

Proposals for the Disclosure of Origin of Genetic Resources in Patent Applications

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ABSTRACT

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.

The first section examines the various versions of the disclosure of origin concept as a means to clarify its meaning and provides some commercial and political context in order to understand why the disclosure of origin proposal has been formulated and to explain the problems it is intended to solve.

The disclosure of origin debate at the TRIPS Council, WIPO and the Conference of the Parties to the Convention on Biological Diversity is examined and surveys efforts to introduce the various forms of disclosure of origin into national and regional access and benefit sharing (ABS) and intellectual property laws and regulations.

The next section considers the practical and commercial benefits and disadvantages of disclosure of origin for business and for developing countries. Among the questions which are considered here are: (i) would disclosure of origin achieve its proponents' objectives? (ii) is it feasible to expect companies to be able to trace the source of biogenetic material and associated traditional knowledge from which an invention or new plant variety is derived? (iii) would disclosure of origin turn out to be burdensome or damaging for industry, especially SMEs, to the extent that bioprospecting, research or business development would be discouraged; and (iv) would compliance impose excessively high costs on SMEs?

The concluding section offers proposals and recommendations with respect to the ongoing international negotiations on this subject.

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, including
 - *the Conference of the Parties*
 - *the Ad Hoc Open-ended Inter-sessional Working Group on Access and Benefit-sharing*

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- *the Ad Hoc Open-ended Inter-sessional Working Group on Article 8(j) and Related Provisions*
- 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.ⁱ 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 resourcesⁱⁱ. "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.ⁱⁱⁱ

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).^{iv} 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 "take legislative, administrative or policy measures, as appropriate" 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

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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.”^v 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.”^{vi}

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:

1. 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.
2. 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^{vii} 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) (identical text): ‘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.

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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^{viii} 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^{ix}:

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.³⁷ 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

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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 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 property rights.”

The Decision also listed a number of issues for further examination, including the:

- Consistency and applicability of requirements for disclosure of country of origin and prior informed consent in the context of international legal obligations;
- 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;
- Efficacy of country of origin and prior informed consent disclosures in monitoring compliance with access provisions;
- 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. ^x Following this request, a draft Study was prepared by WIPO, based on responses to a questionnaire circulated to the Member States of WIPO. ^{xi} 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. ^{xii}

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: (i) an invitation by WIPO Member States to submit comments and proposals, by December 15, 2004; (ii) preparation of a draft examination and its circulation for comments; (iii) observations and comments on the draft to be submitted by Member States and accredited observers by the end of March 2005;

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(iv) publication on the website and in a consolidated document of all comments and observations received; (v) 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; (vi) 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^{xiii} and an ad hoc Intergovernmental meeting was convened for June 3, 2005 to consider a revised draft of this document.

National and Regional Legislation

Several countries and regions have applied disclosure of origin measures in relation to IPR applications for inventions derived from genetic resources. These can be classified according to whether weak, medium, or strong disclosure options have been adopted.

‘Weak Disclosure’ measures

Egypt

Egyptian Law (2002, article 13) states that:

Where the invention involves biological, plant or animal product, or traditional medicinal, agricultural, industrial or handicraft knowledge, cultural or environmental heritage, the inventor should have acquired the sources in a legitimate manner.

European Union

The EU Directive on the Legal Protection of Biotechnological Inventions. Recital 27 states that

Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.

Thus, under EC law disclosure of geographical origin is encouraged, but it is not obligatory, and failure to comply does not affect the granting of patents.

Regarding the definition of biological material, the EC Biotechnology Directive states:

2 (a) ‘biological material’ means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.

The EC has highlighted the fact that disclosure of the origin of genetic resources and TK is often made within patent applications under three different patent principles^{xiv}:

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1. The enabling-disclosure – Article 13(1)(b) of the EC Directive 98/44/EC states that where an invention concerns biological material which is not available to the public and which cannot be described in a patent application in such a manner as to enable the invention to be reproduced by a person skilled in the art, the description shall be considered inadequate for the purpose of patent law. Therefore, in some cases, such as the case of resources which are rare or exotic, disclosure of country of origin may be necessary, to enable a person skilled in the art to reproduce the invention.
2. Relevant prior art – Rule 27(1)(b) of the European Patent Convention requires that the description of the patent should indicate the background art which, as far as known to the applicant, can be regarded as useful for understanding the invention. This may include references to traditional uses or properties in its country of origin.
3. Identification of the true inventor – Article 81 of the European Patent Convention requires that ‘the European patent application shall designate the inventor. If the applicant is not the inventor or is not the sole inventor, the designation shall contain a statement indicating the origin of the right to the European patent’. Therefore, failure to identify the origins of TK for an invention substantially based on this could result in revocation of a patent.

