



## Mandatory Disclosure of the Source and Origin of Biological Resources and Associated Traditional Knowledge under the TRIPS Agreement

### I. Introduction

One of the most critical multilateral processes for developing countries rich in biodiversity and traditional knowledge is the establishment of a *Disclosure of Origin of Biological Resources and/or Associated Traditional Knowledge* in patent applications (Disclosure Requirement). The disclosure requirement is under discussion at the WTO in the context of examining the relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD), an outstanding implementation issue and part of the agenda of the Council for the TRIPS. As such, the discussion is integral to any outcome of the Doha Round of multilateral trade negotiations.

Over a third of the WTO membership supports the introduction of a mandatory disclosure requirement as proposed by developing countries.<sup>1</sup> The group of Least Developed Countries (LDC) have also expressed their support at the TRIPS Council. Norway has made a similar proposal that puts forward key principles for introducing the disclosure requirement.<sup>2</sup> The developing country proposal would introduce a new *Article 29bis* to the TRIPS Agreement. The amendment would require all member states to establish a mandatory disclosure requirement of the origin of biological resources and/or associated traditional knowledge (TK) in patent applications.

Though the proposal from

### Executive Summary

The discussion on TRIPS and CBD in the WTO demonstrates the growing convergence on content, scope, relevance and effectiveness of an international mandatory obligation on disclosure of source and country providing biological resources and traditional knowledge. Remaining divergences focus on the substantive and procedural functions of the disclosure requirement and in particular, the legal consequences on the processing, granting and validity of a patent. The availability of discretionary power for national administrative and judicial authorities to revoke a patent for non-compliance with the disclosure requirement would be important in the absence of an alternative effective mechanism for its enforcement.

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developing countries was officially submitted in May 2006, discussions on the mandatory disclosure requirement have proceeded for over five years at international fora, including the CBD, WTO and WIPO. In particular, the Bonn Guidelines adopted by the CBD recommended that countries encourage disclosure of origin in patent applications. Nonetheless, some countries oppose an international obligation, based on concerns related to its efficiency and effect on the patent system. The United States is a core critic. Switzerland, on the other hand, has proposed in the World Intellectual Property Organisation (WIPO) that the disclosure requirement be voluntary for states via amendment of the Patent Cooperation Treaty (PCT).<sup>3</sup> The European Community (EC) has gone further, submitting a proposal to the WIPO in support of the mandatory disclosure requirement by amending the PCT and the Patent Law Treaty.<sup>4</sup> Both the EC and Switzerland forwarded their proposals to the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC).<sup>5</sup>

The objective of this policy brief is to analyse the main elements of the disclosure requirement, the approaches of WTO member states and recommend a way forward. The first section discusses the debate on the substantive scope, definition and content of the disclosure requirement. The second section discusses the procedural requirements and the proposed legal effects of non-compliance with the disclosure requirement. A conclusion of the main ideas is provided in the last section.

## II. Mandatory Disclosure Requirement: Subject Matter and Link to Patents

The aim of the disclosure requirement is two fold: 1) to address the fact that the TRIPS Agreement, whilst promoting the granting of patents to inventions based on biological resources and associated TK, contains no effective provisions to protect those resources from misappropriation and misuse, 2) to support the implementation of the CBD, in particular, the CBD obligations regarding access to biological resources

and TK. The CBD provides that access, where granted, should be subject to prior informed consent (PIC) of the country providing the resource, and countries should take measures to ensure fair and equitable benefit sharing arising from the commercialization or other utilisation of genetic resources on mutually agreed terms. The disclosure requirement is also facilitating the traditional functions of the IP system in assessing the patentability of a claimed invention.<sup>6</sup>

The disclosure requirement does not bring in new substantive element, either to the patent system or to the CBD. It merely creates a linkage between the acquisition and protection of the subject matter of the patents – namely, patentable inventions- and the substantive objects of protection under CBD- namely, biological resources, TK. Members of the WTO are discussing the disclosure requirement only by looking at conditions to be placed on the *patent applicant* (under Article 29) as opposed to defining patentable subject matter or conditions of *patentability* (under Article 27) of TRIPS. The proposal by Norway clarifies that the disclosure requirement would not function as additional criteria for patentability. The proposal from developing countries as it stands also does not add new criteria for patentability.

