

National Group: South African Group

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Questionnaire February 2010

**Special Committees Q 94 – WTO/TRIPS and Q166 – Intellectual Property and
Genetic Resources, Traditional Knowledge and Folklore**

on the

**Requirement of indicating the source and/or country of origin of
genetic resources and traditional knowledge in patent applications**

Questions

1) Is there a legal requirement in your country that the source and/or country of origin of biological/genetic resources and traditional knowledge must be indicated in patent applications for inventions based on such biological/genetic resources or traditional knowledge? If yes, please quote the corresponding text from the law or regulations and reply to the following questions, if applicable:

The Patents Amendment Act no. 20 of 2005 and the Regulations issued under this Act were put into effect on 14 December 2007.

The Amendment Act amended the South African Patents Act no. 57 of 1978 as follows:

(1) by insertion into section 2 of the following definitions:

‘genetic resource’, means –

(a) any indigenous genetic material; or

(b) the genetic potential or characteristics of any indigenous species;

'indigenous biological resource' means an indigenous biological resource as defined in section 1 of the National Environmental Management: Biodiversity Act, 2004 (Act 10 of 2004);

'traditional knowledge' means the knowledge that an indigenous community has regarding the use of an indigenous biological resource or a genetic resource;

'traditional use' means the way in which or the purpose for which an indigenous community has used an indigenous biological resource or a genetic resource.

(2) insertion into section 30 of the following subsections:

(3A) Every applicant who lodges an application for a patent accompanied by a complete specification shall, before acceptance of the application, lodge with the registrar a statement in the prescribed manner stating whether or not the invention for which protection is claimed is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use.

(3B) The registrar shall call upon the applicant to furnish proof in the prescribed manner as to his or her title or authority to make use of the indigenous biological resource, genetic resource, or of the traditional knowledge or use if an applicant lodges a statement that acknowledges that the invention for which protection is claimed is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use.

(3) substitution in section 61(1) of the following paragraph (g):

- (g)** that the prescribed declaration lodged in respect of the application for the patent or the statement lodged in terms of section 30(3A) contains a false statement or representation which is material and which the patentee knew or ought reasonably to have known to be false at the time when the statement or representation was made.

The Regulations were amended as follows:

(1) by insertion of new paragraph (eA) in Regulation 22(1):

22.(1) An application for a patent shall be made on Form P1 and shall be accompanied by the following documents:

(a) - (e)

(eA) a statement in terms of section 30 (3A) on Form P.26, if the application is accompanied by a complete specification.

(2) by insertion of new Regulation 33A:

33A.(1) Form P.26 shall be lodged within six months of the lodging of an application accompanied by a complete specification, or within such further time as the registrar may on request allow.

(2) Where the Form P.26 contains a statement that the invention for which protection is claimed is based on or derived from an indigenous biological resource, a genetic resource, or traditional knowledge or use, the applicant shall, before acceptance of the application furnish the registrar with proof of his or her title or authority to make use of the indigenous biological resource, the genetic resource, or the traditional knowledge or use, by lodging with the registrar one or more of the following:

(a) a copy of the permit issued in terms of Chapter 7 of the National Environmental Management: Biodiversity Act, 2004;

- (b) if applicable, proof that prior consent had been obtained as contemplated in section 82(2)(a) or 82(3)(a) of the National Environmental Management: Biodiversity Act, 2004;
 - (c) if applicable, proof of a material transfer agreement as contemplated in section 82(2)(b)(i) of the National Environmental Management: Biodiversity Act, 2004;
 - (d) if applicable, proof of a benefit-sharing agreement as contemplated in section 82(2)(b)(ii) or 82(3)(b) of the National Environmental Management: Biodiversity Act, 2004;
 - (e) if applicable, proof of co-ownership of the invention for which protection is claimed;
 - (f) any other proof to the satisfaction of the registrar.
- (3) Any delay which occurs in the lodgment of a document as contemplated in subregulation (2) and which is not due to any act or omission on the part of the applicant shall be deemed to be a delay as contemplated in section 40(c).

