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INTERGOVERNMENTAL COMMITTEE ON INTELLECTUAL PROPERTY AND GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE

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POLICIES, MEASURES AND EXPERIENCES REGARDING INTELLECTUAL PROPERTY AND GENETIC RESOURCES: SUBMISSION BY NORWAY

Document prepared by the Secretariat

1. At its fifteenth session, held from December 7 to 11, 2009, the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ('the Committee'):

> "invited Member States and observers to make available to the Secretariat papers describing regional, national and community policies, measures and experiences regarding intellectual property and genetic resources before February 12, 2010, and requested the Secretariat to make these available as information documents for the next session of the Committee." […]

2. Further to the decision above, the WIPO Secretariat issued a circular to all Committee participants, dated January 15, 2010, recalling the decision and inviting participants to make their submissions before February 12, 2010.

3. Pursuant to the above decision, the Delegation of Norway submitted a document entitled “Paper from Norway describing Disclosure Obligation in Patent Applications” and requested it be made available as an information document for the sixteenth session of the Committee.

4. The document is reproduced in the form received and contained in the Annex to this document.

[Annex follows]

ANNEX

PAPER FROM NORWAY DESCRIBING DISCLOSURE OBLIGATION IN PATENT APPLICATIONS

The Norwegian Patents Act[1] has since February 1st 2004 regulated a patent applicant's obligation both with regard to disclosure of origin of biological material and also prior consent if required in the country of origin. The disclosure obligation was expanded July 1st 2009 to also include traditional knowledge. The Norwegian Plant Variety Act Section 4 third paragraph has the similar provision as the Patents Act Section 8 b.

The relevant provisions from the Patents Act are reproduced here:

Section 8 b. *If an invention concerns or uses biological material or traditional knowledge, the patent application shall include information on the country from which the inventor collected or received the material or the knowledge (the providing country). If it follows from the national law in the providing country that access to biological material or use of traditional knowledge shall be subject to prior consent, the application shall state whether such consent has been obtained.*

If the providing country is not the same as the country of origin of the biological material or the traditional knowledge, the application shall also state the country of origin. For biological material, the country of origin means the country from which the material was collected from its natural environment and, for traditional knowledge, the country in which the knowledge was developed. If the national law in the country of origin requires that access to biological material or the use of traditional knowledge shall be subject to prior consent, the application shall state whether such consent has been obtained. If the information set out in this subsection is not known, the applicant shall state that.

For biological material, the duty to disclose information under the first and second paragraphs applies even where the inventor has altered the structure of the received material. The duty to disclose information does not apply to biological material derived from the human body. If access to biological material has been provided in pursuance of Article 12.2 and Article 12.3 of the International Treaty of 3 November 2001 on Plant Genetic Resources for Food and Agriculture, a copy of the standard material transfer agreement (MTA) stipulated in Article 12.4 of the Treaty shall be enclosed with the patent application instead of the information stipulated in the first and second paragraphs.

Breach of the duty to disclose information is subject to penalty in accordance with the General Civil Penal Code § 166. The duty to disclose information is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.

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[1] The Norwegian Patents Act in full can be accessed at this address: http://www.patentstyret.no/en/english/Legal_texts/The-Norwegian-Patents-Act/#chapter%203

Section 1 third paragraph *in fine*. *Biological material means, for the purpose of this legal text, material that contains genetic information, and can reproduce itself or be reproduced in a biological system.*

Section 33 second paragraph, extract. The provisions in sections 8 b and 8 c [human material] do not apply to international applications.

Section 166 of the Civil Penal Code: *Any person shall be liable to fines or imprisonment for a term not exceeding two years who gives false testimony in court or before a notary public or in any statement presented to the court by him as a party to or legal representative in a case, or who orally or in writing gives false testimony to any public authority in a case in which he is obliged to give such testimony, or where the testimony is intended to serve as proof.*

The same penalty shall apply to any person who causes or is accessory to causing testimony known to him to be false to be given by another person in any of the above-mentioned cases.

Because the disclosure obligation only applies to national patent applications and also Norway's membership to the European Patent Organisation, we receive very few applications within this field. The experience with regard to disclosure is therefore limited. However, in the national patent applications which concern or use biological material we can report that the experiences are varied. Many applicants do not have problems with submitting the information but we do not have a complete picture of the situation due to the fact that some applications are abandoned for other reasons. We have not received oppositions based on information of disclosure nor experienced other consequences such as prosecution before the courts. We have not yet received any patent application that discloses an invention which concerns or uses traditional knowledge.

The following Questions and Answers are based on legislation in force in Norway and could be of interest to the Committee:

1. PROVIDING COUNTRY AND COUNTRY OF ORIGIN

(1) We understand that "[if] the Providing Country is different from Country of Origin, the applicant shall also state the country of origin" and "[if the] Country of Origin is unknown to the applicant, this shall be stated."

