IS - ICELAND

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1. Requirements for Deposit

Art. 8(6) of the Patents Act No. 17/1991 (as amended in 2004):

If it is necessary for the invention to use biological material which is neither available to the public nor can be described in the application in such a manner that, based on the application, a person skilled in the art would be able to execute the invention, a sample of the biological material must be deposited no later than the filing date of the application.

Art. 44 of Regulation on Patents No. 477/2012:

Samples of biological material as referred to in Art. 8(6) of the Patents Act must be deposited with an institution which is an internationally recognized depositary under the Treaty done at Budapest 28 April 1977 on the International Recognition of the Deposit of Biological Material for the Purposes of Patent Procedure (the Budapest Treaty) or with other depositaries recognized by the European Patent Office.

Deposits shall be in accordance with the provisions of the Budapest Treaty.

WIPO publishes a list of those institutions which are internationally recognized depositaries for biological material under the Budapest Treaty.

2. Time of Deposit

Art. 8(6) of the Patents Act No. 17/1991 (as amended in 2004):

[...a sample of the biological material must be deposited no later than the filing date of the application.]

Art. 45 of Regulation on Patents No. 477/2012:

If an applicant has deposited a sample of biological material, he/she shall, within 16 months from the date of filing or, if priority is claimed, from the priority date, inform the Icelandic Intellectual Property Office in writing of the institution where the deposit has been made and which deposit number the institution has allotted the sample. In the case of international applications, WIPO shall be provided with this information within the same time limit.

If, prior to the expiry of the time limit referred to in the first paragraph, the applicant requests that documents relating to the application be made available to the public

earlier than prescribed in Art. 22(1) and (2) of the Patents Act, the applicant shall provide the information referred to in the first paragraph at the latest when the request is submitted. If, prior to the expiry of the time limit referred to in the first paragraph, the applicant of an international application requests early publication of the application under Art. 21(2)b of the PCT, the applicant shall provide WIPO with the said information at the latest when the request is submitted.

If a deposited sample of biological material has been transferred from one international depositary to another, as provided for in Rule 5.1 of the Regulations under the Budapest Treaty, the applicant shall, as soon as possible after receiving a receipt for the transfer of the sample, inform the Icelandic Intellectual Property Office of the new deposit number and the depository.

The Icelandic Intellectual Property Office may require the applicant to submit a copy of the receipt issued by the depository for deposit of a sample as referred to in the first or third paragraph.

3. <u>Duration of Storage</u>

Art. 8(6) of the Patents Act No. 17/1991 (as amended in 2004):

From that time on, the sample shall remain constantly on deposit so that whoever has authorization according to this Act will be able to receive a sample of the biological material in this country. Regulations shall stipulate where such deposits may be made.

4. Conditions for the Provision of Samples

Art. 22(6)-(8) of the Patents Act No. 17/1991 (as amended in 2004):

If a sample of biological material has been deposited in accordance with the provisions of Article 8, anyone may be supplied a sample in accordance with the provisions of Paragraphs 1, 2 and 3. However, this does not mean that anyone is to be supplied with a sample who according to regulations or legal provisions is unauthorized to deal with deposited biological material. Nor shall samples be supplied to anyone who due to the harmful properties of the biological material is considered incompetent of processing the sample without considerable risk.

Notwithstanding the provisions of Paragraph 6, the applicant may demand that a sample of the biological material be supplied only to independent experts until a patent is granted. If an application has been refused or dismissed or may be considered withdrawn the applicant may, for 20 years from the filing date of the application, demand that samples of the biological material be supplied only to independent experts. The Minister issues rules on such requests, on time limits for presenting such requests and on who may be considered independent experts according to this stipulation.

The request for the furnishing of a sample shall be filed in writing with the Patent Authority and shall contain a declaration of observance of the restriction on the use of the sample in accordance with the rules laid down by the Minister. If the sample is to be furnished to an expert in the art then he shall make the declaration rather than the person requesting the sample.

Art. 47 of Regulation on Patents No. 477/2012:

A request for provision of a specimen of deposited biological material as referred to in the first sentence of Art. 22(8) of the Patents Act shall be presented in accordance with Rule 11 of the Regulations under the Budapest Treaty.

