



# Disclosure Requirement of Origins in Patent Law the Pros and Cons of the 'Layer' between Patents and Genetic Resources and Traditional Knowledge

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## Abstract

The sharing of benefit arising from utilization of genetic resources and traditional knowledge has been concerned by countries particularly the developing countries which hold amounts of genetic resources and traditional knowledge. Since the CBD was signed in 1992, countries have adopted and provided various methods to facilitate the compliance of the access-benefit sharing system, prior informed consent and mutually agreed terms, including introducing disclosure requirement of origins into patent law. The disclosure requirement of origins requires the patent applicant to present the origins of the material if the invention includes the materials which are subject to ABS regulations set up by the CBD. Today, there are considerable countries which adopted the disclosure requirement of origin into patent law or any other ABS legislations/regulations. This study aims to analyse the disclosure requirement of origin in the context of present concerns of equitable and fair benefit sharing of genetic resources and traditional knowledge to address whether the disclosure requirement of origins can facilitate the equitable and fair benefit sharing and provide aims for countries to monitor the compliance of ABS legislation. This study will assess the disclosure requirement of origins in practical perspective and legal perspective. The insufficient parts of the disclosure requirement will be pointed out and suggestion will be given to improve the disclosure requirement in the final part.

**Keywords:** ABS Legislation; Regulation; Genetic resources; Traditional knowledge

## Introduction

The disclosure requirement of origins and sources of genetic resources and traditional knowledge was considered as an essential method to prevent misappropriation of genetic resources and traditional knowledge and bio-privacy by some countries. In present, in order to achieve certain objectives such as protecting genetic resources and traditional knowledge and ensure the benefit sharing arising from utilization of genetic resources and traditional knowledge, complementing and mutual supporting varieties of international treaties, some countries established the patent disclosure requirement of origins and sources. On the other hand, some views against the establishment of the disclosure requirement demonstrated that the disclosure could have certain drawbacks such as damaging the integrity of the patent law and generating burdensome costs on the companies and entrepreneurs. In addition, they also have concerns and doubts upon whether the disclosure requirement could end the bio-privacy, misappropriations of genetic resources and traditional knowledge and unfair benefit sharing arising from utilization of genetic resources and traditional knowledge.

This article will assess the different approaches of patent disclosure requirement adopted by different countries, the reasons caused the advent of the disclosure requirement, the pros and cons of disclosure requirements and then give some suggestions of disclosure requirement to help improve the disclosure requirements and go through the disadvantages of it. In other words, even if the disclosure requirement has some positive effects on the protection and access-benefit sharing involved by the CBD and the Nagoya protocol, the objectives of the CBD, ensuring the fair and equitable sharing of the benefit of utilization of genetic resources and traditional knowledge could hardly achieved by the disclosure requirement well and the disclosure requirement itself could have some defects in legal aspects and practice aspects and still need more improvement on the legal basis and practice basis.

## Concepts and approaches of disclosure requirements

Patent disclosure requirement of genetic resources and traditional

knowledge refers to a type of requirement that the patent applicant shall mandatorily or voluntarily indicate the sources and origins. Basically, the types of disclosure requirement divided into three: a. voluntary disclosure requirement; b. mandatory disclosure requirement; c. mandatory disclosure requirement with benefit sharing, prior informed consent and mutual agreed terms. Apart from this, different legal consequences such as no specific outcomes, sanctions or fines and invalidity of patents and different legislations and regulations will be relied on such patent law system or access and benefit sharing legislation.

## Voluntary disclosure requirement

The first type of disclosure requirement was voluntary disclosure requirement, also can be described as weak disclosure requirement. This is the least burdensome type of disclosure requirement not producing extra burdens and obligations to the patent applicant to provide extra documents and evidences. Besides, this kind of disclosure requirement will not cause the legal consequences of invalidity of patent or administrative or civil sanctions and fines. The main objectives of the voluntary disclosure requirement are to enhance the transparency of the patents and facilitate the information sharing of genetic resources and traditional knowledge within the international instruments. On the other hand, the effects of voluntary disclosure requirements could be questionable. As it is totally voluntary, the rate of companies and applicants who will like to disclose and the effectiveness and accuracy of the disclosure could be doubtful.

In 1998, European Union adopted the Directive 98/44EC on the

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Legal Protection of Biotechnological Inventions of July 6, 1998 to harmonize legislation of biotechnological inventions into patent laws of member states. It focus on the eligibility of patentable biotechnological inventions including the requirement of mention of the geographical origin of biological material in the patent application. In order to enhance the transparency of the patent application and facilitate the innovations of biotechnology, the Biotech Directive encourages the patent applications to disclose the geographical origin of the material appropriately which is “based on biological material of plant or animal origin or if uses such material” if known. Such disclosure requirement of geographical origin is not “prejudice to the processing of patent applications or the validity of rights arising from granted patents.” Similar regulation appears on the invention which is based on biological material of human origins and the “opportunity of expressing the free and informed consent” must be included according to nation law. Another countries which adopted voluntary disclosure requirement is German. In Germany Patent Act 1980, Section 34(a) states that

“Where an invention is based on biological material of plant or animal origin or if it uses such material, the application should include information on the geographical origin of such material, if known. This shall be without prejudice to the examination of applications or the validity of rights arising from granted patents.”

In 2013, Denmark’s Patent and Trademark Office provided an Order on Patents and Supplementary Protection Certificates and in the Chapter 2 3(5) biological material, it states that:

“If an invention relates to or makes use of a biological material, the patent application shall contain information about the geographical origin of the material if the applicant is aware thereof. If the applicant is not aware of the geographical origin of the material, that shall appear from the application. Lack of information about the geographical origin of the material or about the applicant’s non-awareness thereof shall not affect the examination and other processing of the patent application or the validity of the rights conferred by the granted patent.”

As mentioned previously, like the regulations of European Union and German, basically the voluntary disclosure requirement was introduced as a formality requirement as the articles use the phrases “where appropriate” and “without prejudice to the processing of patent applications or the validity of rights arising from granted patents.” In other words, the absences of the information of the origins of genetic resources or traditional knowledge will not produce any negative effect on the process of the patent application and the validity of the granted patents. Under such legislations, the patent disclosure requirement was not considered as an eligibility or patentability of a patent but a method to facilitate innovations by improving the transparency of the patents and inventions.

It shall be mentioned that basically the voluntary disclosure requirement only requires to submit or provide the origins as a formality and such formality is just an option of the patent application process. It means the authorities or other related agencies will not assess the accuracy of the indications of the origins and if the patent applicant provides false information, there could be no related legal consequences for them as the requirement was not prejudice to the process and validity. This could be one of the reasons why voluntary DR could have little impact on preventing misappropriations of genetic resources and traditional knowledge and bio-privacy. The extent of allowing countries to manage, trace and track the genetic resources and traditional knowledge within their jurisdictions of voluntary DR could be not enough to meet the need of developing countries.

