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1. Requirements for Deposit

The deposit of a culture of a microorganism is required: a) if the invention is a microorganism, or b) if the invention involves the use, modification or cultivation of a microorganism which is not reasonably available to a person skilled in the art and if, without a sample of such microorganism, such person could not reasonably be expected to be able to perform the invention.

(Patents Act 1990, Sections 6, 41(1A), 41(1) - (3) and 43(2B); Patents Regulations, Regulations 1.5(1) - (4) and 3.12(5))

2. <u>Time of Deposit</u>

The microorganism deposit must be made on or before the filing date of the application. Where the application claims priority from an earlier application, the deposit must have been made on or before the filing date of the earlier application.

(Patents Act 1990, Section 6(a)); Patents Regulations, Regulations 3.13A(6), 3.13B(5), 3.13C(4) and 3.13D(5) and 3.32(1), (2))

3. Duration of Storage

A deposited microorganism shall be stored for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism was received by the international depositary authority and, in any case, for a period of at least 30 years after the date of the deposit.

(Budapest Treaty Regulations Rule 9.1)

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

Samples of deposited microorganisms may be made available to a requesting party

provided the specification lodged in respect of the patent application or patent is open to public inspection (OPI).

The Commissioner must grant the certification: a) if the request is in respect of an application that has lapsed, been refused or been withdrawn, b) if the request is in respect of a patent that has expired, ceased, or been revoked, or c) in certain other prescribed circumstances as defined in the Act and Regulations.

(Patents Regulations, Regulation 1.5(5), 3.24(1), 3.25, 3.25B, 3.25C, 3.25D, 3.25E and 3.25F)

(ii) Restrictions Concerning the Furnishing of Samples

If a request is made in respect of an application that has not lapsed, been refused or been withdrawn, or in respect of a granted patent that has not expired, ceased or been revoked, the requesting party must give an undertaking:

- (a) not to make the microorganism, or any culture derived from the microorganism, available to any other person during the specified period, and
- (b) to use the microorganism only for experimental purposes, or in relation to the following specified proceedings:
- opposition proceedings under Chapter 5 of the Patents Act in relation to the grant of a standard patent on the application; or
- opposition proceedings under section 101M of the Patents Act in relation to an innovation patent; or
 - relevant proceedings in relation to the patent.

(Patents Regulations, Regulation 3.25C; Form P/00/031)

The Commissioner may require, before granting the certification referred to in Rule 11.3(a) of the Budapest Treaty Regulations, that a requesting party comply with such conditions as are reasonable, including a condition that the requestor give security for damages for any breach of the undertaking.

(Patents Regulations, Regulation 3.25G)

The Commissioner must not grant the certification if the request relates to a microorganism (or its use, modification or cultivation) that is the subject of a PCT application, and the applicant of the PCT application has not complied with subsection 29A(5) of the Patents Act.

(Patent Regulations, Regulation 3.25B(5))

The applicant may, at any time <u>before</u> the specification relating to the application is OPI, notify the Commissioner that a sample of the deposited microorganisms is only to be provided during the period;

- (a) only once the application is OPI, and
- (b) only to a person who is a skilled addressee without an interest in the invention, and is nominated by the person who made the request.

The above conditions only apply until the application has lapsed, been withdrawn or been refused, or until a patent is granted on that application.

(Patent Regulations, Regulation 3.25A)