With respect to plant variety protection, Council Regulation 2100/94 on Community Plant Variety Rights indicates that a disclosure requirement is ‘foreseen’. Article 50 of the Regulation requires applicants for a community plant variety right to state the geographic origin of the variety. However, this disclosure is limited to the variety, and does not cover the parent material.

The European Community and its Member States have submitted a specific proposal as an ‘attempt to formulate a way forward that should ensure, at global level, an effective, balanced and realistic system for disclosure in patent applications.’ This proposal is summarized as follows:

- (a) a mandatory requirement should be introduced to disclose the country of origin or source of genetic resources in patent applications;
- (b) the requirement should apply to all international, regional and national patent applications at the earliest stage possible;
- (c) the applicant should declare the country of origin or, if unknown, the source of the specific genetic resource to which the inventor has had physical access and which is still known to him;
- (d) the invention must be directly based on the specific genetic resources;
- (e) there could also be a requirement on the applicant to declare the specific source of traditional knowledge associated with genetic resources, if he is aware that the invention is directly based on such traditional knowledge; in this context, a further in-depth discussion of the concept of “traditional knowledge” is necessary;
- (f) if the patent applicant fails or refuses to declare the required information, and despite being given the opportunity to remedy that omission continues to do so, then the application should not be further processed;
- (g) if the information provided is incorrect or incomplete, effective, proportionate and dissuasive sanctions should be envisaged outside the field of patent law;
- (h) a simple notification procedure should be introduced to be followed by the patent offices every time they receive a declaration; it would be adequate to identify in particular the

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Clearing House Mechanism of the CBD as the central body to which the patent offices should send the available information.

Germany

Germany has no specific requirement for disclosure of information concerning genetic resources or TK in its national law. However, it was reported at the 2nd meeting of the Working Group on ABS that Germany is amending its legislation to include disclosure of origin, but that non-disclosure would not affect the granting of patents. To date, no amendment to patent law has been made.

Romania

Implementing regulation of the Patent Law 64/1991, rule 14, point (1)(c) states that:

When the state of the art includes also traditional knowledges they shall be clearly indicated in the description including their source, when known.

The implementing regulation was republished on 15 October 2002, and approved on 18 April 2003. There are no consequences for non-compliance either under patent law or civil law.

Romania notes that the information requirements for genetic resources used in an invention 'apply to patent applications for any inventions, regardless of the technology involved' and equally to applications by domestic and foreign nationals.

Spain

Spanish patent law allows for the voluntary disclosure of geographical origin of biological resources upon which an invention is based. Spain conducted a review of applications for patents using biological material and found that the geographic origin of this material was usually stated in applications. On this basis it was suggested that for patents using biological resources from 'exotic' or 'rare' material, applicants 'are aware that for their applications to comply with such requirements [regarding the description of the invention to enable someone else to carry it out] they must mention the country of origin of the material.' Further, that 'in order to comply with the requirement of indicating the background art... he usually mentions the traditional uses of such a material'. This would suggest to some that mandatory disclosure may not be necessary.

Sweden

Sweden has implemented a new Rule 5(a) of the Patents Regulations (SFS 2004:162) (under the Patents Act) which came into effect on 1 May 2004. This was developed in response to an EC Directive on this issue, and mainly reiterates paragraph 27 of the Preamble of the EC-Directive and contains provisions on the disclosure of the geographical origin of biological material as follows:

5(a) If an invention concerns biological material of plant or animal origin, or if it uses such material, the patent application shall include information on the geographical origin of such material, if known. If the origin is unknown, this shall

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be said. Lack of information on the geographical origin or on the knowledge of the applicant regarding the origin is without prejudice to the processing of the patent application or the validity of rights arising from a granted patent.