(3) by insertion of new sub-section 67B(5):

67B.(5) Within six months of complying with section 43E(1)(a), or within such further time as the registrar may on request allow, an applicant shall lodge a statement in terms of section 30(3A) on Form P.26.

- a) Are these regulations found in patent law, general IP laws or in legislation implementing the Convention on Biological Diversity?

The above provisions were introduced into the South African Patents Act no. 57 of 1978 and the Regulations issued under the Act.

- b) What "triggers" the disclosure requirement, i.e. how close must the relationship of the invention to the biological/genetic resource be to require disclosure?

Every applicant for a patent must lodge the prescribed Form P.26.

If the invention claimed is

- **‘based on or derived from’ an indigenous biological or genetic resource, or**
- **‘based on or derived from’ the knowledge that an indigenous community has regarding the use of an indigenous biological or genetic resource, or**
- **‘based on or derived from’ the way in which, or the purpose for which an indigenous community has used in indigenous biological or genetic resource**

the applicant must mark the affirmative statement on these points on the relevant Form P.26.

If the invention claimed is not so based or derived, the applicant must mark the negative statement on these points.

If the affirmative statements have been marked, the applicant must furnish the Registrar with proof of his title or authority to make use of the indigenous resource by lodging –

- **a copy of the bioprospecting permit issued in terms of the National Environmental Management: Biodiversity Act no. 10 of 2004**
- **proof of prior informed consent**
- **proof of a material transfer agreement**
- **proof of a benefit-sharing agreement.**

It is evident that only the use of an indigenous biological resource, or of an indigenous genetic resource, or of indigenous traditional knowledge or use needs to be disclosed.

- c) Is it clear what the concept of “source” or “country of origin” or “country providing the resource”, and “based on genetic resource/traditional knowledge” or “derived from biological resource and associated traditional knowledge” means and what information must be included in the patent application?

It seems clear that the intention of the legislature was to require full disclosure only in the case of the use of indigenous biological or genetic resources, or the traditional knowledge or use of indigenous communities.

The supporting information to be lodged in the case of an affirmative disclosure is clearly defined (see Reg 33A(2) above).

- d) Is the disclosure requirement limited to biological/genetic resources or traditional knowledge of your country only or is it applicable also to biological/genetic resources or traditional knowledge obtained or obtainable from other countries and geographical areas?

The full disclosure requirement is limited to biological or genetic resources or traditional knowledge or use only of South Africa.

- e) Are there ways to complement, correct or amend the corresponding text in the patent application after filing?

The Form P.26 can be amended in accordance with the generally applicable provisions for the correction of clerical errors or the amendment of documents, contained in section 50 of the Patents Act and in Regulations 11 and 54 – 57. Section 50 provides that if it appears to the Registrar that the amendment will materially alter the scope of the document, the Registrar may require the request for amendment to be advertised in the Patent Journal, whereupon it is open to opposition by third parties.

- f) Is disclosure of “prior informed consent” and/or agreements on “fair and equitable benefit-sharing” required?

Yes – see answer to question b) above.

- g) Are human genetic resources treated differently or the same way as animal or plant genetic resources falling under the CBD?

The South African Environmental Management: Biodiversity Act, 2004 defines ‘indigenous biological resource’ with reference to ‘any living or dead animal, plant or other organism of an indigenous species’ (ie no express reference to human genetic material); and when the term ‘indigenous biological resource’ is used in relation to bioprospecting, human genetic material is expressly excluded.

The Patents Act (as amended) defines ‘indigenous biological resource’ with reference to the Biodiversity Act, but then has a separate definition of ‘genetic resource’ (see text as set out above). It will be noted that human genetic material is not expressly referred to, ie not expressly excluded.

It is submitted that the inclusion or otherwise of human genetic material may be open for argument.

