities to deal with DO issues generally

In a general context, to prevent PGR misappropriation and support food security, Indonesia needs to improve various strategies of its DO regime to address: (a) the importance and value of PGR 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 PGR management; (c) inventory, identification, and publication of PGR potential and value; (d) PGR management impacts and benefits for various parties, especially the general public.

7. CONCLUSION

DO plays an important role in protecting PGR since it is potentially a source of: (a) identifying scientific or commercial use; (b) defining rights holders; (c) identifying the existence of prior art and patent transparency; (e) facilitating the monitoring and enforcement of rights; (f) preventing illegal and/or unauthorized use; (g) preventing the grant of wrongful patents; and (h) promoting equitable benefit sharing.

Although DO requirements have been incorporated in IPA, it is undeniable that the provisions need to be further regulated to prevent legal uncertainty and loopholes. Given relatively new DO legislation in Indonesia there is, little practical experience in implementing DO regime. The country is still in search of a DO enforcement structure. Thus, it is necessary to develop further regulation to implement DO provision and the related issues in order to achieve the effectiveness, feasibility, and acceptance of a well established national framework on DO. To achieve this, it is necessary to regulate procedural, institutional and other measures related to the compliance of DO such as the standard, procedures, further requirements, penalties, details of circumstances, code of conduct, information content, the timing, format and level of detailed information, the origin of where the material is obtained, institutions authorizing and providing the information/documentation, monitoring and enforcement.

Finally, DO alone will not be able to solve PGR misappropriation and can not be regarded as the only panacea and support food security programs. The effectiveness, feasibility, and acceptance of established national legislation and system on DO must be adequately developed with other schemes. Whatever model chosen, this should widely support the facilitation of PGR access, prevent PGR misappropriation, protect rights over PGR, enable tracking and monitoring of utilization, promote confidence and equity in the patent system through facilitating searches for prior art on genetic resources and improving transparency of the patent system.

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