A related question that has been raised is whether the disclosure requirement can contribute substantively to patent examination. The United States argues that the disclosure requirement will be ineffective in achieving the objective of enabling a better assessment by patent examiners of novelty and inventive step in claimed inventions. However, it upholds that access by patent examiners to databases on genetic resources and traditional knowledge could aid in the discovery of prior art. It would follow from the same logic that the obligation to disclose would aid in the discovery of prior art and reduce the risk of wrongfully granted patents. In a formal submission the United States stated that:

“...patent examiners world-wide could use organized searchable databases of genetic resources and traditional knowledge when examining patent applications. This could aid in the discovery of relevant prior art and thereby improve examination of patent applications in the relevant fields.”<sup>7</sup>

## Proposal of Developing countries on mandatory Disclosure Requirement

### Article 29bis

#### *Disclosure of Origin of Biological Resources and/or Associated Traditional Knowledge*

1. For the purposes of establishing a mutually supportive relationship between this Agreement and the Convention on Biological Diversity, in implementing their obligations, Members shall have regard to the objectives and principles of this Agreement and the objectives of the Convention on Biological Diversity.
2. Where the subject matter of a patent application concerns, is derived from or developed with biological resources and/or associated traditional knowledge, Members shall require applicants to disclose the country providing the resources and/or associated traditional knowledge, from whom in the providing country they were obtained, and, as known after reasonable inquiry, the country of origin. Members shall also require that applicants provide information including evidence of compliance with the applicable legal requirements in the providing country for prior informed consent for access and fair and equitable benefit-sharing arising from the commercial or other utilization of such resources and/or associated traditional knowledge.
3. Members shall require applicants or patentees to supplement and to correct the information including evidence provided under paragraph 2 of this Article in light of new information of which they become aware.
4. Members shall publish the information disclosed in accordance with paragraphs 2 and 3 of this Article jointly with the application or grant, whichever is made first. Where an applicant or patentee provides further information required under paragraph 3 after publication, the additional information shall also be published without undue delay.
5. Members shall put in place effective enforcement procedures so as to ensure compliance with the obligations set out in paragraphs 2 and 3 of this Article. In particular, Members shall ensure that administrative and/or judicial authorities have the authority to prevent the further processing of an application or the grant of a patent and to revoke, subject to the provisions of Article 32 of this Agreement, or render unenforceable a patent when the applicant has, knowingly or with reasonable grounds to know, failed to comply with the obligations in paragraphs 2 and 3 of this Article or provided false or fraudulent information.

The United States also asserted that:

“If the source of biological/genetic resource was unique, an applicant would have to identify it so that a person skilled in the art would be able to carry out the invention. In the US, indigenous/traditional knowledge closely related to an invention had to be identified as prior art if it were known to the applicant. If the invention would have been obvious to one skilled in the art in light of the prior art, no patent would be granted.”<sup>8</sup>

While the disclosure of genetic resources and TK in a patent application may not always influence the patent examination, this is not unique to the disclosure requirement. Here the duty of patent applicants to disclose ‘information material to patentability’ under the United States patent system is a good example. It is not necessary that the ‘materiality’ of the information disclosed affect or lead to the rejection of the claimed patent in all

cases.<sup>9</sup> The information could be relevant to patent examination either procedurally or substantively.<sup>10</sup> Moreover, the availability of a database does not prevent patent offices to request information from the patent applicant as may be reasonably necessary to properly examine or treat the matter. Furthermore, the disclosure requirement should not only be considered in terms of its utility for determination of patentability. It also functions as a mechanism for disclosure of information for the implementation of the CBD, since it identifies the commercial application of inventions that concern or derive from biological resources and associated TK.

#### **a) Biological Resources, Genetic Resources and TK**

‘Biological resources’ and ‘genetic resources’ are the two phrases used in the discussion in the WTO on the relationship between TRIPS and CBD. Article 2 of the CBD states that ‘biological

resources' include genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity. The same Article defines 'Genetic resources' as genetic material of actual or potential value. Genetic materials are 'any material of plant, animal, microbial or other origin containing functional units of heredity.' The proposal from developing countries refers to 'biological resources'. Norway, the EU and Switzerland on the other hand refer to 'genetic resources'. The phrase 'biological resources' covers genetic resources. The use of the 'biological resources' for the disclosure requirement avoids uncertainties for patent applicants and create confidence in the system.

Developing countries' proposal refers to 'biological resources and/or associated traditional knowledge.' Switzerland proposed to focus broadly on knowledge, innovations and practices of indigenous and local communities relevant for the conservation and sustainable use of biological diversity.<sup>11</sup> The EC offers to consider the disclosure requirement for TK only after agreement on what constitutes TK. 'Traditional knowledge' is much more developed as a legal concept in several jurisdictions, and international law.

The draft principles and objectives on the protection of traditional knowledge developed in the IGC of WIPO defined TK comprehensively. Norway deviated from the approach of Switzerland by supporting mandatory declaration of TK, even if the TK has no connection with the genetic resources. This would enable the tracing of the utilisation of all TK in all patent application (See Proposal of Developing Countries on mandatory Disclosure requirement on page 3).