The proposed information requirements ‘would apply to patent applications for any inventions based on biological material of plant or animal origin or using such material, regardless of the technology involved. The requirements would apply equally to patent applications by domestic and foreign nationals’ and ‘regardless of where the biological material was obtained.’ There would be ‘no consequences for the patent applicant or patent holder of any failure to meet the requirements of disclosure of the geographical origin of the biological material.’ As to publication, ‘the information on geographical origin would be available to anyone when the patent was granted (or when 18 months had passed from the filing date or from the date from which priority was claimed).’^{xv}

Sweden has previously stated that ‘false or misleading information could *probably* lead to the rejection of an application or the invalidation of a granted patent. The reason for rejection or invalidity would then however be that the criteria for patentability were not met, not the fact of false or misleading information as such.’

‘Medium Disclosure’ requirements

Denmark

In 2000, a ‘disclosure of origin clause’ was enacted in Denmark’s IPR legislation, requiring patent applicants to declare the geographical origin of the material, if known. Lack of information on this does not affect the patent application, but could imply a violation of the obligation in the Danish Penal Code (para. 163) to provide correct information to a public authority.

Act 412, 31/5 2000 amended the Danish Patent Act (consolidated Patent Act 926 22/9 2000). Based on the Act, the ministerial regulations on patents (Reg.374 19/6/1998) were amended (reg.1086 11/12/2000) by supplementing paragraph 3 with the following provision (unofficial translation):

If an invention concerns or makes use of biological material of vegetable or animal origin, the patent application shall include information on the geographical origin of the material, if known. If the applicant does not know the geographic origin of the material, this shall be indicated in the application. Lack of information on the geographical origin of the material or on the ignorance hereon does not affect the assessment of the patent application or the validity of the rights resulting from the granted patent.

Norway

In 2001 Norway established an expert committee to examine Norwegian legislation relating to the protection of biodiversity in Norway. Its aim is to strengthen the protection of biodiversity, and to examine how legislation responds to issues within the CBD. Access to genetic resources and benefit sharing are identified as separate and priority issues in this work, as this is an area not yet subject to legislation in Norway. The Committee will propose regulations with regard to both access to genetic resources in Norway and regulations

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concerning the use of genetic resources originating from other countries when used in Norway. A report is due by the end of 2004, and this will then be the subject of a government hearing.

An amended Norwegian Patent Act was adopted by Parliament in December 2003. It came into force for patent applications submitted from 1st February 2004.

New paragraph 8 (b) reads:

If an invention concerns or uses biological material, the inventor shall disclose in the patent application the country providing such material. If national legislation in the providing country requires prior informed consent before providing such material, the application shall include information on whether such consent has been sought.

In cases where the providing country is different from the country of origin of the biological material, the country of origin shall also be disclosed. Country of origin is defined as the country from where the material is accessed in *in situ* conditions. In cases where national legislation in the country of origin requires prior informed consent before providing such material, the application shall include information on whether such consent has been sought. If the applicant does not know the country of origin or whether prior informed consent is required, the applicant shall state this fact in the application.

These obligations are applicable even if the inventor has changed the structure of the material. They do not concern human material.

Violations of the requirement to disclose information is punishable under paragraph 166 of the Penal Code. The requirement to disclose information does not affect that handling of a patent application or the validity of a patent.

Under paragraph 33 of the amended Patents Act, these requirements are not applicable to international applications received through the Patent Cooperation Treaty (PCT), as this would be contrary to the obligations under the PCT. Penalties for non-compliance under paragraph 166 of the General Civil Penal Code could be imposition of a fine or up to 2 years in prison.

Switzerland

In the context of the revision of the Federal Law on Patents, an administrative working group has been established, under the Swiss Federal Institute of Intellectual Property to clarify issues linked with the declaration of the source of genetic resource and TK and its integration in the Federal Patent Law.

It is expected that a draft revised law will be submitted to Parliament in 2005. This could enter into force in 2007 at the earliest. The draft submitted for this public consultation contains provisions on the disclosure of the source in Article 49a, requiring disclosure of origin of genetic resources and traditional knowledge.

