

GB – UNITED KINGDOM

Head of Patent Examination Group EX06: Biotechnology, Chemistry and SPCs
Intellectual Property Office
Concept House
Cardiff Road
Newport, South Wales NP10 8QQ

Telephone: (44-1633) 81 40 00
E-mail: information@ipo.gov.uk (may also be used by IDAs)
Internet: <https://www.gov.uk/government/organisations/intellectual-property-office>

1. Requirements for Deposit

The deposit of biological material must be made if an invention which involves the use of or concerns biological material is not disclosed in a manner which is clear enough and completes enough for 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 name of the depositary institution, the date where the material was deposited and the accession number of the deposit should be given in the specification of the patent application or patent. The latest date such information may be added to the specification is whichever expires first of:

- the period of 16 months after the declared priority date or, where there is not declared priority date, the date of filing of the application;
- where the applicant has requested accelerated publication under section 16(1), the date of that request;
- where in accordance with rule 52(2) the comptroller notifies the application that a request has been made for information or inspection of documents under section 118(4), the period of one month from the date of that notification.

(Patents Rules 2007, rule 13(1) and Schedule 1, paragraphs 2 and 3)

- if the deposit is made by anyone other than the applicant a statement needs to be filed which identifies the name and address of the depositor and provides the applicant with the authorization to refer to the biological material in his application and make it available to the public.

(Patent Rules, Schedule 1, paragraph 3 (2) (b))

2. Time of Deposit

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

(Patents Rules 2007, rule 13(1) and Schedule 1, paragraph 3(1)(a))

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

- (i) it is no longer viable;
- (ii) the depositary institution is unable to supply the biological material; or
- (iii) the place where the biological material is deposited is no longer a depositary institution for that type of material (whether temporarily or permanently);

then a new deposit must be made within three months of the date of the depositor is notified of (i), (ii), or (iii), or, where it expires later, within three months of the date of advertisement of (i), (ii), or (iii) in the journal. The deposit should be accompanied by a signed statement that the biological material is the same as that originally deposited. Within the same time period the applicant or proprietor must apply to the comptroller to amend the specification of the patent application or patent so that it provides the appropriate details. Where the biological material ceases to be available because it is no longer viable then the new deposit should be made at the depositary institution where the original deposit was made.

If the biological material is transferred to a different depositary institution then the specification must also be amended within three months of the date the depositor is notified or, where it expires later, within three months of the date of advertisement in the journal.

(Patents Rules 2007, rule 13(1) and Schedule 1, paragraph 8)

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

A sample of deposited biological material may be requested:

- (a) before publication of the relevant patent application, by a person to whom section 118(4) applies and who has made a request under section 118(1) and
- (b) after publication, by any person.

A request must be made on Patents Form 8. The request must also be accompanied by the relevant form required by the Treaty (form BP12).

(Patents Rules 2007, rule 13(1) and Schedule 1, paragraph 4)

(ii) 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 patent applicant or proprietor may agree to limit the effect of the undertaking in a particular case. The undertaking will cease to have effect when the application for a patent is terminated or withdrawn (but it will continue to have effect if the application is reinstated or resuscitated) or when the patent ceases to have effect.

(Patents Rules 2007, rule 13(1) and Schedule 1, paragraph 5)

Before the preparations for publication of a patent application under section 16 have been completed, the applicant may give notice to the comptroller on Patents Form 8A that a sample of the biological material should only be made available to an expert. This restriction lasts until the date on which the patent is granted or, where the application is terminated or withdrawn, for 20 years from the date of filing. A similar restriction applies in relation to an international application for a patent (UK) where the applicant has made reference to the deposited biological material in accordance with the Patent Cooperation Treaty.

(Patents Rules 2007, rule 13(1) and Schedule 1, paragraph 6)

A request for a sample to be made available to an expert must be made on Patents Form 8 and must include details of the expert, who must have given undertakings in accordance with subparagraphs (a) and (b) above. Before the end of the period of one month beginning with the date on which a copy of Patents Form 8 is sent to the application by the comptroller, the applicant may give notice of his objection to the particular expert, and where he objects the comptroller shall determine the matter.

(Patents Rules 2007, rule 13(1) and Schedule 1, paragraph 7)