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# **THE DOCTRINE OF DISCLOSURE OF ORIGIN OF REQUIREMENT**

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## **SCOPE AND LIMITATIONS:**

The scope of the study is limited to the analysis of the disclosure of origin of requirement, its evolution, journey and the critical appraisal of the doctrine in some countries.

## **HYPOTHESIS**

1. That the doctrine Of Disclosure of Origin of Requirement was not included (expressly or impliedly) at the time of incorporation of TRIPS and WTO
2. That the doctrine of Disclosure of Origin of Requirement is still prevalent in some group of developing countries and act as a limitation on patents rights

## **AIMS AND OBJECTIVES:**

The aim of the project is to present a detailed study of the topic i.e.,

1. To understand the doctrine of Disclosure of Origin of Requirement.
2. To understand the basic notions behind the origin of the doctrine
3. To understand the need of the doctrine and the reason why developing countries are supporting it
4. To highlight the present position of the doctrine of Disclosure of Origin of Requirement in different groups of countries
5. To critically analyse the doctrine of Disclosure of Origin of Requirement

## **RESEARCH PLAN:**

The researcher have followed Research Assignment. The Research is purely non- doctrinal. The various case studies, research paper, judicial pronouncement. The search would be based on the other research papers which cover various aspects

### **SOURCES OF DATA:**

The following secondary sources of data have been used in the project-

- Websites
- Case Laws
- Books

### **METHOD OF WRITING AND MODE OF CITATION:**

The method of writing followed in the course of this research project is primarily analytical. The researcher has followed Uniform method of citation throughout the course of this research project.

### **INTRODUCTION**

The annual market for products derived from genetic resources is between US\$500 billion and US\$800 billion<sup>1</sup>. This figure is based on statistics on the following industrial sectors which depend to a greater or lesser degree on biogenetic resources: pharmaceuticals, botanical medicines, agricultural produce (including agricultural seed), ornamental horticultural products, crop protection products, biotechnologies in fields other than healthcare and agriculture, and personal care and cosmetics products. It should be noted that while not all these are normally considered as being high technology industries as such, the largest and most profitable industries, such as pharmaceuticals and industrial biotechnology, tend to require participating firms to have advanced science and technology capacities.

From the early 1990s, conservation of biological diversity became a subject of heated debate, pitting the developing countries against developed countries, and indigenous peoples and their supporters against governments and big business. There are a number of explanations, all of which relate to the fact that as the world was becoming more biologically uniform, rapid advances in the applied life sciences, especially the new biotechnologies, led people to assume that undiscovered biogenetic resources in the developing world, which happened to be richly

endowed in them compared to the developed countries, had massive economic potential. Yet despite this, there was a huge disparity in the way the commercial benefits from industrial use of these resources were distributed, with the lion's share going to large corporations in the developed world. Resentment about this situation made developing countries resistant to pressure from the rich countries to conserve their biological diversity at their own expense for the enrichment, as they perceived it, of these corporations. It also directed attention to modern intellectual property (IP) law, especially patents and (albeit to a lesser extent) plant variety protection, in the skewed distribution of benefits arising from commercialisation of biogenetic resources.

Underlying the current debates on bioprospecting and bio piracy are sharp differences about which of three property-related regimes should apply to naturally occurring and human modified bio-chemicals and genetic materials, and how far these regimes are compatible with each other. These regimes are permanent sovereignty, the common heritage of mankind and intellectual property. The intensity of the debate over which regime should prevail can largely be explained by the size of the economic stakes involved. Unfortunately, it often appears to have much less to do with concerns that the health of the planet and the future of humanity might well depend on an effective stewardship of the world's biological wealth that is presently lacking

The disclosure of genetic resources and associated traditional knowledge (TK) in patent applications was originally mooted by civil society organisations, but has now been adopted by a number of countries. The proposal is intended to help realise fair and equitable benefit sharing as required by the Convention on Biological Diversity. It is supposed to do this by ensuring that the resources and, in some cases, TK, were acquired in accordance with biodiversity access and benefit sharing regulations in the provider countries, and other provisions of the Convention on Biological Diversity relating to national sovereignty, technology transfer and the knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles.