## Mandatory disclosure requirement

Mandatory DR refers to a disclosure requirement within patent legislations or other related ABS legislation which must be complied with by the patent applicant to disclose the origins of genetic resources and traditional knowledge. As the mandatory disclosure requirement set up a legal obligation on the patent applicant to comply with, the failure to comply the requirement will lead to different legal consequences depends on different approaches adopted by countries. In some cases, the absences of information of origins or false indications of origins will lead to consequences of sanctions or fines. A deceptive or false disclosure in bad faith may also cause the administrative or criminal sanctions. Compared with the voluntary DR, mandatory DR makes the disclosure of origins a legal obligation to comply, forcing the patent application to expose the origins of genetic resources and traditional knowledge, otherwise the sanctions or fines will be applied. In this term this could have better effects on facilitating the transparency of inventions and preventing the misappropriation of genetic resources and traditional knowledge and then it could ultimately and indirectly enhance the PIC, ABS and MAT by pushing the companies to seek PIC, ABS and MAT. And this is the reason that countries adopt the mandatory with sanctions and fines to prompt the benefit sharing and prior informed consent/mutual agreed terms.

However, there were two kinds of views which feel arguable on it and they are opposite to each other. On the one hand, some argues that a sanction or a fine as a method of “stick” will combat the enthusiasm of companies on innovations of genetic resources and traditional knowledge. On the other hand, some views will argue that such sanctions and fines within the system of civil law or administrative law could not sufficiently fulfill the need of benefit sharing arising from utilization of genetic resources and traditional knowledge and preventing misappropriation of genetic resources and traditional knowledge. In some cases, the companies prefer to go through the patent application process and launch the products and then they will like to pay the fines or sanctions if the such punishment have lower impact than that of benefit-sharing. After all, the misappropriation and benefit sharing issues will hardly be addressed well.

Countries like Switzerland and Viet Nam have such mandatory DR. In Viet Nam’s detailing and guiding the Implementation of a number of Articles of the Law on Intellectual Property regarding Industrial Property, the DR is regulated as:

“[A]n application for registration of an invention concerning gene source or traditional knowledge must also contain documents explaining the origin of the gene source and/or traditional knowledge accessed by the inventor or the applicant, if the invention is directly based on that gene source and/or traditional knowledge. If the inventor or the applicant cannot identify the origin of the gene source and/or traditional knowledge, he/she shall so declare and bear responsibility for the truthfulness of his/her declaration.”

In Switzerland, mandatory disclosure requirement was introduced by Federal Act on Patents for Inventions. In article 49a, it provides that a patent application must include information of the source of genetic resources the inventor or the patent applicant had access or directly based on or traditional knowledge the inventor or the patent applicant had access or directly based on. In case of these source is ambitious or unknown to the inventor or patent applicant, a statement of unknown must be made by patent applicant. As for the legal consequences, in article 81, it states that a time limit will be applied by the authority for the patent applicant to remedy the deficiencies, otherwise, in the case

of the any person provided false information under article 49a, a fine of up to 100,000 Francs will be charged.

France adopted a more detailed regulations on the mandatory DR of genetic resources and traditional knowledge. According to Law No. 2016-1087 of August 8, 2016 on the recovery of biodiversity, nature and landscapes, Art. L. 412-18.-II, the requirement applied on the Genetic resources and associated traditional knowledge which led to a patent application. Users of genetic resources and traditional knowledge shall submit the information stipulated by the Article 4 EU Regulation 511/2014EC which includes internationally-recognized certificate of compliance or any other relevant documents of origins and sources to National Intellectual Property Institute. Failure to fulfil the requirement set up by Art. L. 412-18.-II could cause one year of imprisonment and a fine of 150,000 euros as the Article 4(3) of EU Regulation 511/2014EC had mandatory requirement of disclosing such document [1-11].

As mentioned above, the countries which established the mandatory DR with sanctions or fines. With the legal obligation of disclosing origins of genetic resources and traditional knowledge, the patent applicant could pay attention to the issues of genetic resources and traditional knowledge as the legal consequences of sanctions or fines exist. However, this is still an indirect method to encourage or push the companies or inventors to prevent misappropriations of genetic resources and traditional knowledge. The influences of facilitating benefit sharing and preventing misappropriations of genetic resources and traditional knowledge could be insufficient as the amounts of the fines or sanctions will be much less than the benefits of granted patents and exclusive rights.

### **Mandatory disclosure requirement with abs, pic or mat**

Mandatory disclosure requirement with ABS, PIC or MAT, which can be considered as 'Strong disclosure requirement' refers to a disclosure requirement with not only the origins/sources of the genetic resources and traditional knowledge, but also the access-benefit sharing, prior informed consent and mutual agreed terms. In most cases, such strong disclosure requirement will have influences on the validity of the patent for instance the absence of PIC/MAT or benefit sharing with the indigenous/local communities and provider countries could lead to a revocation or withdraw to the granted patent or patent application. As this strong kind of disclosure requirement provide a legal consequence on the validity of the patent and the patentability, the influences are considered much effective than other two disclosure. For the companies or the patent applicant, the obligations of getting license of genetic resources and traditional knowledge by PIC, MAT and ABS falls on them in case of applying a patent which is utilized from genetic resources and traditional knowledge. The objective of this strong type of disclosure requirement is to facilitate the compliance with the ABS provided by the CBD and the Nagoya Protocol, improve the system of track and trace of the use of genetic resources and traditional knowledge and promote the establishment of the fair and equitable benefit-sharing system.

The views upon this disclosure requirement could be various. In the perspective of countries adopted such approaches, they seem to agree that setting up a legal obligation of benefit sharing, PIC and MAT in the terms of patentability could make companies and inventors concern more on the fair and equitable benefit sharing and rights of indigenous/local communities. In addition, with the information disclosed by the patent applicant, competent authorities of provider country could monitor and track the use of the genetic resources and traditional knowledge within the territories. On the other hand, views

against the PDR of substantive nature which could cause invalidity on the granted patent and influences on the patentability argue that such disclosure requirement is totally foreign to the patent law. As the inventive step, novelty and industrial application requirements are assessed by the patent law for decades in international term, the origins and sources of genetic resources and traditional knowledge as a substantive patentability was questionable and problematic. Besides, such strong PDR have much more significant influences on the companies and inventors who research and develop based on the genetic resources and traditional knowledge as the patent law will not give exclusive rights on inventions which do not contain origins information and other relevant biodiversity related documents. This could further combat the interests of companies to invest on the field of utilization of genetic resources and traditional knowledge. In other words, the innovations of the science and technology could be affected by the substantive disclosure requirements.

In countries with rich resources of biodiversity like India, South Africa and Andean Community, they prefer to establish such kind of strong requirement to monitor their resources and facilitate the equitable and fair benefit sharing.