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The text of the draft article is as follows:

“Article 49a

For inventions based on genetic resources or traditional knowledge the patent application must contain information concerning the source:

- a) of the genetic resource to which the inventor or the applicant had access, when the invention is based directly on that resource;
- b) of the traditional knowledge of indigenous or local communities related to the genetic resources to which the inventor or applicant had access, when the invention is based directly on that knowledge.

If the source is not known to either the inventor or the applicant, the applicant must confirm this in writing.”

New Zealand

In a submission to WIPO^{xvi}, New Zealand states that for inventions derived from or using TK, or relating to indigenous flora or fauna, applicants are asked to provide an indication or evidence of PIC being given by a relevant Maori group.

Under section 17 of the Patent Acts 1953, the Commissioner of Patents may refuse a patent application where the use of the invention is contrary to morality. Where an invention is either derived from or uses TK, or relates to an indigenous flora or fauna, or products extracted therefrom, applicants are asked to provide an indication or evidence of prior informed consent being given by a relevant Maori group. This requirement is not specifically included in the Patents Act, but is required as a matter of internal office procedure.

‘Strong Disclosure’ measures

Andean Community

Community Decision 391 of the Andean Community (‘Common Regime on Access to Genetic Resources’), signed on 2 July 1996, requires consent for the actual and potential use of a resource, covering both genetic resources and any derivatives of genetic resources. It also states that IPRs for genetic resources that were obtained without compliance with the decision shall not be recognised by member states.

Decision 391 provides for an access contract between the State, represented by the Competent National Authority, and the applicant requesting access. This is subject to the requirement that ‘when access is requested to genetic resources or their by-products with an intangible component, the access contract shall incorporate, as an integral part of that contract, an annex stipulating the fair and equitable distribution of profits from use of that contract.’ This requirement for an access contract provides a linkage with a disclosure requirement that is set out in Decision 486 (‘Common Intellectual Property Regime’)

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Decision 486 ('Common Intellectual Property Regime') took effect in December 2000. Article 26 states that:

Applications for patents shall be filed with the competent national office and shall contain: ...

(h) a copy of the contract for access, if the products or processes for which a patent application is being filed were obtained or developed from genetic resources or by-products originating in one of the Member Countries;

(i) if applicable, a copy of the document that certifies the license or authorization to use the traditional knowledge of indigenous, African American, or local communities in the Member Countries where the products or processes whose protection is being requested was obtained or developed on the basis of the knowledge originating in any one of the Member Countries, pursuant to the provisions of Decision 391 and its effective amendments and regulations;'

Belgium

Belgium has been seeking to link compliance with the CBD to requirements that exploitation of an invention not be contrary to *ordre public* and morality. In 2000, a draft proposal to modify article 4(4) of the 1984 Belgian Patent Act (Patents, Law, (Brevets, Loi) BE_031, 28/3/84) (Loi sur les brevets d'invention) was prepared which 'stipulates that the exploitation of an invention is contrary to *ordre public* and morality when the invention is developed on the basis of biological material that was collected or exported in breach of articles 3, 8(j), 15 and 16 of the CBD'. In addition, 'a patent application should contain, not only a formal request, a description, one or more claims, drawings and an abstract, but also the geographical origin of the plant or animal material on the basis of which the invention was developed'.

This law was never enacted, but a new draft proposal will be submitted to Parliament in late 2004. This also contains the above disclosure requirement, non-compliance with which could result in the patent application not being processed.

Brazil

A disclosure requirement is a condition of patentability in Brazil. Article 31 of Brazil's Provisional Measure No. 2.186-16 stipulates that:

The grant of industrial property rights by the competent bodies for a process or product obtained using samples of components of the genetic heritage is contingent on the observance of this Provisional Measure, the applicant being obliged to specify the origin of the genetic material and the associated traditional knowledge, as the case may be.

This Provisional Measure regulates the access to genetic resources, protection and access to associated traditional knowledge, sharing of benefits and access to and transfer of technology for its conservation and use. Article 16 states that whenever there is a prospect of subsequent commercial use, *in situ* access to samples of components of genetic heritage and associated TK may only be granted after a Contract for Use of the Genetic Heritage and Benefit-Sharing has been signed.