Disclosure of origin proposals take three basic forms, that will be termed 'weak', 'medium' and 'strong' (mandatory) disclosure – albeit while recognising that some proposals may not fit neatly into just one of these categories<sup>3</sup>. The weak form is that such disclosure would be encouraged or even expected but not required and its omission would not disqualify the patent from being granted. The medium form is that disclosure of origin would be obligatory. The

strong form goes beyond disclosure in the patent specification to require that patent applicants comply with national or regional access and benefit sharing regulations.

## **THERE IS A NEED FOR AN INTERNATIONAL SYSTEM OF MANDATORY DISCLOSURE OF ORIGIN**

### **REQUIREMENTS**

An international system of mandatory disclosure of origin requirements is needed to prevent misappropriation of genetic resources and associated traditional knowledge, to promote compliance with CBD access and benefit-sharing requirements, and to prevent misuse of the intellectual property system. As recognized by the Bonn Guidelines, disclosure of origin requirements for intellectual property applications are an important element of the CBD access and benefit-sharing regime, reflecting the interconnection of the CBD regime with the international intellectual property law system. Although national legislation imposing disclosure of origin requirements already exists in some countries, in many others where intellectual property may be sought such requirements have yet to be adopted. Thus new international treaty provisions are required to assure worldwide implementation of disclosure of origin requirements.

Objections raised to mandating adoption of disclosure of origin requirements through new international treaty provisions either do not stand up to analysis or do not outweigh the benefits to be obtained. Specifically, disclosure of origin requirements:

- a) May be useful in improving substantive examinations and in assuring the integrity of determinations under traditional intellectual property legal requirements, in providing greater certainty as to the validity of granted rights or privileges, and in reducing the need for revocation of improperly granted intellectual property;
- b) May assist in identifying situations and facilitating corrective actions where intellectual property is improperly granted, or where access to genetic resources and associated traditional knowledge has been obtained without concluding contracts establishing prior informed consent and equitable benefit-sharing;
- c) Are necessary to prevent misappropriation of commercial benefits that are improperly obtained as a consequence of applying for, owning or transferring intellectual property;

d) May help to make more coherent existing and future national laws regarding misappropriation that affect the validity of intellectual property or the entitlement to own or retain benefits from intellectual property; and

e) May reduce uncertainties of and make more transparent an international system of national access and benefit-sharing, and intellectual property laws.

Mandatory disclosure of origin requirements are needed, and may provide greater coherence to the international system. As noted by many developing countries, although mandatory disclosure of origin requirements exists pursuant to the national legislation of some countries, there are good reasons to adopt new international treaty provisions requiring mandatory disclosure of origin obligations. Without mandatory obligations, national disclosure of origin requirements may not be recognized and enforced by other countries in which intellectual property is applied for, and information provided pursuant to such requirements may not be employed to prevent improper issuance of intellectual property. On the other hand, mandatory disclosure of origin requirements will provide numerous benefits for both the CBD regime and the intellectual property law system, including greater coherence in recognition and enforcement of existing disclosure of origin obligations. In addition, mandatory requirements may: improve determinations of inventorship or other relationship to the subject matter, thereby assisting in the identification of persons involved who should participate in equitable benefit-sharing; facilitate abilities to use the subject matter of the intellectual property; promote compliance with access and benefit-sharing legislation; and help to track commercialization of intellectual property so as to promote more effective benefit sharing.

