

European Community and its Member States

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Disclosure of origin or source of genetic resources and associated traditional knowledge in patent applications

Proposal of the European Community and its Member States to WIPO

1. Introduction

This document outlines the basic features for a balanced and effective proposal on the disclosure of genetic resources and associated traditional knowledge (TK) in patent applications.

The European Community and its Member States already agreed in the 2002 Communication to the TRIPs Council to examine and discuss the possible introduction of a system, such as a self-standing disclosure requirement, that would allow States to keep track, at global level, of all patent applications with regard to genetic resources.¹ Since 2002, several developments in WIPO, WTO, FAO, the CBD and other relevant fora have contributed to the discussion. More recently, the Conference of the Parties of the Convention on Biological Diversity has invited WIPO to examine issues regarding the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications, including, inter alia, options for model provisions on proposed disclosure requirements.² The WIPO General Assembly of 2004 decided that WIPO should respond positively to this invitation. The present proposals reflect the position of the EC and its Member States on this issue.

2. A binding disclosure requirement that should be applied to all patent applications

In the 2002 Communication to the TRIPs Council, the EC and its Member States expressed their preference for a requirement that should be applied to all patent applications. The EC and its Member States also consider that the disclosure obligation should be mandatory. This implies that the disclosure requirement should be implemented in a legally binding and universal manner. A global and compulsory system creates a level playing field for industry and the commercial

¹ Communication by the EC and its Member States to the TRIPs Council on the review of Article 27.3 (b) of the TRIPs Agreement, and the relationship between the TRIPs Agreement and the Convention on Biological Diversity and the protection of traditional knowledge and folklore (WTO document IP/C/W/383).

² See document WIPO/GRTKF/IC/6/13.

exploitation of patents, and also facilitates the possibilities under Article 15(7) of the CBD for the sharing of the benefits arising from the use of genetic resources.

The introduction of such a scheme should take place in an efficient and timely way, and be related to the existing international legal framework for patents. In order to achieve such a binding disclosure requirement, amendment of the Patent Law Treaty (PLT), the Patent Cooperation Treaty (PCT) and, as the case may be, regional agreements such as the EPC will be necessary. The disclosure requirement then applies to all international, regional and national patent applications at the earliest stage possible.

3. The country of origin or, if unknown, the specific source of the genetic resource should be disclosed

It is suggested that, in order to provide patent applicants with a clear idea of what needs to be disclosed, the language used here should be the same as in the CBD definitions of country of origin, genetic resources and genetic material.³

First, the material that would be the subject of the requirement: Article 15 (7) of the CBD states that access and benefit-sharing objectives must be met with regard to “genetic resources”. It is therefore coherent to use the universally accepted CBD language. “Genetic resources” is defined in Article 2 CBD as “genetic material of actual or potential value”. The same provision states that “genetic material” includes “any material, of plant, animal, microbial or other origin containing functional units of heredity”. In this context, human genetic resources are excluded⁴, and this exclusion should be carried over to the proposed system.

Second, the origin of the genetic resource: a disclosure of origin requirement would assist countries providing access to genetic resources to monitor and keep track of compliance with national access and benefit-sharing rules. On this basis, the applicant should be required to declare the country of origin of genetic resources, if he is aware of it. No additional research on his part would be required. It is the disclosure of the country of origin that paves the way for monitoring the respect of the rules on access and benefit-sharing, where such rules are in place.

³ This proposal does not include the disclosure of the source in patent applications based on genetic resources or traditional knowledge acquired before the entry into force of the CBD.

⁴ As clarified by the CBD COP Decision II/11, paragraph 2.

The CBD defines the “country of origin” as the country which possesses those genetic resources in *in situ* conditions. Under the CBD, “*in situ* conditions” means conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.⁵

It is clear that it may not always be possible for the patent applicant to indicate the country of origin. In these situations, it is suggested to make use of the broader notion of “source”. If the country of origin is unknown, the applicant should declare the source of the specific genetic resource to which the inventor has had physical access and which is still known to him. The term “source” refers to any source from which the applicant has acquired the genetic resource other than the country of origin, such as a research centre, gene bank or botanical garden.⁶

Third, the connection between the material and the patented invention: the applicant must have used the genetic resources in the claimed invention. A notion should be applied that makes it possible for the applicant to disclose the material used in the invention in an adequate way, without having the obligation to make further research on the origin of the resource, taking into account the interests of the applicant, the patent office and other stake holders. A good balance can be found by requiring that the invention must be “directly based on” the specific genetic resources. In such circumstances, the invention must make immediate use of the genetic resource, that is, depend on the specific properties of this resource. The inventor must also have had physical access to the genetic resource, that is, its possession or at least contact which is sufficient enough to identify the properties of the genetic resource that are relevant for the invention.⁷

⁵ Article 2.