Costa Rica

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The 1998 Biodiversity Law of Costa Rica (Law No 7,788) requires a certificate of origin to accompany applications for intellectual property rights pursuant to articles 77-85. These refer to ‘innovations *involving elements of biodiversity*’ (Article 81)

This law requires that the patent office must consult with the Technical Office (of the commission responsible for managing biodiversity) and provide a certificate of origin and PIC. Opposition from the Technical Office will prohibit registration of a patent.

India

India has introduced the medium disclosure form into the Patents (Amendment) Act. It states that ‘every complete specification shall... disclose the source and geographical origin of the biological material in the specification, when used in an invention.’ It also adds two new grounds for revocation:

- that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention
- that the invention so far as claimed in any claim of the complete specification was anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere

The Amendment adds the following to the list of things that are not inventions (and so cannot be patented):

- any living thing or non-living substance occurring in nature;
- plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals;
- an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.

The Biological Diversity Act, 2002, limits access to biological resources or related knowledge by foreigners. It institutes a National Biodiversity Authority (NBA) at federal level, and State Biodiversity Authorities at provincial level. All inventors are required to obtain the consent of the NBA before applying for IPR where the invention is based on any biological resource obtained from India. It also grants the Authority the power to impose a benefit sharing fee or royalty or to impose conditions including the sharing of financial benefits arising out of the commercial utilisation of such rights.

The Act imposes some checks on the IPR system by:

- authorizing the Authority to allocate a monopoly right to more than one actor;
- giving the Authority the power to oppose the grant of IPRs outside India (section 18(4));
- setting up a benefit-sharing scheme to address the issue of the rights of holders of local knowledge.

Under the benefit-sharing scheme, the authority can grant joint ownership of a monopoly IPR to the inventor and the authority, or to the actual contributors if they can be identified. It provides for both financial and other forms of benefit-sharing, e.g. transfer of technology. In cases where benefit-sharing is in the form of money, this can be paid to a Biodiversity Fund, which may then either be channelled to the benefit claimers or used generally for biodiversity

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management. The potential claimants do not have automatic access to a share of the benefits, nor to the allocation of property rights, for example if joint ownership is granted. Thus, local rights holders do not have the same rights as those provided to patent applicants or holders, nor does it defend their rights in the same way as those of the Indian state. With respect to local and traditional knowledge it only requires the central government to 'endeavour to respect and protect' such knowledge (section 36(5)).

Andean Community Decision 486 (Common Intellectual Property Regime), provides that applications for patents shall contain, inter alia, "a copy of the contract for access, if the products or processes for which a patent application is being filed were obtained or developed from genetic resources or byproducts originating in one of the Member Countries" and "if applicable, a copy of the document that certifies the license or authorization to use the traditional knowledge of indigenous, African American, or local communities in the Member Countries where the products or processes whose protection is being requested was obtained or developed on the basis of the knowledge originating in any one of the Member Countries, pursuant to the provisions of Decision 391 and its effective amendments and regulations" (Article 26).

Peru

As a member of the Andean Community, Peru is a signatory to Community Decisions, under which patent applicants are required to disclose the access contract and evidence of PIC for genetic resources or TK (see section on the Andean Community for details).

Peruvian Law No. 27811 ('A Law introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples derived from Biological Resources'), was published on August 10, 2002. On patents, the Law states that:

Where a patent is applied for in respect of goods or processes produced or developed on the basis of collective knowledge, the applicant shall be obliged to submit a copy of the license contract as a prior requirement for the grant of the rights concerned, except where the collective knowledge concerned is in the public domain. Failure to comply with this obligation shall be a cause of refusal or invalidation, as the case may be, of the patent concerned.

This law seeks to promote the fair and equitable distribution of benefits derived from the use of indigenous knowledge and to guarantee that such use was made with the prior informed consent of indigenous people. It is also aimed at avoiding the patentability of inventions based on indigenous knowledge that had not been taken into account in examining for inventive steps.

On access to indigenous knowledge, the law states as follows (Articles 6-8):

Those interested in having access to collective knowledge for the purposes of scientific, commercial and industrial application shall apply for the prior informed consent of the representative organizations of the indigenous peoples possessing collective knowledge.

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In the event of access for the purposes of commercial or industrial application, a license agreement shall be signed in which terms are provided that ensure due reward for the said access and in which the equitable distribution of the benefits deriving therefrom is guaranteed.