**Benefit Sharing and the Genesis of the Disclosure of Origin Proposal Discussion on disclosure of origin has taken place in a number of international fora, principally:**

- *The Council for TRIPS of the World Trade Organization*

- *The Convention on Biological Diversity,*

- *The World Intellectual Property Organization, including*

- ✓ *The Intergovernmental Committee on Intellectual Property and Genetic Resources,*

- ✓ *Traditional Knowledge and Folklore (IGC)*

✓ *The Standing Committee on the Law of Patents (SCP)*

✓ *The Working Group on Reform of the Patent Cooperation Treaty.*

A precipitant of the debate on disclosure of origin has been the concern of developing countries to protect local traditional knowledge systems and informal innovations from unauthorised appropriation. The Convention on Biological Diversity (CBD), represented an attempt to provide among other things, for the "fair and equitable sharing" of the benefits arising from the utilisation of genetic resources. "Genetic resources" are defined in Art.2 as meaning "genetic material of actual or potential value". The term "genetic material" is then defined in Art.2 to mean "any material of plant, animal, microbiological or other origin containing functional units of heredity". Thus the Convention would apply to seeds and cuttings and DNA extracted from a plant, such as a chromosome, gene, plasmid or any part of these such as the promoter part of a gene.

Article 15(4) of the CBD envisages that where access is granted it will be subject to mutually agreed terms. Currently the conventional form of access agreement is the Material Transfer Agreement (MTA)<sup>9</sup>. A number of the provisions of the CBD refer to the equitable sharing of benefits arising from the utilisation of the genetic resources of a signatory. Article 15(7) requires each Contracting Party to subject to mutually agreed terms. and in accordance with a number of specified provisions of the Convention, "with the aim of sharing in a fair and equitable way, the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources". Article 8(j) envisaged the "equitable sharing" of benefits with indigenous and local communities, arising out of the use of the traditional knowledge, innovations and practices of those communities. Article 21 provides for the establishment of a "mechanism" for the provision of financial resources to developing country parties to the CBD. A problem with the various benefit-sharing options under the CBD, was that the USA, as the primary place of exploitation of genetic resources has not ratified that convention. As a consequence, various meetings of the Conference of the Parties (COP) have preferred contractual solutions as the most feasible option. Alternative fora were sought in which the benefit-sharing issue could be raised. Perceived as the most useful possibility, was the Council for TRIPS, since the USA was a signatory of the TRIPS Agreement and indeed, was its architect. The opportunity for raising CBD benefit sharing issues arose in the context of the agenda built in to Article 27.3(b) of the

TRIPS Agreement to consider sui generis proposals for the protection of plant variety rights within four years of the commencement of the TRIPS Agreement (ie by the end of 1999). A number of communications from developing country states to the TRIPS Council proposed that the Seattle Ministerial, scheduled for November 1999, should consider this issue.

### **DISCLOSURE OF ORIGIN WITHIN WIPO**

Following the failure of the Seattle Ministerial, agitation for the inclusion of traditional knowledge within the international intellectual property regime, shifted to WIPO. In a Note, dated September 14, 2000, the Permanent Mission of the Dominican Republic to the United Nations in Geneva submitted two documents on behalf of the Group of Countries of Latin America and the Caribbean (GRULAC) as part of the debate on in the WIPO General Assembly on “Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore<sup>10</sup>.” The central thrust of these documents was a request for the creation of a Standing Committee on access to the genetic resources and traditional knowledge of local and indigenous communities. “The work of that Standing Committee would have to be directed towards defining internationally recognized practical methods of securing adequate protection for the intellectual property rights in traditional knowledge” Another WIPO forum was its Standing Committee on Patents, which at the end of 1999 was considering a proposed Patent Law Treaty (PLT) which would harmonise patent office procedures. At its September 6 to 14, 1999 session, the delegation of Colombia proposed the introduction into the PLT an article which provided that

a) All industrial protection shall guarantee the protection of the country’s biological and genetic heritage. Consequently, the grant of patents or registrations that relate to elements of that heritage shall be subject to their having been acquired made legally.