In 2005, India amended the Patent Act, 1970, in Article 10(4)(d) (ii), it stipulated:

"If the applicant mentions a biological material in the specification which may not be described in such a way as to satisfy clauses (a) and (b),<sup>7</sup> and if such material is not available to the public, the application shall be completed by depositing the material to an international depository authority under the Budapest Treaty and by fulfilling the following conditions, namely: disclose the source and geographical origin of the biological material in the specification, when used in an invention." As for the legal consequences, in article 25 on the ground that "the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention", any person could take an opposition to the controller against the grant of the patent. In case of granted patent, if the complete specification does not contain or falsely indicates the source or geographical origin of bio-material of the invention, a patent could be revoked "on a petition of any person interested or of the Central Government by the Appellate Board or on a counter-claim in a suit for infringement of the patent by the High Court on any of the following grounds."

In South Africa, Section 30 of the Patents Amendment Act states that: "3A) Every applicant who lodges an application for a patent accompanied by a complete specification shall, before acceptance of the application, lodge with the registrar a statement in the prescribed manner stating whether or not the invention for which protection is claimed is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use." In 3(B), it further stipulated that the applicant should take the obligation to prove his/her title or authority to "make use of the indigenous biological resource, genetic resource, or of the traditional knowledge or use if an applicant lodges a statement that acknowledges that the invention for which protection is claimed is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use."

Andean Community had such disclosure requirement as well. In Article 26, Decision No. 486 Establishing the Common Industrial Property Regime (2000), the application of a patent which "is sought have been obtained or developed from genetic resources or products derived therefrom of which any of the member countries is the country of origin" shall contain the access contract and where applicable, "the

document accrediting the licensing or the authorization of the use of the traditional knowledge.” In addition, pursuant to Article 75, the competent national could determine the patent absolutely invalid on the ground of failing to obey the disclosure requirement at any time, no matter ex officio or for the request of any person.

To sum up, the mandatory DR with ABS, PIC and MAT provides a strong protection for the provider countries to establish equitable and fair benefit sharing arising from utilization of genetic resources and traditional knowledge as well as monitor the use of genetic resources and traditional knowledge within their countries. By adding the disclosure of origins/sources and benefit sharing, PIC and MAT as one of the patentability with inventive step, novelty and industrial application, the patent applicant has to provide certain documents or evidences to meet to requirement in order to complete the examinations of patentability.

In one perspective for the benefit sharing and rights of provider countries or indigenous/local communities, as it provide a requirement which affects the patentability of patent law, companies and inventors have to concern the benefit sharing with providers countries and indigenous/local people and the PIC, MAT with them. In addition, on the basis of facilitating the transparency of patents and track the use of genetic resources and traditional knowledge, provider countries could further facilitate the compliance with the ABS law and other international treaties through the mandatory disclosure requirement of origins/sources. However, some may argue that this will not solve the issues of misappropriations and unfair benefit sharing. In the perspective of enhancing innovations and development of technology and science, views against it stressed that such strong requirement will reduce the interest which was already minor on the utilizations of genetic resources and traditional knowledge associated with genetic resources. It could be a disadvantage to attract the investment on the R&D on genetic resources and traditional knowledge for provider countries. In addition, the obligations to meet such requirement could be burdensome for companies as the MAT, PIC and ABS may involve the negotiation with provider countries and indigenous community. So, it could be a measure with significant effects but also have problems.

In most cases, countries with rich resources of genetic resources and traditional knowledge will adopt such strong disclosure requirement to prevent bio-privacy and misappropriation like India, South Africa and Andean Community. Basically, they almost state that patents involved genetic resources and traditional knowledge from provider countries must contain the information of origins/sources and the proof of authorization, entitle and benefit sharing must be included as well. The legal consequences may lead to the invalidity of patent such as revocation for granted patents or withdraw for patent application on process depended on the national legislations.

### **Is there any other type of disclosure requirement could be adopted?**

In fact, The Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization provides an instrument which could be clear and easy to adopt by countries. The idea is to make use of the international cooperation and the transparency established by the information sharing system. The basic principle of the Bonn Guidelines is to provide a flexible, easy to establish, practicable, acceptable, complementary and voluntary instrument for provider countries, stakeholders, users and competent authorities to practice the access and benefit sharing, prior informed consent and mutual agree term. The Bonn Guidelines suggests to set up a system that competent national authorities monitoring and is

responsible for the process of the ABS, PIC and MAT, including holding the negotiation process, requiring the authorization and entitle by PIC and MAT, implementing of the ABS, PIC and MAT and promoting the participation of indigenous people and local communities and stakeholders. In addition, the users of genetic resources and traditional knowledge associated with genetic resources need to take the obligation provided by the CBD and they are suggested to seek authorizations and entitles before the utilization of genetic resources and traditional knowledge, respect and respond to the rights, voices, opinion, customs, traditions, values of the indigenous/local people, make use of the resources consistent with the condition of mutual agreed terms, guarantee the safety of the data relevant to the genetic resources and traditional knowledge and share the benefit equitably and fairly with the providers countries according to the Convention and conditions within the mutual agree terms. Besides, the provider countries play a role to provide and introduce the system through national legislation by reviewing the relevant policy, introduce the transparent instruments and information to the users, stakeholders and indigenous communities and harmonize the ABS, PIC and MAT process between users, stakeholders and indigenous communities. Bonn Guideline encourages the contracting parties to establish a system running as mention above in order to practice the ABS, PIC and MAT convenient in international term. On the basis of this, Bonn Guideline further suggests the means for verification, which is provided as:

“57. Voluntary verification mechanisms could be developed at the national level to ensure compliance with the access and benefit-sharing provisions of the Convention on Biological Diversity and national legal instruments of the country of origin providing the genetic resources.

58. A system of voluntary certification could serve as a mean to verify the transparency of the process of access and benefit-sharing. Such a system could certify that the access and benefit-sharing provisions of the Convention on Biological Diversity have been complied with.”

In other words, the idea of this system of voluntary certification is that the users who complied with the ABS, PIC and MAT pursuant to the relevant legislation of the provider countries will be certificated by the competent authorities of the provider countries. Such certification could be an evidence or proof of the users take measures of ABS, PIC and MAT and are granted by the competent parties of provider countries. This measure could be considered as a method of disclosure requirement of origins as it has further requirement the compliance of ABS law of provider countries.

Serval proposals were provided in the lights of the certification ideas, they are certificate of origin, certificates of sources, certificates of legal provenance and certificates of compliance. Even if all of them have different views on the various issues, the Group of Technical Experts on Certificates of origin/source/legal provenance (GTE) of COP 8 considered four proposals have common characteristics such as: “(i) a certificate would be a public document issued by a competent national authority; (ii) it would serve to provide evidence of compliance with national ABS legislation; (iii) it could be required for presentation at specific checkpoints in user countries.” The common idea of the certificate system is to encourage or require the users to obtain the genetic resource through legal method such as mutual agreed terms, prior informed consent and benefit sharing. Following with the obtainment, the competent authorities can grant the certificate to the users as a proof of legal compliance with the law and such certificate could be a evidence for the disclosure requirement of origins or a claim by the user to prove the compliance when facing the doubts on the origins and the validity of the material.

