

DIRECTIVE 98/44/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 July 1998 on the legal protection of biotechnological inventions

CHAPTER IV

Deposit, access and re-deposit of a biological material

Article 13

1 Where an invention involves the use of or concerns biological material which is not available to the public and which cannot be described in a patent application in such a manner as to enable the invention to be reproduced by a person skilled in the art, the description shall be considered inadequate for the purposes of patent law unless:

- a the biological material has been deposited no later than the date on which the patent application was filed with a recognised depository institution. At least the international depository authorities which acquired this status by virtue of Article 7 of the Budapest Treaty of 28 April 1977 on the international recognition of the deposit of micro-organisms for the purposes of patent procedure, hereinafter referred to as the 'Budapest Treaty', shall be recognised;
- b the application as filed contains such relevant information as is available to the applicant on the characteristics of the biological material deposited;
- c the patent application states the name of the depository institution and the accession number.

2 Access to the deposited biological material shall be provided through the supply of a sample:

- a up to the first publication of the patent application, only to those persons who are authorised under national patent law;
- b between the first publication of the application and the granting of the patent, to anyone requesting it or, if the applicant so requests, only to an independent expert;
- c after the patent has been granted, and notwithstanding revocation or cancellation of the patent, to anyone requesting it.

3 The sample shall be supplied only if the person requesting it undertakes, for the term during which the patent is in force:

- a not to make it or any material derived from it available to third parties; and
- b not to use it or any material derived from it except for experimental purposes, unless the applicant for or proprietor of the patent, as applicable, expressly waives such an undertaking.

4 At the applicant's request, where an application is refused or withdrawn, access to the deposited material shall be limited to an independent expert for 20 years from the date on which the patent application was filed. In that case, paragraph 3 shall apply.

5 The applicant's requests referred to in point (b) of paragraph 2 and in paragraph 4 may only be made up to the date on which the technical preparations for publishing the patent application are deemed to have been completed.