If a request is made, cf. the first paragraph, before a final decision has been made on the application to which the deposited sample relates, the person requesting the specimen shall undertake to use the specimen solely for research until a final decision has been made on the application. The person concerned shall also undertake not to allow any other person access to the specimen until a final decision has been taken on the application or, if a patent is granted, until that patent has ceased to have effect. The above shall also apply to specimens of deposited samples which relate to a patent granted.

The person requesting the specimen shall make the same undertakings in regard to cultures which are derived from the specimen and which still exhibit those characteristics important for the use of the invention.

A request for a specimen shall be accompanied by a written declaration that the person requesting the specimen undertakes to fulfil the obligations above.

Art. 48 of Regulation on Patents No. 477/2012:

An applicant's request pursuant to Art. 22(7) of the Patents Act, to the effect that specimens be provided only to independent experts, must be submitted to the Icelandic Intellectual Property Office no later than the date on which the application is made available to the public as provided for in Art. 22 of the Act.

The Icelandic Intellectual Property Office shall lay down requirements as to who are to be considered independent experts. Only those persons who satisfy the requirements or who are approved by an applicant or patent holder in each instance may be provided with specimens.

A request for provision of a specimen as referred to in Art. 22(7) of the Patents Act shall be presented in accordance with Rule 11 of the Regulations under the Budapest Treaty. If a specimen may only be provided to an expert, the request shall state the name of the expert who is requested to undertake examination of the specimen. Furthermore, the request shall be accompanied by a statement from the expert obliging him-/herself towards the applicant to the extent described in Art. 47(2) and (3) of this Regulation.

Art. 50 of Regulation on Patents No. 477/2012:

If a request for a specimen has been submitted, and nothing in the Patents Act or this Regulation prevents it being granted, the Icelandic Intellectual Property Office shall issue a statement to that effect. The Icelandic Intellectual Property Office shall send the request for provision of the specimen and the statement to the institution where the biological material is deposited, with a copy to the applicant or patent holder.

If the Icelandic Intellectual Property Office is of the opinion that the statement referred to in the first paragraph cannot be issued, the party requesting provision of the specimen shall be notified thereof. Such a decision may be referred to the Board of Appeal for Industrial Intellectual Property Rights within two months of the notification by the Icelandic Intellectual Property Office.

5. New deposit of a sample

Art. 8(7) *of the Patents Act No.* 17/1991 (as amended in 2004):

If a deposited biological material becomes inactive or it is impossible for other reasons to supply samples of it, it may be exchanged with a sample of the same culture within the prescribed time and in other aspects in accordance with the provisions of regulations. In such instances, the new deposit is considered to have been made on the same date as the previous deposit.

Art. 46 of Regulation on Patents No. 477/2012:

A new deposit of a sample of a biological material, as referred to in Art. 8(7) of the Patents Act, must comply with the provisions of the Budapest Treaty and the Regulations under the treaty regarding new deposits. The new deposit shall be made within three months from the date on which the depositor received notification from the depositary that provision of a sample of the deposited biological material was not possible.

If a depositary recognised under the Budapest Treaty or by the European Patent Office has ceased operations as an international depositary for the type of biological material which the deposit involved, or if the depositary no longer fulfils the requirements stipulated for depositaries, and if the depositor has not obtained knowledge of this within 6 months of WIPO publishing an announcement thereof, the new deposit may be made within nine months of the publication of that announcement.

The applicant shall, within four months of the date on which the new sample of biological material was deposited with another institution, provide the Icelandic Intellectual Property Office with information on the deposit with the new depositary. If the time limit provided for in Art. 45(1) and (2) expires later, however, it will suffice to provide the information within that time limit.

6. Deposit of derived samples

Art. 49 of Regulation on Patents No. 477/2012:

In spite of the issuance of a statement, as referred to in Articles 47 and 48, the deposit of a sample of biological material, which is derived from a specimen provided, is permitted for a new patent application if deposit of the derived sample is necessary for the new application.