## The legal basis of the disclosure requirement

The legal basis of the disclosure requirement gives the rights for countries which will like to introduce the disclosure requirement to protect the genetic resources and traditional to enact the disclosure requirement. Firstly, the Convention on Biodiversity and the Nagoya Protocol stipulate the sovereign rights of member states on genetic resources and traditional knowledge and the access-benefit sharing system upon the genetic resources and traditional knowledge. Secondary, the TRIPS agreement which is the international agreement on IP rights does not give the lowest format of IP rights protection for member states but also give the flexibility for member states to introduce the disclosure requirements into their IP rights law. Most of the countries adopting the disclosure requirement of origins rely on these two legal instruments to introduce their own disclosure requirements.

## The CBD and the Nagoya protocol

The Convention on Biodiversity (CBD) is a significant legal instrument on the regime of genetic resources and traditional knowledge. The CBD recognize the sovereign rights of countries on genetic resources and traditional knowledge as well as the identification of genetic resources and traditional knowledge (formally identified in the Nagoya Protocol). In addition, the CBD also introduce the ABS system of genetic resources and traditional knowledge which includes the prior informed consent, mutually agreed on the access and the benefit sharing arising from utilization of genetic resources and traditional knowledge.

In article 6 of the CBD, it requires the contracting parties to take measures to preserve the genetic resources and traditional knowledge and ensure sustainable use, which is described as follow:

“Each Contracting Party shall, in accordance with its particular conditions and capabilities:

(a) Develop national strategies, plans or programmes for the conservation and sustainable use of biological diversity or adapt for this purpose existing strategies, plans or programmes which shall reflect, inter alia, the measures set out in this Convention relevant to the Contracting Party concerned; and

(b) Integrate, as far as possible and as appropriate, the conservation and sustainable use of biological diversity into relevant sectoral or cross-sectoral plans, programmes and policies.”

This article of the CBD reveals that the contracting parties have the obligation and rights to ensure the conservation and sustainable use of biological diversity by making national strategies, plans or programmes. In other words, the parties of the CBD also have the rights to introduce disclosure requirement of origins into their national legislations as a method to achieve national strategies.

In the article 15 of the CBD, it recognizes the sovereign rights of States on the genetic resources as well as the traditional knowledge and the sovereign rights on genetic resources and traditional knowledge is the basis of the sustainable use of genetic resources and traditional knowledge. With the recognition of sovereign, the further rights of the provider countries and local/indigenous people are ensured. Before the access and the utilization to genetic resources and traditional knowledge, it shall be subject to the mutually agreed terms and the prior informed consent of the contracting party. These are stipulated as follow:

“1. Recognizing the sovereign rights of States over their natural

resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation. [...]

4. Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.

5. Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.”

Besides, the traditional knowledge was recognized by the article 8(j) of the CBD, it was regulated as follow:

“(j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.”

On the other hand, the CBD could also realize the implement could be influenced by the IP rights, which could be more detailed, the conflicts could exist between the CBD and the TRIPS agreements. To this regard, the article 16 of the CBD calls the contracting parties to facilitate the cooperation between the countries and enhance the mutual supportiveness of the national legislation and the international instruments. It was described as follow:

“The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.” Besides, it is also the only reflection to the IP rights on the CBD. In other words, the CBD focus on the preservation and sustainable use and only reflect to the IP rights as the mechanism of the CBD could cause conflict to other IP rights instruments, encouraging the further review to enhance the supportiveness between the national implement of the CBD and the IP rights law.

In order to improve and facilitate the access and benefit sharing of genetic resource and traditional knowledge, the Nagoya Protocol was adopted as an additional instrument of the CBD. A transparent and clear legal framework aiming to achieve the three objectives of the CBD, particularly in the third objective of the access and benefit sharing. The Nagoya Protocol has three relevant contents: improving the ABS system, recognizing the rights of local/indigenous people and interpreting the concept of traditional knowledge.

In the article 5 of the Nagoya Protocol, it set up an obligation for parties to take action to ensure the fair and equitable benefit-sharing. They are described as follow:

“2. Each Party shall take legislative, administrative or policy measures, as appropriate, with the aim of ensuring that benefits arising from the utilization of genetic resources that are held by indigenous and local communities, in accordance with domestic legislation regarding the established rights of these indigenous and local communities over these genetic resources, are shared in a fair and equitable way with the communities concerned, based on mutually agreed terms. [...]

5. Each Party shall take legislative, administrative or policy measures, as appropriate, in order that the benefits arising from the

utilization of traditional knowledge associated with genetic resources are shared in a fair and equitable way with indigenous and local communities holding such knowledge. Such sharing shall be upon mutually agreed terms."

In article 7, compared with CBD using the phrase "knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity" the Nagoya Protocol uses the phrase "traditional knowledge associated with genetic resources" to interpret the traditional knowledge. Article 7 recognizes the rights of indigenous and local people as well, stipulating that access to genetic resources and traditional knowledge must involve the participation of local community, prior consent and mutual agreed terms.

As the Nagoya protocol focus on the implement of the ABS system, giving the obligations of parties to take measure to ensure the fair and equitable sharing the benefit of genetic resources and traditional knowledge, which includes the option of adopting the disclosure requirement of origins to encourage and push the users to share the benefit equally and fairly.

To sum up, the CBD recognizes the sovereign rights of the countries on the genetic resources and traditional knowledge and the access and utilization of the genetic resources and traditional knowledge should be subject to prior informed consent, mutual agreed terms and fair and equitable benefit sharing. The Nagoya protocol further stipulated that parties shall take measures to ensure the benefit sharing of genetic resource and traditional knowledge associated with genetic resource is fair and equitable and the rights of local community shall be regarded. As two legal instruments provides the obligations for parties to implement, the parties could seek multiple measure to achieve the objectives, which contains the disclosure requirement of origins. In other words, the CBD and the Nagoya protocol provide the legal basis for parties to practice and introduce the disclosure requirement of origins.

### WTO Agreement on Trade-Related Aspects of Intellectual Property Rights

The WTO agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS agreement or TRIPS) is a mandatory agreement to agree by the member states of the WTO organization. TRIPS agreement stipulates lowest level of protections for various IP rights including patents, copyrights, trademarks etc. With the lowest requirement of IP rights protections, the member states also have the flexibility to regulated additional regulations on IP rights. As for disclosure requirement of origins which is set into the patent law, the TRIPS agreement stipulates the lowest level protection for patents, which are patent protection without discrimination, uniformed patentability and exclusions from patentability.

The legal basis of disclosure requirement relies on two articles of the TRIPS agreement. One of them is the article 27. The article 27 is the basis of the patent protection set up by the TRIPS agreement. It contains three parts: protection without discrimination, patentability and exclusions.

The article 27 of patent protection related to disclosure requirement is listed below:"2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law."

Regard to the article 27(2), it could be clear that the member states can exclude the inventions even if it fulfills the requirement of the patentability set up by the TRIPS to achieve certain objectives such as protecting the environment etc. It includes the method of introducing the disclosure requirement of origins by the member states as the fair and equitable benefit sharing of genetic resources and traditional knowledge can be amount to the scope of the order public within article 27(2).

