

## SCHEDULE 2

Rule 17

### MICRO-ORGANISMS

#### Applications

1.—(1) The specification of an application for a patent, or of a patent, for an invention which requires for its performance the use of a micro-organism—

- (a) which is not available to the public at the date of filing the application; and
- (b) which cannot be described in the specification in such a manner as to enable the invention to be performed by a person skilled in the art,

shall, in relation to the micro-organism itself, be treated for the purposes of the Act as disclosing the invention in such a manner only if one of the conditions set out in subparagraph (2) below is satisfied.

(2) The conditions referred to in subparagraph (1) above are—

- (a) a condition that,—
  - (i) not later than the date of filing of the application, a culture of the micro-organism has been deposited in a depositary institution which is able to furnish a sample of the micro-organism; and
  - (ii) the name of the depositary institution, the date when the culture was deposited and the accession number of the deposit are given in the specification of the application; and
- (b) a condition, in the case of a European patent (UK), an application for a European patent (UK) or an international application for a patent (UK) which is treated, by virtue of section 77, 81 or 89 as a patent under the Act, or, as the case may be, an application for a patent under the Act, that the corresponding provisions of the Implementing Regulations to the European Patent Convention or, as the case may require, the Patent Co-operation Treaty have been complied with,

and, where a new deposit is made under paragraph 4 below, a further condition that the applicant or proprietor makes a new deposit in accordance with that paragraph.

(3) Where the information specified in subparagraph (2)(a)(ii) above is not contained in an application for a patent as filed, it shall be added to the application—

- (a) before the end of the period of 16 months after the declared priority date or, where there is no declared priority date, the date of filing of the application;
- (b) where, on a request made by the applicant, the comptroller publishes the application before the end of the period prescribed for the purposes of section 16(1), before the date of the request; or
- (c) where the comptroller sends notification to the applicant that, in accordance with subsection (4) of section 118, he has received a request by any person for information and inspection of documents under subsection (1) of that section, before the end of one month after his sending to the applicant notification of his receipt of the request,

whichever is the earliest.

(4) The giving of the information specified in subparagraph (2)(a)(ii) above shall constitute the unreserved and irrevocable consent of the applicant to the depositary institution with which a culture (including a deposit which is to be treated as having always been available by virtue of paragraph 4(2) below) is from time to time deposited making the culture available on receipt of the comptroller's certificate authorising the release to the person who is named therein as a person to whom the culture may be made available and who makes a valid request therefor to the institution.

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(5) The specification of an application for a patent described in paragraph (1) above shall mention any international agreement under which the micro-organism concerned is deposited.

(6) In relation to an application for a patent filed before 7th January 1991, rule 17 of the Patents Rules 1982(1) shall continue to have effect notwithstanding its revocation by rule 123(3) of the Patents Rules 1990(2).

### Availability of cultures

2.—(1) Save where paragraph 3 below has effect, a request that the comptroller certify a person as a person to whom a depositary institution may make available a sample of a micro-organism,—

- (a) before publication of the application for a patent, to a person who has made a request under section 118(1) in the circumstances mentioned in paragraph 1(3)(c) above; and
- (b) at any later time, to any person,

shall be made on Patents Form 8/77 (which shall be filed in duplicate) together, in the case of a micro-organism of which a culture is deposited under the Budapest Treaty with an international depositary authority, with the form provided for by the Regulations under that Treaty.

(2) The comptroller shall send copies of the forms lodged with him under subparagraph (1) above and of his certificate authorising the release of the sample—

- (a) to the applicant for, or proprietor of, the patent;
- (b) to the depositary institution; and
- (c) to the person making the request.