- h) Is traditional knowledge properly defined, and is the source of traditional knowledge to be indicated only if it is connected to genetic/biological resources (e.g. falling under the CBD) or in general?

Traditional knowledge/use is defined in the relevant provisions of the Patents Act to be limited to the knowledge/use of indigenous communities. The term ‘indigenous community’ is not defined in either of the two statutes, although the term ‘indigenous species’ is defined in the Biodiversity Act as a species which occurs, or has historically occurred, within the borders of South Africa.

It is submitted that the legislature did not intend to require disclosure of traditional knowledge/use of communities other than indigenous communities of South Africa.

Taking into account the fact that the definition of ‘indigenous biological resource’ in the Patents Act expressly refers to South Africa’s Biodiversity Act, it is submitted that the intention of the legislature was to limit the disclosure requirement of traditional knowledge or use to cases where it is connected to genetic/biological resources falling under the CBD.

- i) Are sanctions foreseen for non-compliance (e.g. patent invalidation, revocation or lack of enforceability, patent transfer to the owner of the resource, fines, criminal sanctions etc.)?

A sanction (revocation) is provided for the lodging of a false declaration: section 61 of the Patents Act, 1978 provides that any person may apply for the revocation of a patent on a number of grounds; one such ground is set out in section 61(1)(g) – see text above – namely that the disclosure statement

contains a false statement or representation that the patentee knew or reasonably ought to have known to be false.

The disclosure statement (Form P.26) is a formal requirement to be met for acceptance of the application. Accordingly, non-compliance will prevent the application to be accepted and the patent to be granted.

- j) Does the law/regulation indicate that access to a genetic/biological resource would not mandate a disclosure in the patent application, if such access had occurred prior to a particular date, e.g. prior to the date of entry into force of the CBD?

No, the relevant statutory provision does not provide for a cut-off date. This is viewed as a shortcoming in the legislation to be corrected by way of a legislative amendment.

- 2) Please indicate your *experience* with the application of the legal requirement as listed under 1) when filing and prosecuting patent applications in your country.

The disclosure requirement has been in operation for only two years, so that there is limited experience with the implementation thereof. However, the following practical problems have been identified:

- (a) All patent applicants, regardless of the subject matter of the application, are required to lodge a disclosure declaration on Form P.26. This is viewed as extremely onerous on applicants with patents in unrelated fields of technology. A proposal has been made that the disclosure requirement should be subject matter specific, eg classification specific.
- (b) Reg 33A(1) requires the disclosure declaration to be lodged within six months of the filing of the application. This period is viewed as being too short. In relevant cases, an extensive investigation may be required in order to determine whether or not an indigenous biological resource and/or indigenous traditional knowledge or use played a part in the inventive process.

- 3) Please give *statistical data* on the number of applications mentioning source and/or country of origin of genetic resources and/or traditional knowledge, following the legal requirement as listed under 1) in your country. If such data are not available, please give an estimate of the number of such applications.

No exact statistical data is available. The experience of practitioners is that very few applications require an affirmative declaration, probably fewer than 5% of cases filed.

- 4) Please indicate whether *administrative or judicial decisions* on the application of the legal requirement as listed under 1) are available. If yes, please provide the text of such decisions.

No administrative or judicial decisions yet available.

- 5) If there is no legal requirement of indicating the source and/or country of origin of genetic resources and/or traditional knowledge in patent applications for inventions based on such genetic resources or traditional knowledge in your country: Do you know of any *project of law* in your country dealing with the topic? If yes please provide the corresponding text and review it for the questions a) to i) as under 1). Please include also links to websites which would allow us to follow the progress on these projects of law.

No applicable.

Procedure

It would be most helpful if the National Groups would fill out the Questionnaire and send in their answers to the General Secretariat of AIPPI by **12 March 2010** to:

f.martin@aippi.org

Please use a separate sheet for indicating your answers or include the answer in the present text at the end of each question.

For inquiries, please contact any of the chairs of Q94 and Q166:

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