The section (1) and (3) stipulated the protection without discriminations and the exclusion of patents. The section (1) also could be used to argue against the disclosure requirement and it will be discussed in the later chapter. The section 3 listed the exclusion on the patentability of life except the micro-organism, which was argued by some developing countries. The sections are listed as follow:

"1. [...] 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. [...] patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

[...]

3. Members may also exclude from patentability: [...]

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement."

### Disadvantages of the disclosure requirement

Even if a lot of countries particularly the developing countries adopt the approach of disclosure requirement into their national patent legislations or ABS relevant legislations in order to ensure the appropriated access and fair and equitable benefit sharing of genetic resource and traditional knowledge, it can be fair to consider that disclosure requirement of origins is insufficient to achieve the objectives as the disclosure requirement has defects not matter on legal basis and practices terms as well as the possibility on discouraging the innovations on genetic resources and traditional knowledge if the disclosure requirement was too strict.

### Problems with the TRIPS agreements

As the paragraph above discussed, the legal basis of the disclosure requirement which are the article 27 and article 29 of TRIPS agreement is considered arguable by some views. The most controversial perspective is targeting to the strong disclosure requirement which may have influences on the patentability of the patent in the case of failure to present the information of origins. Basically, the views against the strong disclosure requirement hold the opinion that the strong disclosure requirement which will have influences on the validity of the patent is not different than adding a new patentability to the TRIPS agreement. In 2000, a report was adopted by the European Chemical Industry Council (CEFIC). In this report, the disclosure requirement of origins with effects on the validity of the patents is described as a foreigner to the patent law, which makes the companies and the patent offices strange to it and causes the doubts on the capacity of the patent

offices and examiners. In this paper, the views are indicated as follow:

“There are many reasons to justify why such an indication should not be made a condition in the patent procedure. First of all, it is totally ‘foreign’ to patent law (it has no link with the novelty requirement, inventiveness, or the utility of the invention).

In addition, in practice, it will be extremely difficult, if not impossible in some cases, to be managed by patent offices, since they are not equipped to judge whether in a particular patent application an indication of origin is correct, and whether the patent applicant lawfully obtained that biological material.”

In other words, disclosure requirement with consequence on the patentability of the invention may be an external introduction of new patentability into the existing patentability: inventive step, novelty and industrial application. As it is totally novel to the patent law regime and no sufficient knowledge on the huge amount of genetic resources and traditional knowledge, the effectiveness of patent offices and examiners appropriately identifying the origins of the inventions is questionable and ultimately it also causes inconvenience to the users of genetic resources and traditional knowledge and companies. The views conclude that the patent law is not suitable for introduction of disclosure requirement to concern the access and benefit sharing of genetic resources and traditional knowledge.

In a more neutral way, the WIPO use the word of “layer” to describe such strong disclosure requirement. In its report entitled “Key Questions on Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge” (published in 2017, updated in 2020), it states that a new “layer” was input to the conventional disclosure requirement by introducing an “additional duty to disclose more technical or legal information or evidence”. Besides, the disclosure requirement may be subject to the disclosure of the information of the invention as the patent requires the description to present the working process and the reproduction or the disclosure requirement may just be subject to a formality requirement. The WIPO report on the disclosure requirement also recognizes the opposing views on the disclosure requirement and lists the views of them. Within the list, the WIPO report recognizes some views which were discussed above and raised by the CEFIC:

- The patent system is not suited for, and should not serve to implement, exogenous objectives or goals (such as ABS objectives) because this will compromise its integrity.

- It will be burdensome, expensive and time-consuming for patent applicants and patent offices to implement new PDRs.

- Patent offices will not be equipped to judge whether information regarding the disclosure of origin or source of a genetic resources or traditional knowledge was correct and accurate, and whether any national ABS requirements had been fulfilled.

- If an examiner had to carry out substantive examination of a PDR, patent validity will no longer be an exclusive function of novelty, inventive step and industrial application.”

To this regard, strong disclosure requirement may have insufficient parts on the legal basis of the patentability provided by the TRIPS agreement on the article 27(1) as it stipulates non-discrimination in patent availability. In addition, the article 27(2) which allows the countries to introduce the disclosure requirement on the basis of ordre public or morality. However, in the context of the article 27(2), such ordre public or morality is subject to protection of human, animal or plant life and environment. The disclosure requirement of the origins

may be indirect on the terms of such aspects and it could be more subject to the fair and equitable benefit sharing of genetic resources and traditional knowledge, which may be more in the economical context.

The article 29 is another legal basis of the disclosure requirement which require the applicant to disclose the invention “in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art”. To this regard, some countries and unions like EU who may not have enthusiasm on introducing strong disclosure requirement agree the legal basis of the article 29 on disclosure requirement. However, this is not the objectives of the article 29 which is disclosure to allow the reproduction of the invention according to EU position. On the other hand, if the origins of the materials play a significant role in the reproduction of the invention, the objective of the article 29 is fulfil. It is fair to suggest that article 29 as a legal basis of the disclosure requirement has insufficient parts as well.

### Legal uncertainty on the disclosure requirement

The issues of the legal basis of the disclosure requirement can be considered as a kind of legal uncertainty. As the disclosure requirement is set up to ensure the fair and equitable benefit sharing of genetic resources and traditional knowledge, there are more legal uncertainties which may cause negative effects on achieving the objective or even cause negative influences on the science and technology innovation.

### The concepts of genetic resources and traditional knowledge does not involve the nature of genetic resources, the gene sequence

Informational form such as a DNA sequence or tomographic scan can describe and held value of the biological material now and the ABS regime may not concern and cover this perspective. Most of the countries adopt the concept of genetic resources and traditional knowledge within the CBD and apply it into the regulation of disclosure. With the development of biotechnology, especially the bioinformatics, the nature of gene is discovered, which is that the nature of the species or the characteristics of species are determined by the information or data carried by the genes within the certain lives. As the CBD was signed in 1992, it may not cover the board definition of genetic resources with the lack of concerns on the bio-information. According to CBD article 2, the genetic resources is defined as “genetic material of actual or potential value” and the genetic material is defined as “any material of plant, animal, microbial or other origin containing functional units of heredity.” As the definition given by the CBD, the genetic resources which is protected and ensured by the CBD are limited to the physical material of certain “plant, animal, microbial or other origin containing functional units of heredity”. However, also according to article 2 of CBD, “biological resources” has boarder definition: “genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity”. The CBD gives the definition to the genetic resources on the basis of the actual or potential value of such material. However, this definition is considered “lack of clarity in the use of terminology”.

As for the gene sequence which present the characteristic, the CBD may not cover the bio-information carried by the genes as the CBD’s definition only covers the material from the plant, animal or microbial. Even though the CBD recognizes that the characteristics of certain species is the value of genetic resources, the CBD does not concern the nature of the characteristics which is determined by the gene sequences. With the legal uncertainties on the bio-information, the gene sequences or bio-information is put beyond the scope of the CBD and the disclosure requirement could not cover such bio-information.