⁶ This other source can include the “Multilateral System” as a source of genetic resources belonging to taxa included in annex 1 of the International Treaty on Plant Genetic Resources for Food and Agriculture. According to Article 12.3 (b) of the International Treaty, “access shall be accorded expeditiously, without the need to track individual accessions”. The Multilateral System is the source of the genetic resources, as well as the beneficiary of the sharing of profits from their commercialisation.

⁷ See similarly the additional comments by Switzerland on its proposals regarding the declaration of the source of genetic resources and traditional knowledge in patent applications, PCT/R/WG/6/11, paragraph 27.

4. Disclosure of associated traditional knowledge

In this specific case, there are good reasons for an obligation to disclose that an invention is directly based on traditional knowledge associated with the use of genetic resources. According to Article 8 (j) of the CBD, there is a commitment to respect, preserve and maintain traditional knowledge.⁸

Traditional knowledge is of intangible nature and the obligation to disclose cannot be based on physical access. It could therefore be proposed that the applicant should declare the specific source of traditional knowledge that is associated with genetic resources, if he is aware that the invention is directly based on such traditional knowledge. In this context, the European Community and its Member States refer to Article 8 (j) of the CBD where the notion “knowledge, innovations and practices” is used.

However, there are concerns about the possibly unclear scope of the term "traditional knowledge". In order to achieve the necessary legal certainty, a further in-depth discussion of the concept of TK is necessary.

5. A standardised and formal requirement

In order to become effective, the way that the relevant information will be submitted from the patent applicant to the patent offices must be standardised. This should be organised in a non-bureaucratic and cost-efficient manner. An overwhelming majority of patent applicants do not base their inventions on genetic resources and/or associated TK and for them the burden should be limited to an absolute minimum.

Competent patent authorities, in particular patent offices, are not required to make an assessment on the content of the submitted information. They must also not be obliged to keep track whether the patent applicant has obtained the relevant material in a way compatible with benefit-sharing and prior informed consent provisions. Their role can be limited to checking whether the formal requirements are fulfilled, in particular, whether the applicant who declares that the invention is directly based on genetic resources and/or associated TK has subsequently disclosed information.

⁸ The Bonn Guidelines adopted under the CBD to implement its Articles 15 and 8(j) address specifically all genetic resources and associated TK.

The EC and its Member States propose that the disclosure of the information be organised by including questions to be answered in the standard patent application form. The applicant then can give either a negative or a positive response to the question whether the invention is directly based on genetic resources and/or associated TK. If the answer is negative, the applicant does not need to fulfil any other administrative requirement on this issue. A positive answer triggers the requirement to disclose the country of origin or source as foreseen. In the exceptional case that both the country of origin and the source are unknown to the applicant, this should be declared accordingly.

If the patent applicant fails to give a negative or positive response, or if he fails or refuses to disclose information on the country of origin or source in cases where he claims that the invention is directly based on genetic resources and/or associated TK, the patent application is not shaped in accordance with formal requirements, except where the applicant has declared that the country of origin and the source are unknown to him. An applicant should be given the possibility to remedy the omission within a certain time fixed under patent law. However, if the applicant continues to fail to make any declaration, then the application shall not be further processed and the applicant will be informed of this consequence.

6. What should happen in cases of incorrect or incomplete information?

Meaningful and workable sanctions should be attached to the provision of incorrect or incomplete information. Where it is proved that the patent applicant has disclosed incorrect or incomplete information, effective, proportionate and dissuasive sanctions outside the field of patent law should be imposed on the patent applicant or holder. If the applicant provides supplementary information during the processing of the application, the submission of this supplementary information should not affect the further processing of the application. For reasons of legal certainty, the submission of incorrect or incomplete information should not have any effect on the validity of the granted patent or on its enforceability against patent infringers.

It must be left to the individual Contracting State to determine the character and the level of these sanctions, in accordance with domestic legal practices and respecting general principles of law. Both within WIPO as in other international fora means could be discussed to develop such sanctions.

7. Exchange of information

An indispensable measure that makes the disclosure requirement outlined in the previous sections an effective incentive to comply with access and benefit-sharing rules is the introduction of a simple notification procedure to be followed by the patent offices. The latter, every time they receive a declaration disclosing the country of origin or source of the genetic resource and/or associated TK, should notify this information to a centralised body. This could be done, for instance, by means of a standard form. That would facilitate the monitoring – by countries of origin and TK holders – of the respect of any benefit-sharing arrangements they entered into. The relevant information must be made available in accordance with the present rules on the confidential nature of applications.

The notification should be as simple as possible and must not lead to an unnecessary administrative burden for patent offices. The exchange of information should also be managed in a cost-effective way and without unnecessary additional charges imposed on patent applicants. This could be achieved, for example, by using electronic means.

It would be adequate to identify in particular the Clearing House Mechanism of the CBD as the central body to which the patent offices should send the information available from the declarations on disclosure.

8. Summary

In summary, the EC and its Member States propose the following:

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

These proposals attempt to formulate a way forward that should ensure, at global level, an effective, balanced and realistic system for disclosure in patent applications.
