Disclosure of Origin

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Abstract

This Briefing Paper provides an overview of disclosure of origin. It begins with discussion of the history, nature and scope, of disclosure proposals. It then considers whether disclosure requirements are substantive or procedural in nature. The Paper goes on to examine disclosure systems in national and regional laws and the role of certificates of compliance in the development of an international disclosure of origin regime. Finally, it considers some of the implications of disclosure of origin systems for CGIAR Centres and other ex-situ collections.

Introduction

Disclosure of origin is a collective term or concept referring to requirements to disclose, in intellectual property applications, the origin/source of genetic material and/or traditional knowledge, evidence of prior informed consent for access to them and evidence of fair and equitable benefit sharing for their use. The concept first emerged in 1994 in, independently developed proposals by Danish and Peruvian researchers. The Danish proposal suggested applicants for intellectual property rights be required to identify the origin of genetic material, the extent of its use and the conditions under which it was acquired.[1] The Peruvian proposal called for mandatory disclosure in intellectual property applications of the origin of genetic resources and traditional knowledge and evidence of prior informed consent for their use. It also proposed the establishment of an international system for certifying the origin of resources and traditional knowledge and of compliance with prior informed consent for their use.
[2]

Broadly stated, disclosure of origin requirements shift the burden of proof regarding the right to use genetic resources and traditional knowledge from the provider to the user [3] in order to reduce possibilities for misappropriation and minimize the granting of invalid intellectual property rights.[4] More specifically disclosure of origin requirements are intended to help:

- identify the existence of prior art;
- enable reproduction of the protected invention;
- facilitate the monitoring of the use of genetic resources by source countries;
- prevent the illegal and/or unauthorised use of genetic resources;
- prevent the grant of 'bad' patents or plant variety rights;
- promote equitable benefit sharing;
- Provide recognition for the source of traditional knowledge; and
- place the relevant information in the public domain (this may be problematic where sensitive or secret traditional knowledge is involved).

Disclosure requirements have been adopted in at least 19 countries, and up to 50 countries have adopted some form of regulation requiring evidence of the origin, prior informed consent and/or mutually agreed terms, as a condition for access to and/or use of genetic resources and traditional knowledge.[5]

There is, however, no concrete, harmonized approach to disclosure of origin and many questions about the nature and scope of disclosure regimes, as well as the consequences of non-compliance, remain. This includes questions as to whether disclosure should be voluntary or mandatory and whether disclosure requirements may have substantive effect or not.

[1] Hendrykx, F.,Koester,V. and Prip,C. (1994) 'Access to Genetic Resources: A Legal Analysis', in V. Sanchez and C. Juma (eds), Biodiplomacy: Genetic Resources and International Relations, ACTS Press, Nairobi, 148

[2] Tobin, B. (1994) 'Alternativas a las Legislaciones de Propiedad Intelectual, Reunion Regional Sobre Propiedad Intelectual y Pueblos Indigenas', PNUD/COICA Santa Cruz: Bolivia, 28–30 September. 9. Available at https://www.academia.edu/1315002/

[3] Tobin, B., (1997) 'Certificates of Origin: A Role for IPR Regimes in Securing Prior Informed Consent', in Mugabe et al. (eds.) Access to Genetic Resources, ACTS, Nairobi

[4] Sarnoff, J. and C. Correa (2004) 'Analysis of options for implementing disclosure of origin requirements in intellectual property applications' , UNCTAD

[5] Vivas, D (2012) Bridging the Gap on Intellectual Property and Genetic Resources in WIPO's Intergovernmental Committee (IGC), Issue Paper No. 34, (Geneva: ICTSD, 2012),31

Are disclosure requirements substantive or procedural?

A key aspect of the debate is whether disclosure amounts to a requirement for grant of an intellectual property right (similar to novelty or non-obviousness in patent law) or is a procedural requirement that needs to be complied with? Substantive requirements are those which must be met in order to obtain a grant of a patent or plant breeders' right or other intellectual property right. Countries that are members of the World Trade Organization ('WTO') and/or the International Union for the Protection of New Varieties of Plants ('UPOV') may be constrained in their ability to make some disclosure of origin requirements a substantive requirement for patent or plant variety rights respectively. Article 27.1 of the WTO Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), for example, requires that patents "… be available for any inventions … provided they are new, involve an inventive step, and are capable of industrial application". For some, this means that requirements with substantive effect would breach TRIPS [6]. However, formalities may entail substantive legal consequences [7] and no formal challenge has yet been made to disclosure regimes with substantive effect on patent grants.[8]

The UPOV Convention (1991) sets out the conditions of grant for a new plant variety as new, distinct, uniform and stable. Article 5(2) states:

> The grant of the breeder's right shall not be subject to any further or different conditions, provided that … the applicant complies with the formalities provided for by the law of the Contracting Party with whose authority the application has been filed...

