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1. Requirements for Deposit

The deposit of biological material must be made if an invention, which involves the use of or concerns biological material (which is not available to the public at the date of filing of the application) is not disclosed in a manner as to enable the invention to be performed by a person skilled in the art. In addition to the requirement for a deposit, the specification of the patent application as filed must contain such relevant information as is available to the applicant on the characteristics of the biological material.

The application for a patent shall be treated as disclosing the invention if:

- (i) A sample of the biological material concerned has been deposited in a depositary institution not later than the actual filing date of the application
- (ii) the name of the depositary institution and the accession number of the deposit are given in the specification of the application, and
- (iii) where the deposit has been deposited by a person other than the applicant, the name and address of the depositor are stated in the application and a document is filed satisfying the Controller that the depositor has authorised the applicant to refer to the deposit in the application and has given his, her, their or its unreserved and irrevocable consent to the deposit being made available to the public,

The latest date such information (seen in (i), (ii) and (iii) above) may be added to the specification, except in the case of a divisional application, is:

(a) before the end of the sixteenth month after the date of priority or, if no priority has been claimed, the date of filing of the application,

(b) where, on a request made by the applicant, the Controller publishes the application before the end of the period specified in section 28(1), before the date of the request,

whichever is the earliest.

(Patents Rules 1992, Rule 14(1), 14(2), 14(3)), (Patents Act 1992, Section 28)

2. Time of Deposit

The deposit must be made on or before the date of filing the patent application.

(Patents Rules 1992, Rule 14(2))

Where the biological material ceases to be available at the depositary institution because:

(i) a deposit ceases to be available from the institution with which it was deposited because the biological material comprising the deposit is no longer viable, or for any other reason the institution is unable to supply samples, or

(ii) the depositary institution ceases to be a depositary institution, or discontinues, temporarily or permanently, the performance of its functions as regards deposited biological material, and no sample of the biological material has been transferred to another depositary institution, from which it continues to be available;

an interruption in availability of the deposit shall be deemed not to have occurred if (within a period of three months from the date on which the depositor was notified of the interruption by the depositary institution),

(a) the depositor makes a new deposit of a sample of that biological material, and

(b) the applicant or proprietor makes a request for amendment of the specification to indicate the accession number of the new deposit and the name of the depositary institution with which the deposit was made.

In the case that the biological material comprising the deposit is no longer viable, the new deposit shall be made with the depositary institution with which the original deposit was made. In other states cases, it may be made with another depositary institution.

In the case where no notification of the interruption of availability of the deposit from the depositary institution is received by the depositor within six months from the date of such event, the three-month period shall begin on the date on which this event is announced in the Journal.

Any new deposit shall be accompanied by a statement signed by the person making the deposit certifying that the sample of biological material newly deposited is of the same biological material as was the sample originally deposited.

(Patents Rules 1992, Rule 14(17))

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

Time of Availability of Samples

A request may be made to the Controller to issue a certificate authorising a depository institution to make available a sample at any time after publication of an application for a patent, to any person.

A request must be made in Form No. 6. This request may also be accompanied by the relevant form required by the Regulations under the Budapest Treaty, if applicable.

(Patents Rules 1992, Rule 14(6))

Restrictions Concerning the Furnishing of Samples

A request for a sample of biological material must include an undertaking:

- (a) not to make the biological material, or any material derived from it, available to any other person; and
- (b) not to use the biological material, or any material derived from it, except for experimental purposes relating to the subject matter of the invention.

The undertaking shall have effect:

(i) during any period before the application for a patent has been withdrawn, is deemed to be withdrawn, or is the subject of a final refusal, but excluding, if an application is reinstated, the period before it is reinstated, and

(ii) if a patent is granted on the application, during any period for which the patent is in force and during the period of six months referred to in section 36(3) – Term of a patent.

(Patents Rules 1992, Rule 14(8), 14(9)), (Patents Act 1992, Section 36)

Before the preparations for publication of a patent application under section 28 have been completed, the applicant may give notice to the controller on Form No. 7 that a sample of the biological material should only be made available to an expert (laid down in rule 14(14)). This restriction lasts until the date on which the patent is granted or, where the application is withdrawn, deemed to be withdrawn or is the subject of a final refusal, for 20 years from the date of filing.

(Patents Rules 1992, Rule 14(13), 14(14), 14(15)), (Patents Act 1992, Section 28)

A request for a sample to be made available to an expert must be made on Form No. 8 and must include details of the expert. The requester shall at the same time file undertakings by the expert as listed above.

(Patents Rules 1992, Rule 14(16))