(3) A request under subparagraph (1) above shall comprise, on the part of the person to whom the request relates, undertakings for the benefit of the applicant for, or proprietor of, the patent—

- (a) not to make the culture, or any culture derived from it, available to any other person; and
- (b) not to use the culture, or any culture derived from it, otherwise than for experimental purposes relating to the subject matter of the invention,

and—

- (i) subject to (iii) below, both undertakings shall have effect during any period before the application for a patent has been withdrawn, has been taken to be withdrawn, has been treated as having been withdrawn, has been refused or is treated as having been refused (including any further period allowed under rule 100 or rule 110(1) or (4) but excluding, where an application is reinstated under either of those rules, the period before it is reinstated);
- (ii) if a patent is granted on the application, the undertaking set out in subparagraph (a) above shall also have effect during any period for which the patent is in force and during the period of six months referred to in section 25(4); and
- (iii) the undertaking set out in paragraph (b) shall not have effect after the date of publication in the Journal of a notice that the patent has been granted,

and, in this subparagraph, references to a culture derived from a deposited culture of a micro-organism are references to a culture so derived which exhibits those characteristics of the deposited culture essential for the performance of the invention.

(4) For the purpose of enabling any act specified in section 55 to be done in relation to the culture for the services of the Crown, the undertakings specified in subparagraph (3) above—

- (a) shall not be required from any government department or person authorised in writing by a government department for the purposes of this paragraph; and

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(1) S.I.1982/717, to which there are no relevant amendments.

(2) S.I. 1990/2384, to which there are no relevant amendments.

(b) shall not have effect in relation to any such person who has already given them.

(5) An undertaking given pursuant to subparagraph (3) above may be varied by way of derogation by agreement between the applicant or proprietor and the person by whom it is given.

(6) Where, in respect of a patent to which the undertaking set out in subparagraph 3(a) has effect,

(a) an entry is made in the register under section 46 to the effect that licences are to be available as of right; or

(b) a compulsory licence is granted under section 48,

that undertaking shall not have effect to the extent necessary for effect to be given to any such licence.

### **Availability of cultures to experts**

3.—(1) Subject to paragraph (2A) below, where, before the preparations for publication under section 16 of an application for a patent have been completed, the applicant gives notice to the comptroller on Patents Form 8A/77 of his intention that a sample of the micro-organism should be made available only to an expert, the provisions of this paragraph shall have effect.

(2) The comptroller—

(a) shall publish with the application notice that the provisions of this paragraph have effect; and

(b) notwithstanding paragraph 2 above, shall not, until the patent is granted or the application has been withdrawn, has been taken to be withdrawn, has been treated as having been withdrawn, has been refused or is treated as having been refused, issue any certificate authorising release of a sample otherwise than under this paragraph.

(2A) Where, for the purpose set out in sub-paragraph (1) above, an applicant for an international application for a patent (UK) gives notice in writing to the International Bureau under rule 13bis.3 of the Regulations under the Patent Co-operation Treaty before the technical preparations for international publication of the application are complete of his intention that a sample of the micro-organism should be made available only to an expert, he shall be treated by the comptroller for the purposes of this paragraph as having complied with the conditions in sub-paragraph (1) above and sub-paragraph (2)(a) above shall not apply.

(3) Any person wishing to have a sample of the micro-organism made available (“the requester”)

(a) shall apply to the comptroller on Patents Form 8/77 (which shall be filed in duplicate together, in the case of a micro-organism of which a culture is deposited under the Budapest Treaty with an international depositary authority, with the form provided for by the Regulations under that Treaty) nominating the person (“the expert”) to whom he wishes the sample to be made available; and

(b) shall at the same time file undertakings by the expert as set out in sub-paragraph (3) of paragraph 2 above in accordance with the provisions of that paragraph.

(4) The comptroller shall send a copy of Patents Form 8/77 filed under sub-paragraph (3) above to the applicant for the patent and shall specify the period within which the applicant may object, in accordance with sub-paragraph (5) below, to a sample of the micro-organism being made available to the expert.