Why does your system require that the Country of Origin as well as the Providing Country be disclosed?

Answer to Question 1 (1):

The identification of the country of origin is important because according to the CBD – to which Norway is a party – only the country of origin or a Contracting Party that has acquired the resources in accordance with the CBD is competent to provide consent to access to genetic resources.

Further Question on Answer 1 (1)

Paragraph 5 and 7, Article 15 of the CBD provides that the prior informed consent (PIC) shall be obtained from the "Contracting Party providing" such resources and the benefits arising from the use of the resources shall be shared with "Contracting Party providing" such resources.

On the assumption that certain genetic resources X are passed in the following process:

Country of Origin A → Cultural Collection B (Country B) → User C (Country C)

In this case, User C is required to obtain a PIC from Country B or Cultural Collection B under the CBD.

As regards the access to genetic resources held by Country of Origin A, not User C but Cultural Collection B is obliged to obtain a PIC from and share benefits with Country of Origin A. The CBD is not considered as imposing any obligations on User C regarding the access by Cultural Collection B to the genetic resources held by Country of Origin A. The CBD is also not considered as imposing any research of information on what country Collection B got the resource from.

Please let us know the reason that your disclosure system oblige to disclose the information on country of origin.

Answer to Further Question on Answer 1 (1):

The reason for going beyond the CBD in this regard is that the provision in the Norwegian Patents Act furthers the aims of the Convention. Even if the supplier country is obliged to secure the fulfillment of the obligations under the Convention, it is the system of the Patents Act of Norway that the patent applicant should give information known to him about the country of origin of the biological material. The duty to disclose is however based on what facts that can be obtained depending on the circumstances, and if the applicant cannot establish the information based on reasonable questions to the supplier he is considered to be in compliance if he answers that the information is not known to him.

Further Question 2 on Answer 1 (1)

Where certain genetic resources are passed in the following process:

Country of Origin A → Cultural Collection B (Country "B") → User B (Country "B")

Are we correct in understanding that User B should disclose the name of Country B as "the country from which the inventor collected or received the material" in your disclosure system?

Answer to Further Question 2 on Answer 1 (1):

You are correct in your understanding.

2. BIOLOGICAL MATERIAL

(1) Is commercially obtained Biological Material within the scope of the disclosure requirements? If the answer is "yes," how can we identify the sources or country of origin of such Biological Material?

Answer to Question 2 (1):

The answer is yes. The patent applicant will have to ask the provider about the origin of the biological material. If the applicant does not receive an answer from the provider, the applicant can state that he does not know where the material comes from. According to the preparatory legal works this would suffice and the Norwegian Industrial Property Office will not make further enquiries.

Further Question on Answer 2 (1)

One of the purposes of disclosing the country of origin could be to ensure the compliance of provisions on PIC obtainment and benefit sharing.

Could you give us your rationale for obliging to disclose providing countries of already-marketed genetic resources?

Answer to Further Question on Answer 2 (1):

The rationale is as stated in our answer to question 1 above to further the objectives of the CBD. In order to secure a certain balance in the obligation to disclose, it is our understanding that all biological material should be treated in the same manner and hence further transparency.

(2) Also, for patent applications containing plant names, in many cases, those plants actually used in the invention are not the raw plants themselves but processed products such as condensed extracts or dry powders that are commercially available. Will such processed genetic resource products be covered by disclosure requirements? If the answer is "yes," does this mean that (i) information regarding the raw plants used in the product must be disclosed, (ii) information regarding the processed product itself must be disclosed, or (iii) both (i) and (ii)?

Answer to Question 2 (2):

The answer is no. Condensed extracts and dry powders would normally be outside the scope of what constitutes "biological material" according to the Patent Act Section 1 paragraph 4 *in fine*, since such material would not fulfill both of the requirements namely content of genetic information and the ability to reproduce or to be reproduced in a biological system.

(3) Some genetic resources, such as animals and fish, cross national borders on their own while engaged in natural activities such as migration. Will the disclosure of the origin of such resources be required under your system? If the answer is "yes," please explain.

Answer to Question 2 (3):

The answer is yes. Animals and fish would in such cases have multiple origins and it will suffice to state one such origin similar to where the resources have been accessed.

(4) The genetic resources obtained before the CBD came into effect are not within the scope covered by disclosure requirements. Is our understanding correct?

If yes, how can an applicant and patent examiners judge if a certain genetic resource has been obtained before or after the CBD came into force?

Answer to Question 2 (4):

The understanding is not correct. The disclosure requirement applies to all biological material.

(5) Until the CBD came into effect, users of genetic resources had not been obliged to obtain PIC or share benefits. On the assumption that the purpose of introducing the disclosure lies in ensuring compliance of provisions on PIC and benefit sharing, imposition of such obligation on genetic resources obtained before the CBD took effect is excessive.

Could you give us your rationale for that?