#### **b) Country of Origin, Country Providing, and Source**

'Source,' 'country of origin,' 'country providing' and 'supplier country' are used in proposals and submission of countries in defining the scope of the disclosure requirement. Switzerland limited the declaration only to the 'source' of genetic resources and knowledge. Norway on the other hand does not refer to 'source' as an

element for declaration. The EC focuses on origin and source of genetic resources. Developing countries, EC and Norway require the disclosure of country of origin, if known. For developing countries the patent applicant has to make reasonable inquiry to identify the country of origin. Norway requires such disclosure to be made only if different from the supplier country (in case of genetic resources) and if relevant - in case of TK.

The underlying motivation for the proposals remains that of ensuring mutual supportiveness between the TRIPS and CBD. The terminologies to be used to determine the scope and content of the disclosure requirement should be 'relevant' and 'effectively applicable' for both instruments. The CBD refers to 'country of origin of genetic resources' and 'country providing genetic resources.'

*Country of origin* is the country which possesses those genetic resources in *in-situ* conditions - within ecosystems and natural habitats as well as in the surroundings where they have developed their distinctive properties;

*Country providing* is the country supplying genetic resources collected from *in-situ* sources, including populations of both wild and domesticated species, or taken from *ex-situ* sources (outside natural habitats), which may or may not have originated in that country. Article 15 of the CBD further define the term '*Country providing*', stating that such country should either be the country of origin, or should have obtained the genetic resources in accordance with the CBD.

The definition of '*Country providing*' and its use under Article 15 of the CBD makes it directly relevant for disclosure requirement and broad to covers both *in situ* and *ex situ* resources occurring in a country. It prevents any potentially inconclusive debates as regards whether the '*country providing*' a resource is also the *country of origin* of the resource.

Positions and Proposals of Developing Countries, Norway and Switzerland					
	Obligations of countries	Subject matter	Disclosure of...	Qualifications	Effect of Non-compliance
Developing Countries	a) to adopt mandatory disclosure requirement; b) publication of information provided; c) effective enforcement procedures.	'subject matter of a patent application' that concerns, is derived from or developed with biological resources and/or associated TK	<b>country providing</b>		a) prevent the processing or the grant of the patent concerned; b) revoke or render unenforceable a patent where the applicant has knowledgeably or with reasonable ground to know failed to disclose, correct and supplement the information required.
			from whom the resources were obtained in the country providing;		
			the country of origin	as known after reasonable inquiry	
			Information on compliance with PIC and FEBS	Based on the legal requirements in providing country	
Norway	a) Same as (a) above. b) notification of all declarations of origin to the CBD Clearing-House Mechanism c) effective and proportionate penalty outside the patent system.	(not clear)	supplier country of genetic resources and TK;	even if the TK has no connection with the genetic resources;	a) Same as (a) above b) effective and proportionate penalty outside the patent system, if subsequently discovered; c) revocation if the patent does not differ from the TK to the degree required for patentability.
			country of origin of genetic resources,	if known and different;	
			country of origin of TK	if relevant;	
			information on PIC	where required	
Switzerland	None- optional to member states of WIPO	-an invention directly based on genetic resources, knowledge, innovations and practices of indigenous and local communities relevant for the conservation and sustainable use of biological diversity.	the source of a specific genetic resource;	-to which the inventor has had access; -when relevant to the national application	
			the source of knowledge, ...	-if the inventor knows the invention is directly based on the knowledge ...	
EC	Similar to Norway but only in WIPO	the invention must be directly based on the specific genetic resources	the country of origin or source of genetic resources	If the country of origin is unknown, the 'sources' to which the inventor has had access and which is still known to him	effective, proportionate and dissuasive sanctions should be envisaged outside the field of patent law

The disclosure of the 'source' of biological resources and TK is relevant to assess the compliance with the CBD. If the resources were obtained under the multilateral system of the *International Treaty on Plant Genetic Resources for Food and Agriculture* (ITPGRFA) of the Food and Agriculture Organization (FAO), the disclosure of the immediate source would lead to a whole set of information that would assist compliance with the treaty provisions. The disclosure of bio-prospecting organisations, botanic gardens, research centres, government agencies, members of traditional communities and other immediate sources of biological resources and associated TK would be critical to identify the form in which the resources were obtained and the manner they were accessed.

### c) Prior Informed Consent (PIC) and Fair and Equitable Benefit Sharing (FEBS)

Developing countries' proposal requires further disclosure of information, including evidence of compliance with the applicable legal requirements in the providing country on PIC and FEBS. Norway also supports disclosure of PIC where required by the supplier country or country of origin.

