

Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore

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INFORMATION REGARDING THE DISCLOSURE REQUIREMENT IN NORWEGIAN LAW

Document submitted by the Delegation of Norway

1. On January 31, 2013, the International Bureau of the World Intellectual Property Organization (WIPO) received a request from the Delegation of Norway to issue a document entitled “Communication from Norway to the IGC – Information regarding the disclosure requirement in Norwegian Law”, as an information document, under Agenda Item 6, for the Twenty-Third Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (“the IGC”).
2. Pursuant to the request above, the annex to this document contains the document as submitted by the Delegation of Norway.

3. *The IGC is invited to take note of this document and the Annex to it.*

[Annex follows]

COMMUNICATION FROM NORWAY TO THE IGC – INFORMATION REGARDING THE DISCLOSURE REQUIREMENT IN NORWEGIAN LAW

1. INTRODUCTION

On previous sessions of the IGC several delegations have asked for information regarding enforcement of the disclosure requirements in national patent laws. In this communication Norway presents the disclosure requirements in its Patent Act and Plant Breeder's Act and some preliminary findings from an ongoing review of the disclosure requirements. This document mainly summarizes information presented to the IGC on earlier occasions. However, the information regarding the ongoing review has not been presented before.

2. PATENTS ACT – DISCLOSURE OF ORIGIN FOR BIOLOGICAL MATERIAL

When the EU directive concerning patenting of biotechnological inventions (98/44/EC) was implemented in the Norwegian Patents Act (from 1 February 2004) an additional provision was introduced. This provision sets forth an obligation on the applicant in a patent application to disclose the origin of biological material that the invention concerns or uses. The purpose of this provision is to fulfill the objectives of the Convention on Biological Diversity (CBD). In the draft resolution to the Norwegian Parliament (Stortinget) it was stated (unofficial translation from Norwegian):

“If the patent applicant disclose the country of origin, it can be easier to control whether genetic resources have been collected in compliance with national legislation related to consent, and if possible conditions for such consent have been complied with. The duty to disclose can also make patent applicants conscious on the importance of compliance with the CBD as it has been implemented in the various countries. If it is given information about country of origin, it can furthermore be easier to decide if the conditions for patentability are fulfilled, or whether the application concerns something which is known (traditional knowledge or similar).”

If an invention concerns or uses biological material it follows from the Patents Act Section 8 b first paragraph first sentence that the applicant in the application shall disclose the country from which the inventor obtained or collected the biological material (the providing country). Furthermore, Section 8 b first paragraph second sentence sets forth that when the national law in the providing country requires consent to obtain or collect biological material, the applicant shall provide to the Norwegian Industrial Property Office information confirming whether such consent is given.

Section 8 b second paragraph first sentence sets forth that, if the country providing the biological material is another country than the country of origin, the applicant shall inform the Industrial Property Office of both countries. It follows from Section 8 b second paragraph second sentence that the biological material's country of origin is the country from which the material was collected from its natural environment. If the national law in the country of origin requires that consent for the collection of biological material must be given, the applicant in the application shall inform whether such consent has been obtained, see Section 8 b second paragraph third sentence. If the applicant does not know either the biological material's country of origin or the national law in the country of origin, the applicant must inform the Industrial Property Office of this, see Section 8 b second paragraph fourth sentence.

Section 8 b third paragraph first sentence sets forth that the disclosure obligation concerning biological material in Section 8 b first and second paragraph applies even if the inventor has changed the structure of the biological material. Section 8 c (and not 8b) applies if the biological material originates from human beings.

It follows from the Patents Act Section 33 second paragraph first sentence that the disclosure requirement for biological material does not apply to international patent applications; that is applications filed under the PCT. The reason being that the legislator considered it to be inconsistent with the PCT to require disclosure from international applications.

Applications for European patents are processed by the European Patent Office according to the EPC. This convention does not regulate disclosure and does not mirror Section 8 b of the Patents Act. The obligation to disclose accordingly applies only to national patent applications. Filings under PCT and EPC constitute approximately 80 percent of the patents granted in Norway during the recent years.

A violation of the obligation to disclose according to Section 8 b is punishable if the action falls within the General Civil Penal Code Section 166, see Section 8 b fourth paragraph first sentence. The General Civil Penal Code Section 166 regulates and covers a situation in which a person intentionally gives incorrect information. This, for example, may be incorrect information on the country of origin or whether consent has been obtained. Also a person incorrectly stating that he does not have information concerning country of origin etc. can be punished if he did so willfully. A mere refusal to give information is not punishable under the General Civil Penal Code Section 166.

