Intellectual Property Office

National Implementation of the Budapest Treaty

National Seminar on the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (Virtual), 21 October 2020

Aquila Brandon-Salmon, Legal Advisor, Intellectual Property Office, United Kingdom

History

- The United Kingdom ratified the Budapest Treaty on 29 September 1980 and the Treaty entered into force on 29 December 1980.
- National implementation of the Budapest Treaty was facilitated by the introduction of rule 17 in The Patents Rules 1978.
- The Copyright, Designs and Patents Act 1988 then introduced Section 125A, which allowed for the patents rules to provided the requirements for the depositing of biological samples.
- The Patents Regulations 2000 substituted references to “microorganisms” with references to “biological material” and introduced a definition of the term “biological material”.
- The Patents Act 1977 (Isle of Man) Order 2003 (SI 2003 No. 1249) amended these definitions for the Isle of Man.

Current implementation

- Section 125A (1):
- *“Provision may be made by rules prescribing 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.”*
- (2) Requirements:
    - (a) to [make] available to the public samples of the biological material, and
    - (b) not to impose or maintain restrictions….
- (3) …..[the rules make clear who can obtain samples].
- (4) Cease to comply: grounds for revocation

Depositing Samples

- Rule 13(1) of the Patents Rules 2007 links to Schedule 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 14 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."*
- Schedule 1, paragraph 2: If disclosure in application is insufficient, this can be remedied if:
  a) the application contains relevant information on the characteristics of the biological material AND:
  b) On or before the date of filing the biological material has been deposited (Sch 1, para 3 (1)).

- Before the end of 16 months (Sch 1 para 3) the following must be provided to the Office:

a) the name of the depository,

b) the accession number of the deposit,

c) name and address of depositor,

d) statement by depositor to authorise applicant to refer to the material in their application and irrevocably authorises making the material available to the public (in accordance with the Schedule) (sch 1 para 3(2)).

Accessing samples

- Paragraphs 4-7 provide for third parties to access the deposited biological material.
- Must make a request to the comptroller to issue an authorisation certificate, by filing:

a) Form 8 – available here on our website and;

b) Form BP/12 – available on this page of the WIPO website

Restrictions on use

- However, there are restrictions on use (Sch 1, para 5):
- *“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”.*
- Conditions cease upon termination or withdrawal of patent.
- Applicant can also specify the deposited sample be only made available to an expert (Sch 1, paras 6-7).

Sample accessibility issues

- Schedule 1, Paragraph 8 provides remedies for the following occurrences:

a) Biological material ceases to be viable

b) Depositary institution is unable to supply the biological material or is no longer a depositary institution for that type of material

c) Biological material is transferred to a different depositary institution

- In these cases, within three months of the depositor being notified by the depositary institution a new sample must be provided at the same or another depository institution, accompanied by a signed statement to the effect that the biological material deposited is the same as that originally deposited; and the comptroller must be notified.
- The sample must be stored for the lifespan of the patent.

Depository Institution Requirements

- The UK has a number of International depositary authorities:

a) CABI Bioscience, UK Centre (IMI)

b) Culture Collection of Algae and Protozoa (CCAP)

c) European Collection of Cell Cultures (ECACC)

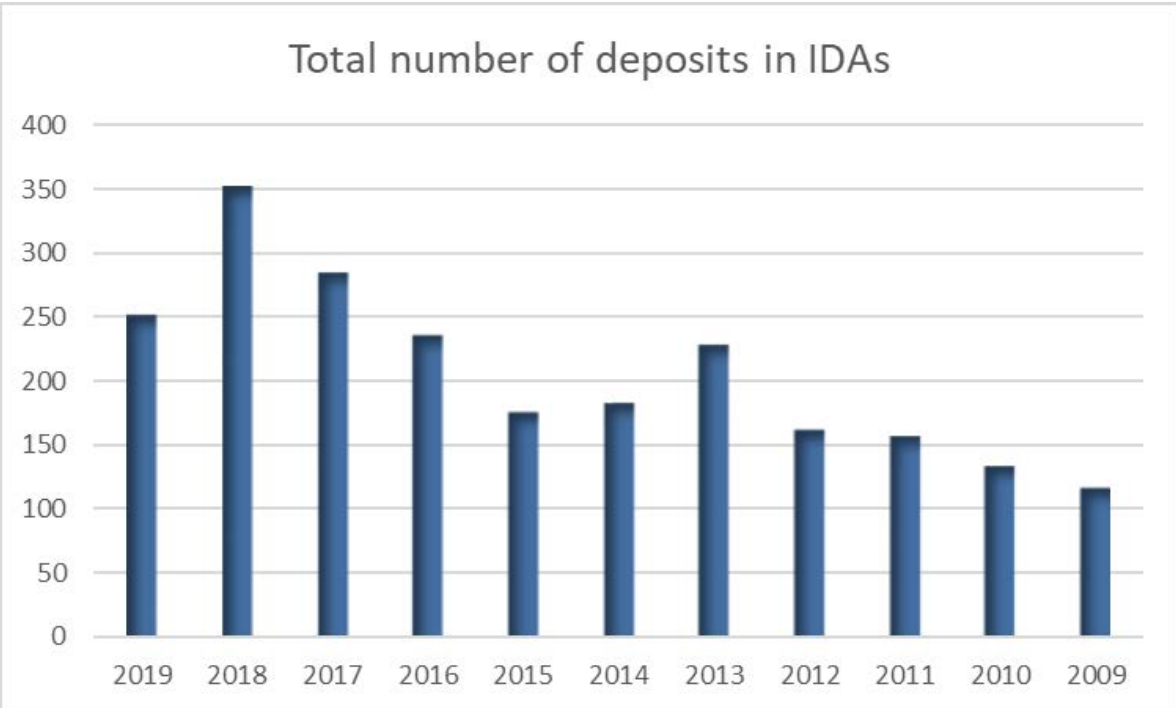
d) National Collection of Type Cultures (NCTC)

