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THE RELATIONSHIP BETWEEN THE TRIPS AGREEMENT, THE CONVENTION ON BIOLOGICAL DIVERSITY AND THE PROTECTION OF TRADITIONAL KNOWLEDGE

AMENDING THE TRIPS AGREEMENT TO INTRODUCE AN OBLIGATION TO DISCLOSE THE ORIGIN OF GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE IN PATENT APPLICATIONS

Communication from Norway

The following communication, dated 13 June 2006, is being circulated to the General Council, to the TNC and to the Regular Session of the Council for TRIPS at the request of the Delegation of Norway.

I. INTRODUCTION

1. The TRIPS Agreement and the Convention on Biological Diversity (CBD) can and should be implemented in a mutually supportive manner. However, the interaction between the two treaties would be enhanced by introducing a mandatory obligation in the TRIPS Agreement to disclose the origin of genetic resources and traditional knowledge in patent applications. This communication outlines the key principles Norway believes must be taken into account in this context.

2. An obligation under the TRIPS Agreement to disclose the origin of genetic resources when applying for patent protection would ensure transparency as regards the origin of biological materials that are to be patented. This would make it easier for parties to enforce their rights to their own genetic resources when these are the subject of a patent application, which in turn would make the CBD provisions on prior informed consent and benefit-sharing more effective. Furthermore, such a disclosure obligation would be a significant step towards giving effect to Article 16.5 of the CBD, which provides that the Contracting Parties should cooperate to ensure that intellectual property rights are supportive of and do not run counter to the objectives of the CBD. A disclosure requirement would ensure that novelty criteria are met, which accords with the basic intentions and principles of the patent system and increases its credibility.

3. An equivalent disclosure obligation should apply where the claimed invention relates to or applies traditional knowledge, even where the traditional knowledge is not directly linked to genetic resources. The CBD only applies to traditional knowledge linked to genetic resources. However, a general obligation to disclose any traditional knowledge upon which an invention is based would help to prevent patents being wrongfully granted.

II. KEY PRINCIPLES FOR A DISCLOSURE OBLIGATION

4. Norway is of the opinion that such a disclosure obligation should be based on the following key principles:

(a) A binding international obligation should be introduced to include information on the supplier country (and the country of origin, if known and different) of genetic resources and traditional knowledge in patent applications. The supplier country (or country of origin, if relevant) of traditional knowledge must be disclosed even if the traditional knowledge has no connection with genetic resources. If the national law of the supplier country or country of origin requires consent for access to genetic resources or traditional knowledge, the disclosure obligation must also encompass a duty to state whether such consent has been given. If the country of origin is unknown, that fact must be disclosed.

(b) The disclosure obligation should apply to all patent applications (international, regional and national).[1]

(c) If the applicant is unable or refuses to give information despite having had an opportunity to do so, the application should not be allowed to proceed.

(d) If it is subsequently discovered that incorrect or incomplete information has been given, this should not affect the validity of the granted patent, but should be penalised in an effective and proportionate way outside the patent system.

(e) A simple notification system should be introduced, under which patent offices send all declarations of origin they receive to the CBD Clearing-House Mechanism.

III. REASONS FOR THIS PROPOSAL

5. A disclosure of origin obligation as described above would support the aims of the CBD, and in particular the aim to secure an equitable sharing of the benefits of exploiting genetic resources. A disclosure obligation would make it easier to verify whether genetic resources have been collected in accordance with national rules requiring consent, and whether the conditions for such consent have been met. The disclosure obligation would also make patent applicants aware of the importance of complying with the CBD, as implemented by the various states. The same would apply where states have rules requiring consent for exploitation of traditional knowledge independently of the CBD.

6. Information on origin would also make it easier to ascertain whether the patentability requirements in the TRIPS Agreement have been met, and e.g. help to prevent patenting in cases where the novelty or inventive step requirements have not been met (even where genetic resources are

[1] The specific provisions of the disclosure obligation should be fully compatible with the International Treaty on Plant Genetic Resources for Food and Agriculture and the Multilateral System established under it.

not involved). A disclosure obligation would, therefore, also be useful in ensuring that patents are not granted contrary to the fundamental principles of patent law.

IV. FURTHER DETAILS ON THE EFFECTS OF NON-COMPLIANCE WITH THE DISCLOSURE OBLIGATION

7. At the application stage, a breach of the disclosure obligation should be treated as a formal error, i.e. the application should not be processed until the required information has been submitted. Where appropriate, the application could eventually be rejected.

8. If, however, the breach of the disclosure obligation 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 outside the patent system, for example criminal or administrative penalties. If the applicant has acted in good faith, the fact that incorrect or incomplete information has been given may have no consequences at all. Upholding post-grant patent protection despite non-compliance with the disclosure obligation is important to avoid creating unnecessary uncertainty in the patent system. Moreover, revoking a patent as a consequence of non-compliance with the disclosure obligation would not benefit those who consider themselves to be entitled to a share of the benefits of the invention. Once patent protection is revoked, there are no exclusive rights from which benefits could be derived.

9. A patent can be revoked if the substantive patentability criteria have not been met, for example if a patent does not differ from traditional knowledge to the degree required to constitute a patentable invention. In such a case, it would be the lack of inventive step that constitutes the reason for invalidity, and not the breach of the disclosure obligation.

V. HOW SHOULD THE TRIPS AGREEMENT BE AMENDED TO INTRODUCE A MANDATORY DISCLOSURE OBLIGATION?

10. The TRIPS Agreement is commonly understood to *permit* Members to introduce disclosure of origin obligations in their national legislation. In order to *oblige* Members to introduce a mandatory disclosure obligation, the TRIPS Agreement would need to be amended. The obligation to disclose origin is linked to the patent application, but does not constitute a substantive patent criterion. In Norway's opinion, it would therefore be most appropriate to introduce a new provision in the TRIPS Agreement immediately following Article 29, which contains provisions on the disclosure of information related to the invention.

VI. SUMMARY

11. Norway supports the amendment of the TRIPS Agreement to introduce a mandatory obligation to disclose the origin of genetic resources and traditional knowledge in patent applications. Such a disclosure obligation should be introduced in a new Article 29*bis* and should provide that patent applications should not be processed unless the required information has been submitted. However, non-compliance with the disclosure obligation discovered post-grant should not affect the validity of the patent.

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