It follows from Section 8 b fourth paragraph second sentence that a violation of the disclosure obligation neither affects the processing of the patent application nor a granted patent's validity. The same follows from the preamble of Directive 98/44/EC recital 27. This implies that the processing of the application must be normal even if the applicant denies giving information or if it has been revealed that the applicant has given incorrect information.

3. PATENTS ACT - DISCLOSURE OF ORIGIN OF TRADITIONAL KNOWLEDGE AND MTA

The provision concerning disclosure in the Patents Act Section 8 b was amended in accordance with the Act of 19 June 2009 no. 100 regarding Nature Diversity to also cover traditional knowledge concerned or used by an invention. The provision entered into force on 1st July 2009. The duty to disclose information relating to traditional knowledge does not apply to applications filed under the PCT or EPC.

At the same time a provision was added to Section 8 b third paragraph third sentence. This provision sets forth that when biological material is acquired in accordance with Article 12 no. 2 and 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 of Section 8 b. The reason is that the Treaty Article 11 establishes a multilateral system with facilitated access to plant genetic material for food and agriculture. Such facilitated access is given according to the Treaty's Article 12 no. 4 based on a standard MTA containing specific provisions on the terms for facilitated access under the multilateral system.

4. THE DISCLOSURE REQUIREMENT IN THE PLANT BREEDER'S ACT

There were no provisions regarding disclosure of origin in the Plant Breeder's Act until the Act of 19 June 2009 no. 100 regarding Nature Diversity entered into force on 1st July 2009. This Act introduced in the Plant Breeder's Act Section 4 an obligation similar to the one in the Patents Act Section 8 b. That is to disclose the origin of biological material and traditional knowledge used in the breeding of the new variety. This means that information about country of origin etc. shall be given for the plant material and possible traditional knowledge. The penal provisions

are the same as in the Patents Act Section 8 b, namely the General Civil Penal Code Section 166. A violation of the obligation to disclose does not influence the processing of neither the application nor the validity of a protected plant variety.

5. EXPERIENCES WITH THE DISCLOSURE REQUIREMENT IN THE PATENTS ACT UP TO JANUARY 2013

Based on a request from the Parliament (Stortinget) the Government is carrying out a review of the enforcement of the disclosure requirement up to date. A consultation paper has been on public consultations in 2012, and the Government will present the conclusions from its review to the Parliament later on in 2013. Some preliminary findings from the review are presented below:

The disclosure requirement for biological material was introduced with effect from February 1, 2004.

The Norwegian Industrial Property Office has introduced routines to safeguard that the obligation to disclose is complied with. If the Industrial Property Office becomes aware of an application covered by Section 8 b, which is lacking the required information, it will inform the applicant of the default.

The Norwegian Industrial Property Office in January 2013 had started the processing of 26 applications covered by Section 8 b. All these cases relate to biological material. No application has concerned traditional knowledge. 20 of the 26 applications are not publicly available. Amongst the 20 applications two are still being processed whereas 18 have been withdrawn or abandoned. The six cases that are publicly available have the following distribution: Two are abandoned, two are granted and two are under processing. Information on disclosure has been provided for in both the granted cases.

Amongst the 26 applications the obligation to disclose was fulfilled already on filing in ten cases. 16 applications lacked the required information according to Section 8 b. The Industrial Property Office informed the applicants in six of these applications that required information was lacking. In one of these six applications information was given afterwards. The Industrial Property Office has not requested information in the remaining ten applications. All these ten applications are shelved.

The experience gained by the Norwegian Industrial Property Office suggests that the information obtained according to Section 8 b is valuable in the processing of the patent applications. The information gives a better foundation for the assessment of whether the requirements of novelty and inventive step have been met. The resources used by the Industrial Property Office to fulfill the obligations according to Section 8 b are limited.

6. CITATION OF RELEVANT LEGAL PROVISIONS

The Patents Act (Act No. 9 of December 15, 1967 on patents, amended last March 26 2010 as from July 1 2010) (unofficial translation from Norwegian) reads:

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.

Section 1 [extract] 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 first sentence The provisions in Sections 8 b and 8 c do not apply to international applications.

General Civil Penal Code § 166:

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.

[End of Annex and of document]