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1. Requirements for Deposit

If, when carrying out an invention, this involves the use of biological material which is not available to the public and cannot be described in the application documents in such a manner as to enable a skilled person to carry out the invention on the basis thereof, a sample of the biological material shall be deposited not later than on the date of filing of the application.

(Patents Act, section 8a, first paragraph, first sentence)

The application shall contain information about whether the application comprises deposited biological material in accordance with section 8a of the Patents Act.

(Patent Regulations, section 2, first paragraph, no. 7)

The deposit of biological material in accordance with section 8a, first paragraph, of the Patents Act shall be made in accordance with the Budapest Treaty on the International Recognition of Deposit of Microorganisms for the Purposes of Patent Procedure of April 28, 1977. The material shall be deposited with an institution that is an international depositary institution in accordance with the Budapest Treaty or with an institution that has been approved by the European Patent Office.

(Patent Regulations, section 12, first paragraph)

When a sample of biological material has been deposited, the applicant shall notify the Norwegian Industrial Property Office in writing about the depositary institution with which the material has been deposited and the reference number that the institution in question has accorded the deposited material. The information shall be provided not later than 16 months after the filing date or, if priority has been claimed, the claimed priority date. If deposited biological material is transferred to another international depositary institution in pursuance of Rule 5(1) of the Implementing

Regulations to the Budapest Treaty, the applicant or the patent holder shall notify the Norwegian Industrial Property Office hereof and of the reference number that the institution has accorded the deposited material.

(Patent Regulations, section 12, second paragraph)

The Norwegian Industrial Property Office may demand a copy of the receipt that the depositary institution has issued as proof of the correctness of the information provided in accordance with the second and third paragraphs.

(Patent Regulations, section 12, fourth paragraph)

A request in accordance with section 22, eighth paragraph, of the Patents Act that samples of biological material shall only be issued to a specially appointed expert must be filed with the Norwegian Industrial Property Office not later than the day before the application becomes available to the public in accordance with section 22 of the Patents Act.

(Patent Regulations, section 12, fifth paragraph)

2. Time of Deposit

If, when carrying out an invention, this involves the use of biological material which is not available to the public and cannot be described in the application documents in such a manner as to enable a skilled person to carry out the invention on the basis thereof, a sample of the biological material shall be deposited not later than on the date of filing of the application.

(Patents Act, section 8a, first paragraph, first sentence)

3. Duration of Storage

The sample shall thereafter always be deposited so that anyone who under this Act is entitled to be furnished with a sample of the biological material should be furnished with a sample in Norway.

(Patents Act, section 8a, first paragraph, second sentence)

If a deposited culture of a microorganism ceases to be viable or a sample of the culture cannot be furnished for other reasons, it may be replaced by a new culture of the same microorganism within the prescribed time limit and on the other conditions laid down by the King. In that case, the new deposit shall be deemed to have been made on the date that the previous deposit was made.

(Patents Act, section 8a, second paragraph)

A new deposit of biological material in accordance with section 8a, second paragraph, of the Patents Act shall be made in accordance with the Budapest Treaty. The applicant or the patent holder shall notify the Norwegian Industrial Property Office of the new deposit of biological material and of the reference number that this institution has accorded the deposited material within four months from when the material was deposited or within the time limit stipulated in the second paragraph.

(Patent Regulations, section 12, third paragraph)

The Norwegian Industrial Property Office may demand a copy of the receipt that the depositary institution has issued as proof of the correctness of the information provided in accordance with the second and third paragraphs.

(Patent Regulations, section 12, fourth paragraph)

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

If a sample of biological material has been deposited according to section 8a, anyone has the right to be furnished with a sample of the material when the documents of the application have been made available in accordance with the first, second or third paragraph. After a patent has been granted anyone who requests a sample of the material shall be furnished with a sample, even if the patent has ceased or been invalidated.