This makes it clear that it is legally possible to establish disclosure of origin as a formal requirement for processing applications for plant breeders' rights.[9] The UPOV Secretariat has expressed its opposition to disclosure requirements with substantive effect in Peru's law implementing UPOV. The law remains, however, unmodified and has not been formally challenged.[10]

In contrast to substantive conditions, procedural requirements are those that do not go to the issue of granting patents or plant variety rights; rather disclosure is a condition that must be met to enable an application to be processed. This is similar to the requirement of naming inventors and plant breeders. Fraudulent or incomplete compliance with procedural requirements may result in severe penalties including the cancellation of intellectual rights and criminal sanctions. Patent applications must, for example, identify inventors and incorrect or incomplete indication including the transfer or invalidation of the patent right.[11] Furthermore, many jurisdictions have obligations to disclose known prior art. Under the Patent Cooperation Treaty the requirement is to include, "... the background art which, as far as known to the applicant, can be regarded as useful for the understanding, searching and examination of the invention, and preferably cite the documents reflecting such art."[12] A study carried out for the Spanish Patent and Trademark Office concluded that a requirement for disclosure of origin would simply regularize current practice relating to the filing of patent applications.[13]

Disclosure of the origin of traditional knowledge, as opposed to disclosure of the relevant traditional knowledge itself, may not necessarily be required to carry out an invention. However, obligations in existing intellectual property regimes to identify the inventor may require disclosure of sources of traditional knowledge where that knowledge amounts to what the World Intellectual Property Organization (WIPO), Initial Study on Disclosure Requirements related to Genetic Resources and Traditional Knowledge has identified as 'inventive contributions'.[14] Where traditional knowledge (known to the applicant) is so close to the claimed invention that it is in fact intrinsic to it under the legal doctrine that determines 'inventive contribution' in the jurisdiction concerned, then it may be necessary to declare the provider of the traditional knowledge as a joint inventor. Existing requirements to disclose prior art would in many cases require disclosure of relevant traditional knowledge in a patent application.

Disclosing traditional knowledge in intellectual property applications is a double-edged sword. On the one hand, disclosure may help to identify the use of tradition. On the other hand, disclosure may result in traditional knowledge being placed in the public domain for the first time, with potential implications for Indigenous peoples' opportunities to control and protect their knowledge from unapproved use.

[6] Carvalho, N (2005) From the Shaman's Hut to the Patent Office: In Search of a TRIPS-Consistent Requirement to Disclose the Origin of Genetic Resources and Prior Informed Consent, 17 *Journal of Law & Policy*, 111- 186, 125

[7] WIPO Technical Study on Disclosure Requirements in Patent Systems Related to Genetic Resources and Traditional Knowledge, WIPO/GRTKF/IWG/3/14, 22

[8] See Sarnoff and Correa (2004) for discussion of the status of substantive requirements in disclosure regimes.

[9] Cabrera J., (2010) The Disclosure Requirement in Central America: Legal Texts, Practical Experience and Implementation Challenges ICTSD, Geneva, 5

[10] Ruiz M. (2010) Disclosure of Origin and Legal Provenance: The Experience and Implementation Process in South America, ICTSD, Geneva

[11] WIPO/GRTKF/IC/4/11, para 33

[12] Rule 5.1(a)(ii)

[13] Sukhwani, A. (2001) Patents Using Biological Source Material, Spanish Patent and Trademark Office, Madrid UNEP/CBD/COP/3/22, para 51

[14] WIPO/GRTKF/IC/4/11, para 52

National and regional legislation requiring disclosure of origin and/or legal provenance

