

Biological deposits



Certain inventions relate to biological materials. Some inventions, such as micro-organisms or their vectors, comprise biological materials themselves. Other inventions make use of biological materials. This creates difficulties when drafting patent applications, which are required to fully disclose the invention with sufficient information so that someone reading them could see how to 'work' the invention with little or no additional direction or information. With some biological inventions it is not possible to provide sufficient information 'on paper'. Lodging biological materials at an approved depository and referencing the details in the patent application overcomes this difficulty and fulfils the requirement for sufficiently disclosing the invention.

A range of biological materials can be deposited. Biological materials include cells (such as bacteria, fungi, cell lines, algae and plant spores), genetic vectors (such as plasmids, phages and viruses), host organisms (such as bacteria containing vectors or modified gene sequences) and expression systems (such as cell lines, hybridomas, plant cell tissues, organelles, chromosomes and nucleic acids).

When filing the patent application, a deposit needs to be made when sufficient information cannot be given 'on paper'; there is a judgement call to be made. When is the written information sufficient? There are no hard and fast rules, but generally speaking, it is better to err on the side of caution, and make the deposit if there is any doubt. For example, if a patent application claims a plasmid having a particular DNA sequence and the description of the application sufficiently discloses how to modify an existing plasmid to arrive at the claimed plasmid, then arguably the deposit of the plasmid is not required. However, the deposit of the plasmid may still be desirable in case a validity attack is made by a third party or in order to satisfy the patent filing requirements in other countries.

The biological material must be deposited in a depository institution or an international depository authority which is recognised under the *Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the purposes of Patent Procedure*. In the UK there are currently seven institutions which are authorised. The type of biological material may dictate which institution should be used.

A list of institutions which handle biological deposits in Europe, the US, Japan and further afield is available on the World Intellectual Property Organization (WIPO) website: <http://www.wipo.int/treaties/en/registration/budapest>.

The deposit should be made on or before the filing date of a patent application. It is important that the depository institution is informed that a deposit is for patent filing purposes. The patent application must give the name of the depository institution and the accession number. It is good practice also to provide the address and deposition date as this additional information is often required in other countries.

The viability of the deposit will be tested by the depository institution before an accession number is issued, and replacement biomaterial may be requested. Therefore deposits should not be filed at the last minute.

One of the requirements for biological deposits is that they are made available to the public, although availability to the public is initially restricted until after publication of the European patent application. Access to the deposit can also be restricted to a recognised expert if desired, under [EPC Rule 32](#).

If a deposit ceases to be viable, a new deposit must be made so it is essential that patent holders ensure that sufficient (and viable) stock is kept during the life of the patent in case it is required at a later date.

Care must be taken when relying on deposits made by others as their availability may not continue for the life of the patent. In such cases it may be preferable to deposit biological material even if such material is commercially available at the filing date of the patent application.

Biological material supporting a patent application may be deposited by someone other than the patent applicant, but in this situation the depositor must be identified and an authorisation from them is required. It is important to consider this when dealing with group companies.

We have explained the general principles of making biological deposits related to patent proceedings in this AL Factsheet but it is only an introduction, and any live situation will need individual assessment. Please contact us if you need more detailed information.