A percentage which shall not be less than ten per cent of the value, before tax, of the gross sales resulting from the marketing of goods developed on the basis of collective knowledge shall be set aside for the Fund of the Development of Indigenous Peoples.

Furthermore, three registers are to be set up as an enforcement mechanism to ensure the conservation and safeguarding of the collective knowledge of indigenous peoples and their rights to that knowledge. The registers would also ensure the availability of information to the competent national intellectual property authority, INDECOPI, to allow it to defend the rights of indigenous peoples to their traditional knowledge. A Fund would be set up to help promote the full development of indigenous people. The mechanism would enable indigenous peoples to grant licences to third parties in order to safeguard against the unfair use of their knowledge. The licensing contracts would have to be registered with the Intellectual Property Office of Peru.

Disclosure of Origin under Patent Law

Proposals for the disclosure of the origin of genetic resources concern the inter-relationship between regimes concerned with access and benefit-sharing and those governing the grant of patent rights for eligible inventions. It is proposed to create new disclosure requirements as a condition of 'patentability'.

As WIPO pointed out in its document: *Examination of Issues Relating to the Interrelation of Access to Genetic Resources and Disclosure Requirements in Intellectual Property Rights Applications*^{xvii} analyzing disclosure requirements can lead to such underlying questions as:

- who is the true inventor of a claimed invention, when the invention uses TK directly or substantially?
- what external circumstances affect the entitlement of the applicant to apply for and to be granted a patent, especially the circumstances that surround the obtaining and use of inputs to the invention, and any broader obligations that arise?
- is the claimed invention truly new and inventive (non-obvious), having regard to already known traditional knowledge and genetic resources having a medical application?
- has the applicant disclosed all known background knowledge (including TK) that is relevant to the claim that the invention is patentable?
- apart from the applicant, are there other interests that should be recognized: ownership interests (e.g. arising from benefit-sharing obligations), licensing or security interests, or interests arising from a TK holder's role in an invention?
- how can the patent system be used to monitor and sanction compliance with laws governing access to GBMR and compliance with the terms of laws or regulations governing ABS, mutually agreed terms, permits, licenses or other contractual obligations, especially when these obligations arise under foreign jurisdictions?

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A fundamental issue to consider is whether a legal requirement relating to genetic resources of traditional knowledge would concern disclosure as such, or whether it would actually function as an effective prohibition on securing a patent if certain preconditions are not met. WIPO's Technical Study sought to clarify the context and impact of disclosure requirements. It set out a structured approach to reviewing the range of possible disclosure requirements based on the following questions:

- (i) What would be the relationship between the claimed invention and the genetic resources and traditional knowledge; or what would be a sufficient link between the two to trigger a disclosure requirement?
- (ii) What legal principle would form the basis of the requirement?
- (iii) What would be the nature of the obligation placed on the applicant?
- (iv) What would be the consequence of failure to comply with the requirement?
- (v) How would the requirement be implemented, verified or monitored?

(i) *Trigger for the disclosure requirement*

Three broad functions were identified for disclosure methods relating to genetic resources and traditional knowledge:

(a) to disclose any actually used in the course of developing the invention (a descriptive, enabling or transparency function, pertaining to the genetic resources and traditional knowledge itself and its relationship with the invention);

(b) to disclose the actual source or origin of the genetic resources and traditional knowledge (a disclosure of provenance function, relating to where the GBMR/TK was obtained, geographically and in what jurisdiction) – this may concern the country of origin (to clarify under which jurisdiction the source material was obtained), or a more specific location (for instance, to ensure that genetic resources can be accessed, so as to ensure the invention can be duplicated or reproduced, or so they can be traced to a specific community or custodian); and,

(c) to provide an undertaking or evidence of prior informed consent and/or of equitable benefit-sharing (a compliance function, relating to the legitimacy of the acts of access to genetic resources and traditional knowledge source material and demonstration of the legitimacy of legal provenance) – this may entail showing that genetic resources and traditional knowledge used in the invention was obtained and used in compliance with applicable laws in the country of origin or in compliance with the terms of any specific agreement recording prior informed consent; that lawful arrangements have been established for equitable benefit-sharing; or that the act of applying for a patent was in itself undertaken in accordance with prior informed consent.