Answer to Question 2 (5):

The principle in the CBD about sovereignty over a country's own resources is considered to be international law even before the CBD came into effect and consequently principles to secure consent and sharing of benefits are only mechanisms furthering countries' ability to safeguard their rights.

3. INVENTION CONCERNING OR USING BIOLOGICAL MATERIAL

(1) Please explain the definition of "an invention concerning or using biological material." Are such inventions those that state biological materials only in the claim of a patent application, or those that also state biological materials in the patent description? How can patent examiners identify those inventions?

Answer to Question 3 (1):

An invention concerning or using biological material encompasses use of such material in the invention. The scope of protection covered by the patent application will be decisive for the determination of the disclosure requirement, hence an invention which purpose is to perform extraction of sap from a tree will not involve said requirement. On the other hand would an invention which use the biological material directly and that also is covered by the patent protection be subject to the disclosure requirement.

(2) As is often the case, the numbers of biological material in claims or a description of one application (sometimes 100 and more biological material indicated in a description of one patent application). In this case, should the applicant disclose all providing countries/countries of origin of the biological materials one by one?

Answer to Question 3 (2):

The answer is yes.

(3) If an applicant uses certain biological materials at the testing stage during the course to complete the invention, but the applicant doesn't use the biological materials for the completed invention in the claims, this invention can be included within the scope of "an invention concerning or using biological material"?

Answer to Question 3 (3):

The answer is no.

Further Question on Answer 3 (1)

Please let us know if the obligation to disclose the country of origin is applicable to the cases cited below. Please also let us know specifically about which genetic resources information should be disclosed.

Answer to Further Question on Answer 3 (1):

The answer is the same for all the following three cases; the applicant has the obligation to disclose the origin of only genetic material A. The reasoning for this is that it is only this resource that is material for the invention. The different drafting techniques of the patent application do not influence the disclosure obligation.

-- CASE 1 –

<Claim>

Health Food Z characterized by containing, as its constituents, Ingredient-a- extracted from Genetic Resource-A- and some additives.

<Specification>

This invention is about a health food with a higher skin-whitening effect than existing products.

This health food (hereinafter referred to as "Health Food Z") contains, as its constituents, Ingredient-a- extracted from Genetic Resource-A- and some optionally selected additives.

By adding Ingredient-a- extracted from Genetic Resource-A-, Health Food Z can achieve a higher skin-whitening effect than existing products.

Additives can be optionally selected from usual additives which have effect to prevent decomposition of Health Food Z. Ingredient-b- extracted from Genetic Resource-B-, Ingredient-c- extracted from Genetic Resource C, Compound D, and Compound E are well known as such additives to prevent decomposition of Health Food Z. Any of them can be used for Health Food Z.

-- CASE 2 –

<Claim>

Health Food Z characterized by containing, as its constituents, Ingredient-a- extracted from Genetic Resource-A- and one of the following compounds as an additive: Ingredient-b- extracted from Genetic Resource-B-, Ingredient-c- extracted from Genetic Resource-C-, Compound D, or Compound E.

<Specification>

This invention is about a health food with a higher skin-whitening effect than existing products.

This health food (hereinafter referred to as "Health Food Z") contains, Ingredient-a- extracted from Genetic Resource-A- and one of the following compounds as an additive: Ingredient-b- extracted from Genetic Resource-B-, Ingredient-c- extracted from Genetic Resource C, Compound D, or Compound E.

By adding Ingredient-a- extracted from Genetic Resource-A-, Health Food Z can achieve a higher skin-whitening effect than existing products.

Additives can be optionally selected from usual additives which have effect to prevent decomposition of Health Food Z. Ingredient-b- extracted from Genetic Resource-B-, Ingredient-c- extracted from Genetic Resource-C-, Compound D, and Compound E are well known as such additives to prevent decomposition of Health Food Z. Any of them can be used for Health Food Z.

-- CASE 3 –

<Claim>

Health Food Z characterized by containing, as its constituents, Ingredient-a- extracted from Genetic Resource-A- and Ingredient-b- extracted from Genetic Resource-B- as additive.

<Specification>

This invention is about a health food with a higher skin-whitening effect than existing products.

This health food (hereinafter referred to as "Health Food Z") contains, as its constituents, Ingredient-a- extracted from Genetic Resource-A- and Ingredient-b- extracted from Genetic Resource-B- as an additive.

By adding Ingredient-a- extracted from Genetic Resource-A-, Health Food Z can achieve a higher skin-whitening effect than existing products.

Ingredient-b- extracted from Genetic Resource-B- is added as an additive to prevent decomposition of Health Food Z. Ingredient-b- extracted from Genetic Resource-B-, Ingredient-c- extracted from Genetic Resource-C-, Compound D, and Compound E are well known as such additives to prevent decomposition of Health Food Z. It is also well known that Ingredient-b- extracted from Genetic Resource-B- particularly has excellent effect to prevent decomposition.

[End of Annex and of document]