The adoption of disclosure requirements in national intellectual property legislation has been encouraged by the Conference of the Parties to the Convention on Biological Diversity.[15] Countries with disclosure requirements include Belgium, Bolivia, China, Colombia, Costa Rica, Denmark, Ecuador, Egypt, Germany, India, Italy, New Zealand, Norway, Panama, Peru, Romania, South Africa, Sweden, Switzerland and Venezuela.[16]

Peru was the first country to establish a disclosure of origin system. Supreme Decree 008-96-ITINCI of 1996 requires applicants for plant breeders' rights to include information on the geographical origin of biological material which constitutes the raw material of the new variety and evidence, issued by the competent national authority where relevant, of the legal provenance of genetic resources. Failure to provide the required information may lead to suspension of the application. Costa Rica's Biodiversity law (1998) conditions the grant of intellectual property, including plant breeders' rights and patents, on evidence of prior informed consent in the form of a certificate of origin issued by the Technical Office of the National Biodiversity Commission. India's National Biodiversity Act (2002) prohibits applications for patents anywhere in the world "… for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of the National Biodiversity Authority".[17]

Among developed countries, Denmark and Norway have adopted mandatory disclosure requirements for patent applications with penal sanctions for failures to comply. In New Zealand under the Patents Act 1953, the Commissioner of Patents may refuse a patent application where the use of the invention is contrary to morality. Although there is no obligation in the Act to provide evidence of prior informed consent from Maori, as a condition for using traditional knowledge or indigenous flora or fauna, it is a matter of internal office procedure. In an application to use oil extracted from kiwi (an endemic, flightless bird and national icon) to manufacture insect repellent, the application was ultimately amended to delete all reference to kiwi from the patent specification.[18] (See Annex for more detail of existing disclosure measures.)

The potential costs of failing to comply with relevant national legislation relating to access to genetic resources and traditional knowledge can be very high. In Brazil, fines in excess of US$59 million have been imposed since 2010 for failure to pay fair compensation for the use of genetic material native to Brazil.[19] Revocation of patents is also possible in a growing number of jurisdictions.

A range of voluntary and binding disclosure requirements have been adopted at the regional level. Andean Community Decisions 391 and 486[20] require users of genetic resources and traditional knowledge to provide evidence of prior informed consent for use of the genetic resources and traditional knowledge from the region in patent applications. Failure to do so can impede the processing of applications and can lead to patents being annulled.[21]

The Organization of African Unity, Model Law outlines a system that makes access to genetic resources dependent upon an undertaking not to apply for intellectual property protection over biological resources or derivatives thereof, and not to apply for intellectual property rights over community innovation, practice or knowledge without the prior informed consent of the original providers.[22]

The European Union has adopted purely voluntary measures. Recital 27 of Directive 98/44/EC on the Legal Protection of Biotechnological Inventions promotes the disclosure of information on the geographical origin of biological material of plant or animal origin used in the development of an invention the subject of a patent application. Recital 27 states that requirements for disclosure in Member State legislation should not affect the "…processing of patent applications or the validity of rights arising from granted patents". The Decision makes no reference to traditional knowledge. In 2013, the European Parliament adopted a resolution calling for adoption of binding disclosure requirements at the international level.[23]

Proposals for mandatory international disclosure requirements have been supported by a majority of countries at the WTO and disclosure is a central component of negotiations for the development of new international instruments on genetic resources and traditional knowledge at the WIPO, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). Free Trade agreements, such as the US-Peru FTA that weaken national and regional disclosure regimes[24], threaten to undermine efforts to develop a binding international disclosure of origin regime.

[15] Convention on Biological Diversity, Decision VI/24
[16] see generally Vivas D. (2012)
[17] National Biodiversity Act 2002, Article 6
[18] New Zealand response to WIPO survey on disclosure requirements, see WIPO/GRTKF/IC/4/11, para 64
[19] Vivas (2012), 36
[20] Third Complementary Provision and Article 26, respectively.
[21] Andean community Decision 486, Article 75
[22] OAU, African Model Legislation for the Protection of the rights of Local communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources, 2000
[23] European Parliament Resolution of January 15, 2013 on development aspects of intellectual property rights on genetic resources (2012/2135(INI)).
[24] Cabrera (2010)

Certificates of compliance and an international disclosure system

One of the principal ways for demonstrating compliance with disclosure requirements is through the development of a standardized certification system. The purpose of certificates of compliance is to facilitate monitoring of compliance by relevant bodies (e.g. patent authorities) whether in the state where resources or knowledge are collected or in another state where research is conducted. [25] Currently, standardized certification is provided for in national compliance measures in Australia, Costa Rica, Fiji, and Panama.