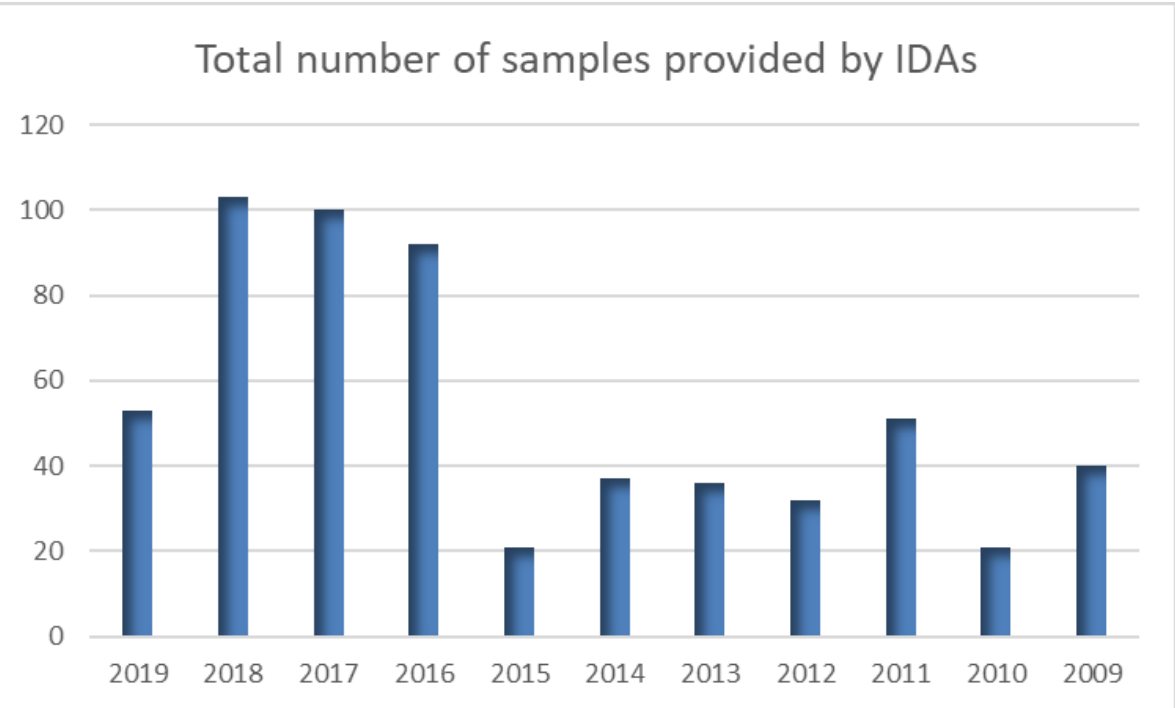
e) National Collection of Yeast Cultures (NCYC)

f) National Collections of Industrial, Food and Marine Bacteria (NCIMB)

g) National Institute for Biological Standards and Control (NIBSC)

- The most versatile in the UK is ECACC at Porton Down





- The UK does not provide an official list of depositary institutions which are deemed acceptable for the purposes of meeting the requirements in the Patents Act and Rules.
- Instead, the deposit may be made in any depository institution, provided that samples will be made available in accordance with Schedule 1.
- This is different to the EPO (European Patent Office) which requires deposit to take place at one of the depositary authorities specifically recognised by it.

How to Submit Biological Material to the European Collection of Cell Cultures (ECACC)

- Deposit by post 12 identically labelled vials: patent supervisor reviews application: some deposits are not appropriate.
- Purchase order number raised
- Eventually you get a provisional accession number
- Patent supervisor does viability testing on vial 1, if this fails, tests vial 2. If there is viability, then a certificate is authorised (electronic copies are sent and followed up by post).
- If all is well then the date of receipt date is the date of deposition
- All of this takes at least 4-5 WORKING days: no 24/7 service!

Any Questions?