(Patents Act, section 22, seventh paragraph, first and second sentences)

An applicant for a patent who invokes his application against another party before it has been made available to the public shall, upon request, be obliged to give that party access to the documents of the application. If the application involves the deposit of a sample of biological material of the microorganism as referred to in section 8a, the other party shall have the right to be furnished with a sample of the culture. The provisions of section 22, seventh paragraph, third and fourth sentences, and the eighth and ninth paragraphs shall apply correspondingly.

(Patents Act, section 56, first paragraph)

(ii) Restrictions Concerning the Furnishing of Samples

If a sample of biological material has been deposited according to section 8a, anyone has the right to be furnished with a sample of the material when the documents of the application have been made available in accordance with the first, second or third paragraph. After a patent has been granted anyone who requests a sample of the material shall be furnished with a sample, even if the patent has ceased or been invalidated. This does not mean, however, that a sample shall be issued to anyone who in consequence of a law or regulation is not entitled to handle the deposited material.

Nor shall a sample be issued to anyone whose handling of the sample must be assumed to involve considerable risk due to the harmful properties of the material.

(Patents Act, section 22, seventh paragraph)

Until a patent has been granted or the application has been finally decided upon without a patent having been granted, the applicant may, notwithstanding the provisions of the seventh paragraph, request that a sample only be issued to a specially appointed expert. If the patent application has been refused or withdrawn the same rule applies for a sentence of 20 years from the date when the patent application was filed. The King shall prescribe a time limit for submitting a claim to limit issuing of the material and shall determine who may be appointed as an expert.

(Patents Act, section 22, eighth paragraph)

A request for the issue of a sample shall be made in writing to the Norwegian Industrial Property Office and must contain a declaration to the effect that the restrictions laid down by the King concerning the use of the sample will be observed. If the sample may only be issued to a specially appointed expert, the declaration shall be made by the expert instead.

(Patents Act, section 22, ninth paragraph)

A request for the issue of a sample of biological material in accordance with section 22, ninth paragraph, of the Patents Act shall be worded in accordance with the provisions in Rule 11 of the Implementing Regulations to the Budapest Treaty.

(Patent Regulations, section 26, first paragraph)

If the request concerns a sample of deposited biological material connected with an application for which a final decision has not yet been made, the party requesting the sample must submit a declaration in which he undertakes vis-à-vis the applicant not to use the sample for any other purposes than for experiments that concern the invention itself and to refrain from granting other parties access to the sample until a final decision has been made regarding the application or, if a patent is granted, until the patent has expired. If the request concerns a sample of deposited biological material connected with a patent, the party requesting the sample must submit a declaration in which he undertakes vis-à-vis the patent holder not to use the sample for any other purposes than experiments that concern the invention itself and to refrain from granting other parties access to the sample until the patent has expired. The first and second periods of this paragraph shall apply correspondingly to biological material that is derived from the sample and that has retained the characteristic features of the material that are important for carrying out the invention. The request for the issue of the sample shall contain a declaration that the requester undertakes these obligations.

(Patent Regulations, section 26, second paragraph)

If a sample may only be issued to a special expert, the request for the issue of the sample shall designate the expert in question. The Norwegian Industrial Property Office will draw up a list of persons who can be used as experts. Only persons who are entered in said list, or whom the applicant accepts in the individual case, may be used as experts. If an expert is used, the request for the issue of a sample shall contain a declaration from the expert in accordance with the second paragraph.

(Patent Regulations, section 26, third paragraph)

The second and third paragraphs shall not apply if it is necessary to deposit derived biological material in connection with a subsequent application.

(Patent Regulations, section 26, fourth paragraph)

When a request has been made for the issue of a sample of biological material and the requirements for this have been complied with, the Norwegian Industrial Property Office shall issue a declaration to this effect. The Norwegian Industrial Property Office shall send the request for the issue of a sample and the declaration to the depositary institution with which the material has been deposited. A copy of the request for the issue of a sample and the declaration shall concurrently be sent to the patent applicant or the patent holder. If the Norwegian Industrial Property Office does not issue such a declaration, the party requesting the sample shall be notified hereof.

(Patent Regulations, section 26, fifth paragraph)