A disclosure requirement may be derived from existing patent law such as:

- (a) The obligation to disclose the invention sufficiently for it to be carried out by a person skilled in the art, and where appropriate to disclose the best mode for carrying out the invention known to the inventor;
- (b) The requirement that patent claims be supported sufficiently by the technical disclosure in the patent;
- (c) The requirement to provide information concerning known prior art relevant to the assessment of the patent claims;
- (d) The requirement to establish entitlement to apply for or be granted a patent;

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- (e) Requirements concerning the registration of licenses and security interests; and
- (f) A requirement derived from the interaction between patent law and principles of *ordre public* and morality.

The obligation placed on the applicant can range from an exhortation or encouragement to a potential ground of refusal or revocation of a patent. Disclosure requirements concerning genetic resources and traditional knowledge have formal or procedural aspects (such as format and documentation requirements, and deadlines for compliance), as well as meeting substantive tests (for instance, in disclosing enough about genetic resources used in the invention to ensure a skilled person can replicate the invention).

Some of the legal and policy questions identified in WIPO's Technical Study were:

- (a) the potential role of the patent system in one country in monitoring and giving effect to contracts, licenses, and regulations in other areas of law and in other jurisdictions, and the resolution of private international law or 'choice of law' issues that arise in interpreting and applying across jurisdictions contract obligations and laws determining legitimacy of access and downstream use of genetic resources and traditional knowledge;
- (b) the nature of the disclosure obligation, in particular whether it is essentially a transparency mechanism to assist with the monitoring of compliance with non-patent laws and regulations, or whether it incorporates compliance mechanisms;
- (c) the ways in which patent law and procedure can take account of the circumstances and context of inventive activity that are unrelated to the assessment of the invention itself and the eligibility of the applicant to be granted a patent;
- (d) the situations in which national authorities can impose additional administrative, procedural or substantive legal requirements on patent applicants, within existing international legal standards applying to patent procedures, and the role of non-IP international law and legal principles in this regard;
- (e) the legal and operational distinction (to the extent one can be drawn) between patent formalities or procedural requirements, and substantive criteria for patentability, and ways of characterizing the legal implications of such distinctions;
- (f) clarification of the implications of issues such as the concept of 'country of origin' in relation to genetic resources covered by multilateral access and benefit-sharing systems, differing approaches to setting and enforcing conditions for access and benefit sharing in the context of patent disclosure requirements, and coherence between mechanisms for recording or certifying conditions of access and the patent system.

Options for Model Provisions

The COP request for assistance from WIPO invited 'options for model provisions on proposed disclosure requirements.' On the substance of potential model provisions on disclosure requirements, WIPO identified two general options: (i) elaborating or extending existing patent law mechanisms and adapting them specifically to genetic resources and traditional knowledge (TK) as appropriate, and (ii) entirely new or specific disclosure and related mechanisms. Based on existing studies and surveys, the first category (adapting or extending existing mechanisms) could include provisions on recognition of TK as prior art; requirements to disclose any known TK relevant to the invention; provisions on entitlement to apply, ownership and other interests as a consequence of access and benefit-sharing

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obligations incurred by the applicant; provisions on disclosure of inventors ensuring the recognition of inventive contributions by TK holders; provisions for deposit and notification of samples of genetic resources relevant to the invention.

Measures or proposals in the second category (new or specific measures) can be variously characterized as follows:

(a) *Origin or source*: disclosure of the source and/or country of origin of genetic resources and/or associated traditional knowledge, where the those matters are connected to the claimed invention in a defined way;

(b) *Prior informed consent*: declaration, submission of specific documentation, or furnishing of other evidence of compliance with prior informed consent under the relevant national regime (relating to genetic resources and/or associated traditional knowledge); and

(c) *Equitable benefit-sharing*: declaration, submission of specific documentation, or furnishing of other evidence of compliance with fair and equitable benefit sharing under the relevant national regime (relating to genetic resources and/or associated traditional knowledge).