(5) Unless, within the period specified by the comptroller under sub-paragraph (4) above (or within such longer period as the comptroller may, on application made to him within that period, allow), the applicant for the patent sends notice in writing to the comptroller that he objects to a sample of the micro-organism being made available to the expert and gives his reasons for his

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objection, the comptroller shall send a copy of any form lodged with him under sub-paragraph (3) (a) above and of his certificate authorising the release of the sample—

- (a) to the applicant for the patent,
- (b) to the depositary institution concerned,
- (c) to the requester, and
- (d) to the expert.

(6) Where, in accordance with sub-paragraph (5) above, the applicant for the patent sends notice to the comptroller of his objection to the issue of a certificate in favour of the expert, the comptroller—

- (a) shall decide, having regard to the knowledge, experience and technical qualifications of the expert and to any other factors he considers relevant, whether to issue his certificate in favour of the expert; and
- (b) if he decides to authorise the release of the sample to the expert, shall send to the persons referred to in sub-paragraph (5) above a copy of any form lodged with him under sub-paragraph (3)(a) above and of his certificate authorising the release of the sample to the expert.

(7) Before making a decision in accordance with sub-paragraph (6) above, the comptroller shall afford the applicant and the requester the opportunity of being heard.

(8) If the comptroller decides under sub-paragraph (6) above not to issue his certificate in favour of the expert, the requester may, by notice in writing to the comptroller and the applicant, nominate another person as the expert for the purposes of this paragraph; and the comptroller shall give such directions as he shall think fit with regard to the subsequent procedure.

(9) Nothing in this paragraph shall affect the rights under section 55 of any government department or any person authorised in writing by a government department.

### **New deposits**

4.—(1) Where the depositary institution with which a deposit or a new deposit of a culture has been made under this Schedule—

- (a) notifies the applicant or proprietor that it—
  - (i) cannot satisfy a request made in accordance with paragraph 2(1) or 3(3) above, or
  - (ii) is not able lawfully, to satisfy such a request, for the culture to be made available;
- (b) ceases temporarily or permanently to carry out the functions of a depositary institution; or
- (c) ceases for any reason to conduct its activities as a depositary institution in an objective and impartial manner,

subject to subparagraph (3) below, the applicant or proprietor may, unless the culture has been transferred to another depositary institution which is able to make it available, make a new deposit of a culture of that micro-organism.

(2) For the purposes of paragraph 1 above and of this paragraph, the deposit shall be treated as always having been available if, within three months of the receipt of such notification or of the depositary institution ceasing to perform the functions of a depositary institution or to conduct its activities as such an institution in an objective and impartial manner, the applicant or proprietor,—

- (a) in a case where the deposit has not already been transferred, makes the new deposit;
- (b) furnishes to the depositary institution with which the new deposit is made a declaration that the culture so deposited is of the same micro-organism as was the culture originally deposited; and

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- (c) requests amendment of the specification under section 19 or section 27, as the case may be, so as to indicate the accession number of the transferred or new deposit and, where applicable, the name of the depositary institution with which the deposit has been made.
- (3) The new deposit referred to in subparagraph (1) above—
  - (a) shall, save as provided in subparagraph (b) below, be made with the same depositary institution as was the original deposit; or
  - (b) in the cases referred to in subparagraphs (1)(a)(ii), (b) and (c) above, shall be made with another depositary institution which is able to satisfy the request.

### **Interpretation of Schedule**

#### **5.—(1) In this Schedule—**

“the Budapest Treaty” means the Treaty on the International Recognition of the Deposit of Micro-organisms for the purposes of Patent Procedure done at Budapest in 1977; and

“international depositary authority” means a depositary institution which has acquired the status of international depositary authority as provided in Article 7 of the Budapest Treaty.

(2) For the purposes of this Schedule a “depositary institution” is an institution which, at all relevant times,—

- (a) carries out the functions of receiving, accepting and storing micro-organisms and the furnishing of samples thereof; and
- (b) conducts its affairs in so far as they relate to the carrying out of those functions in an objective and impartial manner.