As for gene sequence may not present specific characteristic, according to a report prepared by Queen Mary Intellectual Property Research Institute, it could be arguable that although the unidentified DNA sequences with actual or potential value or no-value, is not considered as genetic resources. Notwithstanding, scientists have discovered that even the DNA with no specific roles in presenting characteristic could have important roles "in the development, functioning and reproduction of living organisms".

### **Legal uncertainty on the origins of the genetic resources and traditional knowledge**

There is still a problematic issue for the ABS and disclosure requirement of origins since the genetic resources and traditional knowledge were used, which is the identification of the origins of the genetic resources and traditional knowledge. As the human being have exchanged and transferring the knowledge on agriculture and medicine for thousands of years by migration etc., the origins of the genetic resources and traditional knowledge are difficult to identified and it will cause problems on the implement of the disclosure requirement as different communities or places will argue they are the origins of the genetic resources and traditional knowledge.

According to article 10 of the Nagoya Protocol, in the case of the genetic resources and traditional knowledge "occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent", a global multilateral benefit-sharing mechanism is considered to be established by the parties. In other words, the CBD and the Nagoya do recognize the issues on the identification of the origins and it could be problematic.

In addition, according to a report on the article 10 of the Nagoya protocol, three situations can be divided into three situations: "(1) Shared Ecosystems/Genetic Resources Distributed across National Boundaries; (2) Traditional Knowledge held by Indigenous Peoples and Local Communities across National Boundaries; (3) Migratory Species." Each of them has respective difficulties on the implement of the identification of the origins.

As for the shared ecosystems/genetic resources distributed across national boundaries, it could be a common situation for a genetic resource held by different countries as the species do not consider the limitation of the boundaries and exist cross-boundaries. This could cause the campaign between countries or places to claim on the benefit derived from the genetic resources. Besides, there are lots of plant varieties can be used as examples to provide that the origins and the possessors of the benefit will be hard to identified. One of the examples is the neem tree. In 2005, after 10 years campaign by the India government, the EPO revoked a patent to a product to prevent the insects in planting based on neem which had been used for over 2000 years. In this case, India played a significant role in claiming the prior use of the neem and prevent the misappropriation of the neem. However, this could be a special as other countries did not claim the prior use and origin of the neem, as the use of neem was not only limited to India, but also shared by Nepal, Pakistan, Bangladesh, Sri Lanka, and the Maldives. Changing to subject slightly to the disclosure of origins, this unclearness of the origins of genetic resources will cause ambiguousness and confusion to the disclosure requirement and may cause the arguments on which place is the origins.

As for the second situation, more complex identification problems exist as the traditional knowledge and genetic resources is across a lot of places and held by various communities. Rosy Periwinkle is a plant originating from Madagascar, however it can also be found in India

and it has been grown across Caribbean that could be considered as native. The Eli Lilly found a new use of Rosy Periwinkle to treat cancer by literature search on diabetes treatments treatment in Philippine and was entitled a patent named "Vincristine". In addition, the researchers in University of Western Ontario also found the use on cancer by studying the sample sent from Jamaica which used Rosy Periwinkle to treat diabetes. Turning to disclosure requirement, provided that the disclosure requirement requires the origins of Rosy periwinkle to be disclosed, as the traditional knowledge held in a places other than the origin place, the origins or the holders of the genetic resources and traditional knowledge become untraceable. Any countries or communities to be put on the origins to be disclosed could cause debates and controversial arguments on its accuracy.

As the case provided above, all of those cases provide that if the origin of the genetic resources and traditional knowledge is untraceable or unidentified, the effectiveness of the disclosure requirement of origins could be reduced as more debates and conflicts exist on the origins. In addition, the issues on the uncertainty on the origins of genetic resources and traditional knowledge also cause uncertainty and confusion the patent applicant as they may have not qualified capacity to identify the origins. In other words, the uncertainty of the origins and the possessors of the knowledge and genetic resources have negative effects neither the users and patent applicant nor the authorities adopting the approach of disclosure requirements. For the authorities or countries adopting the disclosure requirements in order to facilitate the transparency and ensure the fair and equitable benefit sharing, at least in terms of facilitating the transparency, the untraceable origins and controversial arguments could make the transparency of the patent applicant and disclosure requirement doubtful. The untraceable and unclear origins is conflicts with the objectives of the transparency of the patent applicant and disclosure requirement and it could create barriers for the fair and equitable benefit sharing. For the users or the patent applicant, as the limitation of their knowledge to the material they used, they might probably acknowledge the source of the material and may make extra efforts to search the origins. As the origins is controversial, it could be more burdensome for the patent applicant in the issues of the origins. Assuming the strong disclosure requirement was adopted and implemented by the countries, as the possibilities for patent applicant to disclose wrong origins exists as the origins could be untraceable, on the one hand, it could be unfair to give influence on the validity of the patent. On the other hand, if no significant influences will be on the validity of the patent, the effectiveness of the strong disclosure requirement that use the validity of the patent to push the patent applicant to disclose the origins could be reduced. To sum up, logically speaking, it could be unreasonable to implement the disclosure requirement of origins if the issues of ambiguousness of the origins were not solved.

Changing the subject slightly, it is unreasonable to require the patent applicant to disclose the origins while the origins are still controversial. If the knowledge and the information was insufficient for authorities and patent applicant to make the clear disclosure of origins, the objectives of the disclosure requirement to ensure fair and equitable benefit sharing could not be achieved well. The reason why the origins are untraceable and unclear could be various. As the paragraph discussed above, the nature of human being exchanging knowledge freely and species exist across the nation borders. Besides this, the lack of information and knowledge sharing on the genetic resources and traditional knowledge or insufficiency of the database could be also one of the reasons cause the conflicts. The conflicts that the issue of the origins is yet to be solved and the disclosure requirements required



disclosure of clear origins is not sound in this perspective. Unless a well and sound system which could ensure the clearance and the relative accuracy information and documentation of genetic resources and traditional knowledge, the objectives of disclosure requirement of facilitating the transparency and ensuring the fair and equitable benefit sharing then could be achieved well.

The issues for the companies or entrepreneur in practice terms.

As the disclosure requirement is considered to be foreign to the patent law, the disclosure requirement could be considered to be foreign to patent applicant and entrepreneur as well. The uncertainty and confusion exist in various places for the patent or companies to implement and practice the disclosure requirement.

To begin with, as the companies or entrepreneurs are facing a novel requirement adopted by the patent law, they could have confusion on the detailed implement and the concepts of the disclosure requirement. They will need times and extra costs to figure out the implement of the disclosure requirement as they could not use the previous experiences on patent law. They might have confusions on which places shall be disclosed as on the one hand the legal uncertainty on the origins issues are yet to be solved, on the other hand, the companies could only acknowledge the sources of material they get access to. Besides, it could be still burdensome for companies and entrepreneur to find the origins of the invention while the consequences of the misinformation are strict.