b) Every document shall specify the registration number of the contract affording access to genetic resources and a copy thereof whereby the products or processes for which protection is sought have been manufactured or developed from genetic resources, or products thereof, of which one of the member countries is the country of origin. This proposal generated a heated debate about whether, in the first instance, it raised a matter of procedural or substantive patent law. Agreement was eventually reached to defer consideration of this proposal to the occasion of the discussion of a proposed Substantive Patent Law Treaty (SPLT). These discussions commenced in 2003. The current draft text of the SPLT<sup>13</sup> provides:

[2(2)] *Nothing in this Treaty and the Regulations shall limit the freedom of a Contracting Party to ... comply with international obligations, including those relating to the protection of genetic resources, biological diversities, traditional knowledge and the environment.* [13 (4) and 14(3)] *A Contracting Party may also require compliance with the applicable law on ... environment, access to genetic resources, protection of traditional knowledge...*The USA Japan and the European Patent Office submitted a joint proposal to the tenth

session of the SCP, which took place between May 10 and 14, 2004, designed to limit the draft SPLT to the provisions relating to the definition of prior art, the grace period, novelty and inventive step. This proposal was supported by the industrialized group of countries. A number of developing countries insisted on the discussion of disclosure of the origin of genetic resources and traditional knowledge, public health, patentability criteria and the general exceptions. In view of this lack of consensus the SCP proposed that this issue be returned to the WIPO General Assembly.

Another forum within WIPO in which the disclosure of origin has been discussed has been the Working Group on Reform of the Patent Cooperation Treaty (PCT), which is an international treaty administered by WIPO, which provides for the simultaneous submission of patent applications to a number of countries. Switzerland proposed an amendment of the Regulations under the PCT to explicitly enable Contracting Parties to require patent applicants to declare the source of genetic resources and traditional knowledge, if an invention is directly based on such resources or knowledge. The Swiss proposal required patent applicants either when the international application was made, or when the international application was forwarded to the countries designated by the applicant, to declare the source of genetic resources and/or traditional knowledge, if an invention is directly based on such resource or knowledge. The Swiss proposal would also require amendment to the PLT, under which the Contracting Parties of the PLT would be able to require in their national patent laws that patent applicants declare the source of genetic resources and/or traditional knowledge in national patent applications. It would also be envisaged that under national law the validity of granted patents would be affected by a lacking or incorrect declaration of the source, if this was due to fraudulent intention.

## **DISCLOSURE OF ORIGIN WITHIN THE TRIPS COUNCIL**



The Doha Ministerial declaration of November 2001<sup>14</sup> instructed the Council for TRIPS, in pursuing its work programme, particularly in relation to its review of Article 27.3(b), “to examine, inter alia, the relationship between the TRIPS Agreement and the [CBD], the protection of traditional knowledge and folklore, and other relevant new developments” raised by members pursuant to the general review of the TRIPS Agreement. Summarizing proposals made within the WTO TRIPS Council up to August 2002, the WTO Secretariat observed:

It has been suggested that the TRIPS Agreement should be amended so as to require, or to enable, WTO Members to require that patent applicants disclose, as a condition to patentability:

- a) the source of any genetic material used in a claimed invention;
- b) any related traditional knowledge used in the invention;
- c) evidence of prior informed consent from the competent authority in the country of origin of the genetic material; and d) evidence of fair and equitable benefit sharing.<sup>37</sup> It has been suggested that such provisions could be incorporated into the TRIPS Agreement by amending Article 27.3(b) or Article 29.

The WTO Secretariat noted that in response, the view has been expressed that these provisions were not suitable for implementing the prior informed consent and benefit-sharing provisions of the CBD, since “intellectual property rights do not aim to regulate the access and use of genetic resources, to regulate the terms and conditions for bio-prospecting or the commercialization of IPR-protected goods and services.” This was best done through contracts between the authorities competent for granting access to genetic resources and any related traditional knowledge and those wishing to make use of such resources and knowledge.