The Technical Study identified a range of disclosure scenarios, which may be correlated with the possible substantial content of model provisions:

- specific mechanisms created to address genetic resources and traditional knowledge, in particular relating to disclosure of origin or source, such as the proposals and existing measures set out in Part II above: these may relate to declaration of origin or source, evidence of prior informed consent, and/or evidence of fair and equitable benefit sharing);
- identifying genetic resources and traditional knowledge explicitly as prior art vitiating the novelty of a claimed invention;
- provisions requiring the disclosure of known genetic resources and traditional knowledge as prior art relevant to the assessment of the patentability of a claimed invention;
- provisions requiring a TK holder as the inventor or as one inventor when TK is a specific component of the claimed invention;
- when the origin of genetic resources is required for to enable the carrying out of the invention;
- when the disclosure of actual genetic resources, or even the physical deposit of a sample, is required for enablement;
- when obligations under access and benefit-sharing laws or agreements affect the entitlement to apply for a patent; and
- when disclosure of other information is required under other legal obligations, arising under contracts or access regulation.

The third element of the CBD COP invitation to WIPO concerned options for incentive measures for applicants. The ‘incentives measures’ discussed include legal, economic, social and moral incentives. The possible objectives of incentives were variously construed as promoting:

- compliance with disclosure requirements as such,
- ensuring prior informed consent and equitable benefit sharing,

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- conservation and sustainable use of genetic resources, and conservation of TK,
- innovation related to conservation and sustainable use, and
- disclosure of new information to the public.

Apart from incentive provisions, legislation could include sanctions where there is insufficient, wrongful or lack of disclosure of source and country of origin is discovered after the grant of a patent. The legal effect could include:

- Revocation of the patent where it is determined that the proper disclosure would have led to the refusal to grant the patent either on the grounds of lack of novelty due to the existence of prior art or on grounds of *ordre public* or morality and where there is fraudulent intention for the insufficient, wrongful or lack of disclosure. In addition to revocation, criminal and/or administrative sanctions may also be imposed, for example, where the insufficient, wrongful or lack of disclosure amounts to a false representation;
- Full or partial transfer of the rights to the invention where full disclosure would have shown that another person or community or governmental agency is the inventor or part inventor or would otherwise be entitled to all or part of the claimed invention; and,
- Narrowing the scope of the claims where parts of the claims are affected due to lack of novelty or fraudulent intention or where full disclosure would have led to refusal to admit those parts of the claims.

Similarly, where the failure to provide evidence of prior informed consent is discovered after the grant of a patent, the legal effect could include: Revocation of the patent or criminal and/or civil sanctions, including the possibility of punitive damages.

Additionally, sanctions should also apply in cases of failure to provide evidence of fair and equitable benefit sharing.

ⁱ See Blakeney, 'Intellectual Property Aspects of Traditional Agricultural Knowledge' in R.E.Evenson, V. Santaniello and D. Zilberman, Eds. *Economic and Social Issues in Agricultural Biotechnology*, Oxford, CABI Publishing, 2002, 43-60.

ⁱⁱ CBD, Art.1.

ⁱⁱⁱ See L. Glowka, *A Guide to Designing Legal Frameworks to Determine Access to Genetic Resources*, Gland, IUCN, 1998, 4.

^{iv} See J.I.Cohen, C.Falconi, J.Komen and M. Blakeney, *The Use of Proprietary Biotechnology Research Inputs at Selected CGIAR Centres*, International Service for National Agricultural Research (ISNAR), The Hague, 1998.

^v WIPO Doc. WO/GA/26/9

^{vi} *Ibid.*, Annex I, 10.

^{vii} WIPO Doc. SCP/10/10.

^{viii} WT/MIN(01)/DEC/1.

^{ix} WTO Doc., IP/C/W/368.

^x Decision VI/24C, para. 4.

^{xi} See WIPO Docs. WIPO/GRTKF/IC/Q.3 and WIPO/GRTKF/IC/5/10.

^{xii} See UNEP/CBD/COP/7/INF/17.

^{xiii} WIPO/IP/GR/05/01, 31 Jan. 2005.

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- xiv COM (2003) 821 – Communication from the EC to the European parliament . (23 Dec. 2003)
pp.17-18
- xv UNEP/CBD/WG-ABS/2/INF/4 (23 Oct. 2003) paras.55 & 67.
- xvi WIPO/GRTKF/IC/5/10 (2 May 2003) para.64.
- xvii *Ibid.*, para 98.