The researchers or companies who used the genetic resources and traditional knowledge may have problems on identifying the origins of the material they used. The researchers or the companies may not have the record on their materials and the application of DR may make them take lots of efforts to figure out the origins of the materials they used which may have no records on it. It could be another reason to trigger the increase on research cost and transaction cost. If the approach of DR applied on the former materials and patent, the researchers and companies had to indicate all of those origins of materials, which was costly. If the approach will not apply on the former materials, it could also be costly as the companies and researchers need to indicate the unrecorded material when they have improvement on the patents or new application of the patents. In common sense, the researchers and companies will know the sources of the suppliers but not the origins.

The lack of legal professional assistants who have certain knowledges on PIC, Mutual agree terms and ABS. basically, the legal assistants or legal teams in huge companies of pharmacy or agriculture will be professional in contract aspect or other business related aspects of civil law. In addition, they could be professional in patent law aspect instead of the genetic resources and traditional knowledge as they could be new to the patent law field. In small companies or entrepreneurs, it could be common that there could not any legal teams or legal assistants as they did not have enough resources to pay attention on the legal issues especially the DR of genetic resources and traditional knowledge. If the approach of DR of patent especially the requirement which will lead to revocation of the patent or invalidity of the patent, the companies specifically the small entrepreneur will have to put lots of efforts on it in order to meet the requirement, which may have negative effects on the research or the business running.

Difficulties on PIC and mutually agree terms when the companies negotiated with the provider countries government or indigenous communities. The huge enterprise or companies may have huge power on contracting process in PIC and MAT, but the small companies and researchers may not have that huge power in contracting process.

In addition, the small companies could not have the access to the traditional knowledge and genetic resources holders or provider countries. This created the barriers for companies to obtain PIC and MAT to meet the DR.

### Problems for patent examiners and patent office

The confusion and unfamiliarity may not just exist on the patent applicant and companies who seek patent protection for their invention. It could also be doubtful for the patent offices and patent examiners to have qualified capacity and to be equipped to identify the origins with sufficient knowledge on the genetic resources and traditional knowledge.

As the paragraph about issues of identification of origins above, it could be doubtful for the patent office and patent examiners to determine the accurate origins of the invention. As the issues of origins are yet to be solved, the results and decision given by the patent examiners and patent office could be arguable by the patent applicant. Besides, the patent law requires the patent examiners to create virtual person skilled in arts to assess the inventive step, novelty and industrial application of the patent application and the resources and information on that term of technology do with the decision made by the patent examiners. It could be unreasonable and impossible for the patent examiners and patent office to possess all the traditional knowledge and genetic resources for thousands of years all over the world. According to the report of Queen Mary Intellectual Property Research Institute, it concluded that ultimately, the question of disclosure of origins will go into the question ‘what is traditional knowledge’ and the examiners had to determine possessors of the existing traditional knowledges. It also quoted the interviewee of SME’s words: “is an enquiry into 5000 years of local superstition required?”

In addition, the lack of database for genetic resource and traditional knowledge and information sharing also make the implement of disclosure of origins and determination of origins by the patent examiners and patent office difficult. The concept of benefit sharing, genetic resources and traditional knowledge was recognized in 1990s and the consensus in the international world was still developing. It causes the related system and mechanism of disclosure requirement of origins still has imperfections. The lack of lack of database for genetic resource and traditional knowledge and information sharing reflects to this subjective situation.

To sum up, in various perspectives, the efficacy of patent examiners on determining the issues of disclosure of origins is doubtful as the impossibility to have access to huge amount of traditional knowledge and genetic resources and the insufficient information which could be helpful for patent examiners on genetic resources and traditional knowledge.

### Suggestions and recommendations

At this stage, the following paragraph will give the suggestions and recommendations which could facilitate the efficacy and the rationality of the disclosure requirement of origins, no matter in legal perspectives or practical perspectives.

Databases which could record and share the information and data of genetic resource and traditional knowledge need to be recognized by countries and be established.

In order to facilitate the implement of disclosure requirement and solve the issues of identification of origins, it is necessary to establish a database by countries to share the data and information of genetic resources and traditional knowledge for the patent office or any other

related ABS authorities. With the help of the database and information sharing mechanism, the patent office and ABS relevant authorities could monitor and have access to the traditional knowledge to make decision on disclosure of origins while they were also required to record the information. In fact, it could be insufficient for this mechanism as it could be costly and impossible to record and identify all the genetic resources and traditional knowledge in the world. However, the database could provide factual references for the patent office and ABS relevant authorities to monitor the use of genetic resources and traditional knowledge and make decision on the disclosure of origins to the extent that could facilitate the efficacy and rationality of the decisions.

The International plant Exchange Network (IPEN) can be considered as an example of a sound system to play an important role in providing helps for users and authorities. Under the IPEN, no matter the material is pre-CBD or post-CBD, the users can have access to the origin and/or source of material and conditions relating to its use. The IPEN also has regulations on the material transfer, such as monitoring the use of the material by the unique IDEN number, new prior informed consent for further commercial use etc.

In addition, the database mechanism could also be considered as an implement of “checkpoint” which was risen and regulated by the Article 17 Nagoya Protocol. According to the article 17 of the Nagoya Protocol, parties have obligation to monitor and facilitate the utilization by setting up the checkpoints and they are stipulated as follow:

“(i) Designated checkpoints will collect or receive, as appropriate, relevant information related to prior informed consent, to the source of the genetic resource, to the establishment of mutually agreed terms, and/or to the utilization of genetic resources, as appropriate;

(ii) Each Party shall, as appropriate and depending on the particular characteristics of a designated checkpoint, require users of genetic resources to provide the information specified in the above paragraph at a designated checkpoint. Each Party shall take appropriate, effective and proportionate measures to address situations of non-compliance;

(iii) Such information, including from internationally recognized certificates of compliance where they are available, will, without prejudice to the protection of confidential information, be provided to relevant national authorities, to the Party providing prior informed consent and to the Access and Benefit-sharing Clearing-House, as appropriate;”

In other words, the parties of the Nagoya Protocol could set up the database to record and sharing the information of genetic resources and traditional knowledge and their utilization as a compliance to the Nagoya Protocol. In addition, this mechanism could also use the article 17 as a legal basis.

In fact, the proposal of the database mechanism is welcomed by most of the countries, even for the countries which have opposite position on the disclosure requirement of origins. The US who has arguments on the disclosure requirement of origins also suggested the establishment of database of documenting the knowledge, innovations and practices relevant for the conservation and sustainable use of biological diversity. The US states that the database could provide sources for licensing of genetic resources and traditional knowledge and further facilitate the implement of the objectives of the CBD. However, it could be fair to suggest that the database approach could not be the sole method to facilitate fair and equitable benefit sharing of the utilization of genetic resources and traditional knowledge as the US opposed the disclosure requirement of origins by providing an

alternative mechanism of database.

To sum up, the establishment of database especially the database set up by countries has fundamentally positive effects to the fair and equitable sharing and disclosure requirement of origins.