### **DISCLOSURE OF ORIGIN WITHIN THE CBD COP**

Paralleling the work at WIPO and in the TRIPS Council a number of the decisions of the COP addressed the relationship between intellectual property rights and the CBD. Decision III/17 on Intellectual Property Rights called for case studies to be developed on the impacts of IPRs on achieving the CBD objectives, including the relationship between IPRs and traditional knowledge relevant for the conservation and sustainable use of biological diversity. The Decision also called for further work to develop a common appreciation of the relationship between IPRs, the TRIPS Agreement, and the CBD.

At COP-6, Decision VI/24 on Access and Benefit Sharing as Related to Genetic Resources was adopted. This Decision included the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization. In paragraph 16(d) of the Guidelines, Parties were property rights urged to take “measures to encourage the disclosure of the country of origin of the genetic resources and of the origin of traditional knowledge, innovations and practices of indigenous and local communities in applications for intellectual.”<sup>16</sup>The Decision also listed a number of issues for further examination, including the:

- a) Consistency and applicability of requirements for disclosure of country of origin and prior informed consent in the context of international legal obligations;
- b) Efficacy of country of origin and prior informed consent disclosures in assisting the examination of intellectual property rights applications and the re-examination of intellectual property rights granted;
- c) Efficacy of country of origin and prior informed consent disclosures in monitoring compliance with access provisions;
- d) Feasibility of an internationally recognised certificate of origin system as evidence of prior informed consent and mutually agreed terms. WIPO was requested to prepare a technical study on methods within the patent system for requiring disclosure relevant to genetic resources and traditional knowledge, and to report its findings to COP VII<sup>17</sup>. Following this request, a draft Study was prepared by WIPO, based on responses to a questionnaire circulated to the Member States of WIPO<sup>18</sup>. In September 2003 a Technical Study on Disclosure Requirements Concerning Genetic Resources and Traditional Knowledge was transmitted to the COP for consideration at its seventh meeting.

*At COP VII WIPO was requested to examine:*

- a) Options for model provisions on proposed disclosure requirements;
- b) Practical options for intellectual property rights application procedures with regard to the triggers of disclosure requirements;
- c) Options for incentive measures for applicants;

d) Identification of the implications for the functioning of disclosure requirements in various WIPO-administered treaties;

e) Intellectual property-related issues raised by a proposed international certificate of origin/source/legal provenance.

*The WIPO General Assembly in July 2004 decided upon a positive response to this invitation and established a timetable for its response, involving five steps: a) an invitation by WIPO Member States to submit comments and proposals, by December 15, 2004;*

*b) preparation of a draft examination and its circulation for comments;*

*c) observations and comments on the draft to be submitted by Member States and accredited observers by the end of March 2005;*

*d) publication on the website and in a consolidated document of all comments and observations received;*

*e) convening of a one-day ad hoc intergovernmental meeting to consider and discuss a revised version of the draft which would be available at least 15 days before the Meeting;*

*f) Preparation of a further revised draft to be presented to the WIPO General Assembly at its ordinary session in September 2005 for consideration and decision.*

In line with the first step, WIPO Member States were invited to submit proposals and suggestions prior to the agreed deadline of December 15, 2004. The draft examination has now been prepared and circulated for comment and an ad hoc Intergovernmental meeting was convened for June 3, 2005 to consider a revised draft of this document.

## **SUGGESTION**

*✓ Intellectual property issues raised by international certificates of origin.*

International certificates of origin were conceived of in the context of registering genetic resources and traditional knowledge and tracking their transboundary flows. As understood here, international certificates of origin are documents issued by entities competent to certify that the source of genetic resources and associated traditional knowledge has the authority to provide access on specified conditions, and also to certify the existence of *ex ante*