A global standardized certification of compliance system is at the heart of the binding access and benefit-sharing regime established by the Nagoya Protocol, which entered into force on October 12, 2014. This regime anticipates the adoption of a number of checkpoints at which certificates of compliance would be reviewed as a means to monitor and ensure compliance with relevant national and international law.

With the framework for a global certification system now in place it becomes more likely that an international disclosure system may be adopted in the not too distant future. A number of countries led by the United States of America and Japan remain strongly opposed to the adoption of any binding global disclosure regime. Despite this opposition the issue of disclosure requirements remains at the centre of negotiations of draft instruments on genetic resources and traditional knowledge at the WIPO IGC. Draft provisions under discussion at the IGC, in early 2016, include proposals for requirements to disclose: (a) the country of origin or, if unknown, source of genetic resources and or traditional knowledge associated with genetic resources; and (b) relevant information regarding compliance with access requirements including prior informed consent, in particular, from Indigenous peoples and local communities [26] Draft IGC text limits patent offices' obligations to verify the contents of disclosure[27] and proposes amendment of the Patent Cooperation and Patent Law Treaties to recognise the rights of States to adopt mandatory disclosure regimes[28],

Differences in the ongoing IGC negotiations show that, even among those countries supporting the adoption of a binding regime, there is significant divergence over the nature and scope of disclosure requirements and of any remedies for the breach of disclosure obligations.

[25] Tobin, B., G. Burton, & J.C. Fernandez-Ugalde (2008) Certificates of Confusion or of Clarity, The search for a practical, feasible and cost effective system for certifying compliance with PIC and MAT, UNU-IAS, Tokyo

[26] WIPO/GRTKF/IC/29/4, Article 3

[27] WIPO/GRTKF/IC/29/4, Article 3.2

[28] WIPO/GRTKF/IC/29/4, Article 5

Relevance of disclosure of origin requirements for CGIAR Centers

Disclosure of origin is very relevant to the work of the CGIAR Centers. For example, at least five mega-diverse countries, which are also important centres of crop diversity, have adopted disclosure of origin systems, which may affect day-to-day activities of the Centers. Centers will need to examine any extra implications for their activities where they are located in countries with disclosure of origin or where they are exporting material into countries with disclosure requirements.

Proposals have been made to include disclosure requirements in areas other than intellectual property applications, such as product approvals, the making of grants for research and development and the publication of journal articles. Obligations to disclose the origin of genetic resources and traditional knowledge may in the future also be required by seed laws, laws regulating the development and dissemination or sale of genetically modified organisms, development of synthetic copies of naturally occurring chemical compounds, etcetera. Where the CGIAR Centers are directly or indirectly involved in any such activity they will need to be aware of and comply with disclosure requirements in relevant national, regional and international legislation.

With legislation ranging from weak voluntary requirements to binding obligations, including penal sanctions and or sanctions in intellectual property law or civil law, CGIAR Centers will need to develop and continually revise guidelines on disclosure requirements under national, regional and international law. Adopting standardized approaches to the collection, documentation, management and transfer, of genetic resources and traditional knowledge, will increase the value of the Centers' collections by ensuring their capacity to provide access to genetic material and traditional knowledge which meet requirements on disclosure of origin, prior informed consent and mutually agreed terms.

The extent of the CGIAR Centers' obligations will depend upon the use being made of the material provided. Where used solely for research purposes not involving intellectual property applications the level of passport data to be provided will be low. Where there is a possibility of applications being made for intellectual property or plant breeders' rights the level of responsibility increases. This is particularly so with regard to any access and or use of traditional knowledge, genetic resources which do not form part of the Multilateral system established by the International Treaty For Plant Genetic Resources for Food and Agriculture (Plant Treaty), and the use of genetic material covered by Annex 1 of the Plant Treaty for purposes other than conservation for research, breeding and training for food and agriculture. This would include, for

example, its use in chemical, pharmaceutical and/or other non-food/feed industrial uses.