A clear definition on genetic resources and traditional knowledge need to be provided on the term of “bio-information” and gene sequence

In present, the ambitiousness of the definition of genetic resources and traditional knowledge creates the barriers for the benefit sharing and conservation of the genetic resources and traditional knowledge. Particularly, the absence of the concept of the “bio-information” within the definitions of the CBD and the Nagoya Protocol.

In fact, the Europe Union has recognized the importance of the “bio-information” and gene sequence. In Directive 98/44 on the legal protection of biotechnological inventions, the article 2 states that:

“1. For the purposes of this Directive, (a) ‘biological material’ means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system;

(b) ‘microbiological process’ means any process involving or performed upon or resulting in microbiological material.”

The definition given by the Directive 98/44 on the legal protection of biotechnological inventions covers the concept of genetic information is more reasonable and it can extend the scope of conservation and benefit sharing of genetic resources and traditional knowledge. The approach of the Europe Union can be considered to adopted by more countries or by the CBD itself. No matter in what ways, an internationally recognition on the definition of genetic resources which covers the genetic sequences and “bio-information” is necessary to conducted. Besides, there are “bio-information” and genetic sequences are still unknown to human being. In the perspective of conservation of biodiversity and genetic resources, the cooperation of countries on discovering the genetic sequences and related data and information sharing is necessary and significant.

In other words, in order to achieve the objectives of the CBD, preserving the biodiversity and facilitating the fair and equitable benefit sharing, it is necessary for the definition of genetic resources and biological material to cover the concept of genetic sequences and “bio-information”.

A recognition on the legal basis of disclosure requirement which are the article 27 and the article 29 of the TRIPS agreement need to be achieved by countries and the concerns on the legal basis of disclosure requirement could be solved

As the paragraphs above described, some concerns and the arguments were arisen on the legal basis of the disclosure requirement which were the article 27 and article 29 of the TRIPS agreement and such concerns need to be solved. It is necessary for countries to achieve a recognition on the legal basis of the disclosure requirement of origins. In fact, according to Doha 4th ministerial declaration, the countries have achieved an agreement on the objectives to review the relationship between the CBD and TRIPS agreement: “19. We instruct the Council for TRIPS, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this declaration, to examine, inter alia, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and

folklore, and other relevant new developments raised by members pursuant to Article 71.1. In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension." In addition, in paragraph 31, it also suggest to negotiate the relationship between WTO rules and multilateral environmental agreements without prejudice to the existing WTO rights of Members.

However, it could not be sufficient for countries to alter the TRIPS agreement and any other related WTO rules. In some developing countries who are for disclosure requirement, support to make modifications on the TRIPS agreement as some conflicts exist. For instance, The Africa Group, Brazil, China, etc., supports amending the Article 27(b). In present, there is insufficient evidence for countries to amend the TRIPS agreement as the amendment may produce huge change to the existing IP rights system. The article 27.3(b) or 29 of TRIPS is difficult to be amended in order to introduce the disclosure requirement of origins. Nevertheless, the countries could have an agreement on the Article 27 to allow the countries which need to introduce disclosure requirement of origins to interpret the Article 27(b) to the extent that could justify the implement of disclosure requirement. With the international cooperation and consistent recognition on the Article 27 of TRIPS agreement, the problem of conflicts between the CBD and TRIPS agreement can be solved.

As for Article 29 of the TRIPS agreement, similar consistent recognition can be made by countries as well. The problem of Article 29 is not as serious as that of Article 27 and it can achieve an agreement more uncomplicatedly.

In fact, according to the Report by Queen Mary Intellectual Property Research Institute, it suggests that the EC could make no comments on the compatibility of disclosure of origins by countries which have introduced them into patent law or any other ABS legislations or regulation and indicate the wiliness to adopt user measures to ensure the ABS regulations within Europe.

After all, the conflicts and ambiguousness exist between TRIPS agreement and the CBD and an agreement and consistent recognition can be made by countries to solve the problem of the concerns on the legal basis of disclosure requirement of origins.

Instructions and guidelines need to be provided by the ABS authorities and patent offices for companies and patent applicants

In order to solve the problem of the confusions and strangeness of the implement of disclosure requirement, the patent offices and ABS authorities and patent offices need to provide certain guidelines and instructions to companies and patent applicants.

Basically, the problems for the companies and patent applicant lies on the capacity of the patent office, confusion on the origins and confusion on related ABS legislations and regulations.

First, the concerns on the capacity of the patent office on examining the origins can be eased by the establishment of the database of traditional knowledge and genetic resources. The ABS authorities and patent offices can publish the instructions and guidelines of the procedure of using database to assess the document of disclosure of origins, which could ease the concerns.

Second, the patent offices and related authorities can provide instructions and guidelines to open an access for companies and patent applicant to the database to use certain information to identify the sources and origins of the material they used. With the help of

the database, not only the authorities and patent office can solve the problems of origins to some extent, but also the companies and patent applicants can use the resources on the database to meet the requirement of disclosure of origins. To be specific, the authorities and patent offices may grant the authorizations to the companies and patent applicants to an extent that could support them to figure out the origins and sources, without any other objectives.

Some countries such as Australia have established such system to help the companies and users to have access to information related to origins and ABS. The Australian national government's Genetic Resources information Database (GRID) is based on the Australia's virtual certificate of origin and provenance system which allows users or concerned parties to verify compliance with law and identify the statues and information of the material. With this method, the users and companies can find the legal certainty from the system without high cost and the positivity of compliance of ABS law and disclosure of origins can be facilitated.

Third, the confusion on the ABS legislations and disclosure requirements still can be eased by the detailed instructions and guidelines. The patent offices and authorities need to provide guidelines and instructions on the procedures of assessing the documents and the requirements of the documents, with the requirement of formality or substantive. The guidelines and instructions need to be detailed as the companies and patent applicants can have less difficulties and confusions on practicing the disclosure of origins. By providing the instructions and guidelines, the whole disclosure requirement will be clear for the companies and patent applicants and the potential risk of breaching or unfollowing the regulations and requirements.

## Conclusion

The disclosure requirement of origins is a mechanism for countries to facilitate the fair and equitable benefit sharing and monitor and trace the utilization of genetic resource and traditional knowledge. The disclosure requirement can be divided into three types base on the legal consequences and requirements: voluntary disclosure requirement, mandatory disclosure requirement and mandatory disclosure requirement with PIC, MAT and benefit sharing. The legal basis of the disclosure requirement is the article 27 and 29 of TRIPS agreement and the CBD/Nagoya protocol. Even if the disclosure requirement has positive effects on benefit sharing and facilitating the transparency of the patent application, the disclosure requirement has certain issues on legal terms and practical terms: the ambiguousness on the concept of genetic resources and traditional knowledge, the difficulties on identifying the origins of the genetic resources and traditional knowledge, argument on the legal basis of the disclosure requirement, concerns on the capacity of the patent office and the concerns by the companies and patent applicants in practical terms. Some recommendations were provided to solve the issues: introducing the concept of genetic sequences into concept of genetic resources, establishment of database, facilitating the cooperation and recognition on the legal basis, and instruction and guidelines for the companies and patent applicants.

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