*benefitsharing requirements* that are compliant with the CBD and with relevant laws and equitable principles of the country providing such resources or knowledge.<sup>54</sup> International certificates of origin thus provide documentation of the legal provenance for the recipient to use the genetic resources and associated traditional knowledge under the identified conditions of access and benefit-sharing. As a result, international certificates of origin may provide highly relevant information regarding the types of disclosures of origin that may be required of intellectual property applicants. Numerous issues are raised by mandatory or facultative disclosures of origin in intellectual property applications using international certificates of origin. These certificates may assist applicants to make required disclosures of origin regarding compliance with access and benefit-sharing requirements of the country providing genetic resources and associated traditional knowledge. The value of the certificates of origin in this context will depend on the types of information contained in them and how they would be verified and tracked to ensure the integrity of their continuing application to the genetic resources and associated traditional knowledge that are relevant to the application for intellectual property. As with other disclosures of origin, use of certificates of origin could impose significant burdens of analysis, investigation and evaluation on applicants, certification entities and intellectual property offices, particularly if it is necessary to track *ex-post* compliance with benefitsharing requirements identified in those certificates. These considerations, however, do not differ significantly from the discussions provided above regarding substantive and procedural triggers, and thus are not repeated below. Instead, the analysis focuses on how certificates of origin may relate to existing intellectual property law requirements, and identifies additional intellectual property law issues (in the context of trademark and unfair competition law) that are raised by such certificates.

✓ ***Subject matter of the certification and the certification standard***

Certificates of origin not only may help to track flows of genetic resources and associated traditional knowledge, they also provide a certification of authority to provide access to the relevant genetic resources and associated traditional knowledge on specified conditions of use and *ex ante benefit-sharing*. Thus, these certificates may require applicants and certification entities to evaluate the genetic resources and associated traditional knowledge used at very early stages of developing the subject matter of intellectual property applications, or that are used as necessary background information for such development. To ensure the integrity and relevance of certificates of origin, certification entities also must verify that the

uses to which genetic resources and associated traditional knowledge have been put conform to the authorized conditions.<sup>56</sup>The certification standard must therefore address the level of confidence required for various determinations before certificates of origin can be issued

Certifying authorized access and equitable benefit-sharing may require extremely complex evaluations. For example, certification may require determinations of how the source acquired the resources under the national laws of multiple jurisdictions, and potentially may require determinations of international legal claims of sovereignty over genetic resources made by different countries. Certificates of origin also may certify additional information relevant to determinations of authorized access and equitable benefit-sharing, thereby facilitating additional disclosures of origin in intellectual property applications. For example, certification entities may perform, or may require certificate applicants to conduct, investigations to identify countries of origin and persons involved. Careful consideration should therefore be given to the types of information to be certified, the levels of investigatory effort and of confidence required by the certification standard with respect to such information, and the burdens and costs of providing certifications. As with disclosures of origin, the nature of the certifications relating to intellectual property applications should depend on the types of evaluations to be performed and the eventual uses for the certificates of origin.

Consideration should also be given to the consequences of certification errors by competent entities, and to misuse of certificates by persons to whom they were issued. For example, where an applicant for intellectual property obtained a certificate of origin based on false representations to the certifying body, that applicant might (depending on the laws and equitable principles involved) lose the right to apply for or own the intellectual property, might be found to have engaged in inequitable conduct that would render the intellectual property invalid or unenforceable, or might be required to transfer ownership or any commercial benefits that have been or will be obtained.

#### *✓ Ex-ante verification and ex-post tracking of certifications*

Some observers have noted the complexities involved in verifying that certificates of origin correspond to the genetic resources being certified, initially and later, particularly with respect to derivative genetic materials.<sup>58</sup>These concerns have particular relevance for certificates of origin relied upon to document compliance with access and benefit-sharing requirements when

applying for intellectual property. Certificates of origin thus may need to provide traceability of the genetic resources and associated traditional knowledge in question from the source providing such inputs, through and including development of the subject matter of the intellectual property application and any granted rights and privileges. Without such traceability, it may be difficult to determine whether disclosures of certificates of origin are required, and to verify that the certifications correspond to the subject matter of the application in the relevant ways disclosed.

