



Intellectual
Property
Office

UK IPO practice on the deposit of biological materials under the Budapest Treaty

WIPO - Meeting of Member states and IDAs

Freddy White – Legal Advisor, UK Intellectual Property Office

Outline

- Background - Legal provisions
- When is a deposit required?
- Filing formalities and requirements

Background - Legal provisions

- Section 14(3) of the Patents Act 1977, requires:
 - “The specification of an application shall disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art.”
- This requirement is the same in all technological fields, including biotechnology
- The ‘skilled person’ is considered to have general knowledge from their field of expertise
- It must be possible to work the invention without an undue burden
- Sufficiency is judged **on the date of filing of the patent**
- Deposit of biological material may be required to disclose the invention in a clear and complete enough manner for the invention to be performed by the person skilled in the art

Background - Legal provisions

- Section 125A of the Patents Act 1977 governs the deposit of biological materials
- The specific requirements for the deposit of biological materials are laid out in Schedule 1 of the Patents Rules 2007 (as amended)
- Schedule 1 of the Rules is given effect by rule 13(1):
 - 13.—(1) The provisions of Schedule 1 prescribe the circumstances in which the specification of an application for a patent, or of a patent, for an invention which involves the use of or concerns biological material is to be treated as disclosing the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art.

When is a deposit required?

- Under UK law, a deposit may be required to provide *sufficient and enabling* disclosure of an invention
- The courts have not tested this law in respect of applications where biological materials have been deposited

Current position of the IPO is that deposits are necessary:

- If an invention relates to a new species of micro-organism
- If novel biological material depends on a random event that cannot be readily reproduced
- If an invention relates to genetically modified strains of known organisms or where those modified strains produce a product (e.g. antibiotics)
- Other circumstances may exist where a deposit is necessary
- Deposits are not required if a biological material is readily available to the public, e.g. baker's yeast

Filing Requirements

- Deposits of biological materials must be made on or before the date of filing
- Applicant must provide:
 - Name of depositary authority at which the material was deposited
 - Accession number
 - Date of deposit
- By whichever is earliest of:
 - **16 months** after the declared priority date (or filing date if no claim to priority)
 - The date of a request for accelerated publication
 - One month after notification of a request by a third party under s.118(4) to inspect the application before publication

Filing Requirements (continued)

- Since 2001, applicants can rely on biological material deposited by a person who is not the applicant
- The applicant must provide a statement which identifies the name and address of the depositor
- The depositor must file a statement authorising the applicant to refer to the biological material in their application and giving irrevocable consent to allow the biological material to be made available to the public

Filing Requirements (continued)

- If a sample is no longer available at the IDA, a new deposit must be made within 3 months of the depositor being notified, or within 3 months of the advertisement of the unavailability in the patents Journal
- The new deposit must be accompanied by a signed statement confirming that it is the same as the original sample
- Patent specification must be amended to provide the details of the new sample
- Patent specification must also be amended if the sample is transferred to a different depository institution
- Failure to make a new deposit will lead to revocation of the patent