In many cases it will be third parties, rather than CGIAR Centers themselves, that will be seeking intellectual property or plant variety protection over inventions and plant varieties. In such cases the Centers will not be required to make any disclosure. Centers are, however, obliged under the Plant Treaty to ensure that all available passport data and, subject to applicable law, any other associated available non-confidential descriptive information shall be made available with the plant genetic resources for food and agriculture.[29] If this includes traditional knowledge falling under the Nagoya Protocol, prior informed consent and mutually agreed terms may be required for transfer.

Centers may require an indemnity excluding them from all liability for any harm, loss or damage arising from any failure to comply with disclosure requirements by those to whom they provide genetic resources or traditional knowledge. They may also seek to exclude liability for loss arising from any error in the information provided. These issues will also need to be addressed in the ongoing process to review the Standard Material Transfer Agreement under the Plant Treaty.

CGIAR Centers and other ex-situ collections of genetic resources and traditional knowledge will now need to analyse their internal procedures for documentation of genetic resources and traditional knowledge in order to determine the extent of data to be retained to meet disclosure requirements and any relevant access and human rights legislation.

Further reading

Correa, Carlos M., *The politics and practicalities of a disclosure of origin obligation*, QUNO Occasional Paper 16 (2005).

Dutfield, Graham, *Thinking Aloud on Disclosure of Origin*, QUNO occasional paper 18 (2005): 131-147.

Hoare, Alison L., and Richard G. Tarasofsky. 'Asking and Telling: Can "Disclosure of Origin" Requirements in Patent Applications Make a Difference?' *The Journal of World Intellectual Property* 10.2 (2007): 149-169.

Lightbourne, Muriel, *Food Security, Biological Diversity and Intellectual Property Rights*. Ashgate Publishing, Ltd., (2013).

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[29] Art 12. 3. (c)

Annex. National and Regional Disclosure Measures

Country or Region	Year	Disclosure status	Disclose use of genetic resources (GR) and/or traditional knowledge (TK)	Disclose origin, source and/or legal provenance	Disclose PIC and or MAT	Remedy inside or outside intellectual property Regime
Andean Community	1996 2000	mandatory	Only applies to GR and TK from Andean Community countries	Origin and legal provenance	PIC and MAT	Refusal of application revocation of IP granted
Belgium	2005	mandatory				None within patent law
Bolivia	2000	mandatory	GR and TK	origin	PIC and MAT	Refusal of application revocation of IP grant
Brazil	2001	mandatory	Only applies to GR and TK from Brazil	origin	MAT	Nullity or suspension of patent
China	2009	mandatory	GR	origin		Inability to obtain patent
Colombia	2000	mandatory	GR and TK	origin	PIC and MAT	Refusal of application revocation of IP grant
Costa Rica	1998	mandatory	Only applies to GR from Costa Rica	Origin and legal provenance	PIC	Application may not be processed
Denmark	2000	mandatory	GR	geographic origin if known		Failure does not affect patent rights but may violate Penal Code
Ecuador	2000	mandatory	GR and TK		PIC and MAT	Refusal of application revocation of IP grant
Egypt	2002	mandatory	GR and TK	Legal provenance		unclear
European Union	1994 1998	voluntary	biological material	geographic origin if known		Does not affect patent rights
Germany	2005	voluntary		origin		
India	2005	mandatory	biological material	Source and geographic origin	PIC required for patent application anywhere in the world	Opposition to patent for failure to disclose or if invention is anticipated by TK from anywhere. Revocation of patents Modify IP ownership Criminal sanctions
Italy	2006	voluntary				
New Zealand	1953	procedural	GR and TK of Maori and Moriori			May refuse application on grounds of morality
Norway	2003 2009	mandatory does not apply to PCT grants	GR	Country of origin and providing country if different	PIC if required by source country	Possible fines and penal sanctions up to 2 years in prison
Panama	2006	mandatory	GR	origin and provenance	PIC	Application may not be processed
Peru	1996 2000 2002	mandatory	GR and TK	origin	PIC and MAT	Refusal of application revocation of IP grant
Romania	1991 2002	mandatory	TK	source		none
South Africa	2005	mandatory	Only applies to South African GR and TK			Inability to obtain patent Patent can be revoked
Sweden	2004	voluntary		geographic origin		Does not affect patent rights
Switzerland	2008	mandatory	GR and TK	source		Inability to obtain patent Fine for deception up to 100,000 Swiss francs
Venezuela	2000	uncertain				unclear