To ensure the integrity of authorized access and equitable benefit-sharing under specified conditions of use, it may be necessary to trace genetic resources and associated traditional knowledge not only from the source to the subject matter of and applicant for the relevant intellectual property, but also to additional uses to which such resources and knowledge may be put (and for which intellectual property applications may not necessarily be sought). For example, genetic resources may lead to the development of subject matter by the applicant, which in turn may lead to the development of additional subject matter by other persons or entities who are not subject to contractual provisions for equitable benefit-sharing.

Alternatively, the applicant may use genetic resources not only to develop the subject matter of the application for intellectual property, but also additional subject matter for which intellectual property applications have not been filed (e.g. trade secrets), and which provides unjustified and inequitable commercial benefits.

Consideration also should be given to how international certificates of origin relate to the actual *ex-post* provision of equitable benefit-sharing based on certification of *ex-ante* arrangements for such benefit-sharing. This is particularly relevant in the context of intellectual property applications, as the premise of such applications is the granting of exclusive rights or privileges that may subsequently result in commercial benefits. Tracing certificates of origin to subsequent conduct, however, may entail substantial levels of effort, administrative burdens and costs.

#### ✓ *Authority to certify*

As noted by others, prior informed consent and mutually agreed terms for access and benefit-sharing may involve, among other things, “research permits, collecting permits, export, and import permits. In most countries, different offices, even different Ministries, have the responsibilities for some or all of these permissions. Research on lands managed by local and

indigenous communities or on their biodiversity knowledge can require additional agreements (not formal permits, per se).” Accordingly, obtaining certificates of origin may require interacting with different levels of government and with multiple agencies or ministries within each level of government. Certificates of origin may need to differentiate between the types of certifications provided (and the entities authorized to provide them), based on when genetic resources and associated traditional knowledge were acquired. For example, it has been proposed to distinguish between access obtained before the CBD (and its recognition of sovereign rights over genetic resources) and access obtained

before and after adoption of CBD access and benefit-sharing legislation in the country providing genetic resources.<sup>61</sup> This is particularly relevant in regard to ex-situ collections and materials provided under the multilateral facilitated access system of the ITPGRFA. <sup>62</sup> Additional consideration is needed of how certificates of origin would assist disclosures of origin and demonstrations of compliance with access and benefit sharing requirements in such situations. Particularly, given the complexities of determining certification authority and of making appropriate certifications, careful consideration should be given to whether to impose mandatory or facultative requirements to obtain and to disclose certificates of origin in order to meet disclosure of origin obligations. Such evaluations will depend in part on the robustness and comprehensiveness of the certificate of origin system and on the degree to which certificates of origin generate the types of information required to be submitted by mandatory disclosure of origin obligations and how useful they are for evaluations within or relevant to the intellectual property law system

## **CONCLUSION**

In summary, there is a need for new international treaty provisions that would mandate disclosures of origin requirements in applications for intellectual property. The most appropriate treaty regime to adopt such requirements is the TRIPS Agreement. Numerous benefits would derive from disclosure of origin requirements, although care should be taken to minimize the administrative costs and burdens of implementation. The treaty provisions will need to specify the substantive and procedural triggers for making required disclosures, the types and timing of evaluations to be performed with disclosed information, the mandatory or facultative consequences of various types of disclosure failures, and whether to mandate or facilitate the use of international certificates of origin in making required disclosures. Although disclosure of origin requirements are consistent with existing intellectual property treaties, such

requirements may be facilitated by revising existing rules, forms and procedures implementing those treaties. Additional research and evaluation relating to the following issues would help to inform policy choices regarding the contents of mandatory disclosure of origin requirements:

*✓ Existing national laws addressing the relationship between misappropriation of genetic resources or traditional knowledge, and their effect on the validity of or entitlement to own or retain benefits from intellectual property; and*

*✓ Applicable legal principles for the recognition and enforcement of existing national access and benefit-sharing laws and contractual provisions that impose disclosure of origin requirements, and their relation to intellectual property laws..*