The disclosure of the source of biological resources and TK may not always lead to information as to compliance with the applicable law on PIC and FEBS. The task of identifying transactions involving biological resource and TK would be facilitated if declaration was made as to the compliance with the applicable laws by the patent applicant. Yet the declaration would only amount to compliance with formal requirement. It does not amount to the determination of compliance with the applicable PIC and FEBS requirement and would not be binding on the patent office. It does not require the patent office to determine the availability and compliance with the legal requirements in the country providing the resources and/or TK. The disclosure of information as to compliance with the applicable law on PIC and FEBS, as formal requirement, would only compel researchers and companies to make a reasonable effort to identify the availability and, where available, to comply with legal requirements on PIC and FEBS and furnish the evidence of compliance. It would also be act

as a good incentive for researchers and companies to acquire biological resources from sources that have complied with such requirements.

### III. The Obligations of Countries and Revocation of Patents for Non-Compliance

The mandatory disclosure requirement would constitute a limited obligation for member states and their patent offices. The member states of the WTO must adopt the disclosure requirement and allow the patent applicant to correct and supplement the information provided.

Norway's proposal to the WTO and the EC and Switzerland proposal in WIPO specifically require that patent offices send all declarations received with respect to biological resources and TK to the CBD Clearing-House Mechanism. The proposal from developing countries requires only the publication of the information disclosed, including subsequent corrections or additions made, as part of the patent application or grant. There would be no additional requirement for the patent offices with respect to notifying the entry of information in patent applications.

The proposals require members of the WTO to put in place effective enforcement procedures to ensure compliance with disclosure requirement. Developing countries' proposal also requires countries to ensure that, when the applicant has knowingly or with reasonable grounds to know failed to comply with the obligations or provided false or fraudulent information, the administrative and/or judicial authorities have the authority to:

- ◆ prevent the further processing of an application or the grant of a patent and
- ◆ Revoke, subject to the provisions of Article 32 of the TRIPS, or render unenforceable a patent.

A mandatory disclosure requirement that functions as both a substantive and procedural condition on patent applicants would have legal consequences for the processing, granting and validity of a patent. The discussion in the WTO reflects the tension on whether patents should be

revoked because of non-compliance with the requirement or fraud committed against patent offices. Developing countries and Norway hold a similar position in support of the suspension of a patent application when non-compliance is discovered upon or during the patent application. Norway has made clear that if non-compliance is discovered only after the patent has been granted, it should not in itself affect the validity of the patent, but rather be subject to appropriate and effective sanctions that would fall outside the patent system, for example criminal or administrative penalties. However, Norway considers that a patent can be revoked if it does not differ from TK to the degree required to constitute a patentable invention.

Developing countries have not proposed that all cases of non-compliance should result in the revocation of a patent. Instead, judicial or administrative authorities should have the authority to revoke the patent when the applicant has, knowingly or with reasonable grounds to know, failed to comply with the obligations. The availability of discretionary power for the administrative and judicial authorities to revoke a patent for non-compliance with the disclosure requirement would be a compelling reason for patent applicants to comply with the requirement. It is onerous on those that object to the revocation of pat-

ents in case of non-compliance to come up with alternative mechanisms to ensure that inequitable conduct and misrepresentations are effectively addressed.

#### IV. Conclusion

The current debate in the WTO demonstrates the growing convergence on content, scope, relevance and effectiveness of mandatory disclosure requirement. The use of terminologies and concepts related to disclosure requirement needs further refinement and consistency to avoid uncertainties and facilitate compliance. Similarly the scope of the obligation can be clarified by designing a better approach to deal with (a) information that would depend on the possible knowledge of the patent applicant, such as country of origin, (b) information on PIC and FEBS that would be available by the declaration of 'source', and (c) obligation that depends on the availability of legal requirements in country providing the genetic resources and TK for compliance. The revocation of patent for certain cases of non-compliance to the disclosure requirement and the availability of procedures for correction and supplementing the information included in the patent application might be going deep into the realm of domestic laws and regulations.

#### End Notes

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2. WTO, IP/C/W/473, 14 June 2007.
3. WIPO, PCT/R/WG/9/8, April 23 to 27, 2007, para. 16. See also WTO, "IP/C/W/400/Rev.1, 18 June 2003.
4. WIPO, WO/GA/32/8, 24 August 2005.
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6. Correa M. Correa and Joshua D. Sarnoff, Analysis of Options for Implementing Disclosure of Origin Requirements In Intellectual Property Applications, UNEP/CBD/COP/8/1 (2006), p. 25.
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9. Price, Heneveld, Cooper, Dewitt and Litton, LLP, *Ideas on Intellectual Property Law*, June/July 2005, available at [http://www.priceheneveld.com/pdf/2005\\_JuneJuly05.pdf](http://www.priceheneveld.com/pdf/2005_JuneJuly05.pdf), p. 4.
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