SCHEDULE 1 Rule 13(1)

BIOLOGICAL MATERIAL

Introductory

1. In this Schedule—

"authorisation certificate" means a certificate issued by the comptroller authorising a depositary institution to make available a sample of biological material;

"Budapest Treaty" means the Treaty on the International Recognition of the Deposit of Micro-organisms for the purposes of Patent Procedure signed at Budapest on 28th April 1977, as amended on 26th September 1980, and includes references to the regulations made under that Treaty;

"depositary institution" means an institution which—

(a) carries out the functions of receiving, accepting and storing biological material and the furnishing of samples of such biological material (whether generally or of a specific type); and

(b) conducts its affairs, in so far as they relate to the carrying out of those functions, in an objective and impartial manner;

"expert" means independent expert;

"first requirement" means the first requirement in paragraph 3;

"international depositary authority" means a depositary institution which has acquired the status of international depositary authority as provided in the Budapest Treaty; and

"second requirement" means the second requirement in paragraph 3.

Specification of an application for a patent, or of a patent, for an invention which involves the use of or concerns biological material

2.—(1) This paragraph applies where the specification of an application for a patent, or of a patent, for an invention which involves the use of or concerns biological material does not 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.

(2) Where this paragraph applies, the specification 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, if—

(a) the first requirement and the second requirement are satisfied; and

(b) the specification of the application as filed contains such relevant information as is available to the applicant on the characteristics of the biological material.

The first and second requirements

3.—(1) The first requirement is that—

(a) on or before the date of filing of the application, the biological material has been deposited in a depositary institution; and

(b) that institution will be able to furnish subsequently a sample of the biological material.

(2) The second requirement is that before the end of the relevant period—

(a) the name of the depositary institution and the accession number of the deposit are included in the specification; and

(b) where the biological material was deposited by a person other than the applicant ("the depositor")—

(i) a statement is filed which identifies the name and address of the depositor, and

(ii) a statement by the depositor has been filed, which authorises the applicant to refer to the biological material in his application and irrevocably authorises the making available to the public of the biological material in accordance with this Schedule.

(3) The relevant period is the first to expire of—

(a) the period of sixteen months—

(i) where there is no declared priority date, beginning with the date of filing of the application; or

(ii) where there is a declared priority date, beginning with that date;

(b) where the applicant has made a request under section 16(1) to publish the application during the period prescribed for the purposes of that section, the period ending with the date of the request; or

(c) where the applicant was notified under rule 52(2), the period of one month beginning with the date of the notification.

(4) Where—

(a) the application is filed with the European Patent Office and documents have been filed under the provisions of the European Patent Convention corresponding to sub-paragraph (2); or

(b) the application in suit is an international application for a patent (UK) and documents have been filed in accordance with the Patent Co-operation Treaty under the provisions of the Treaty corresponding to sub-paragraph (2),

the second requirement shall be treated as having been met.

(5) In this paragraph—

"accession number" means the number given to the deposit by a depositary institution;

"specification" means the specification of an application for a patent.

A request by a person for biological material to be made available

4.—(1) This paragraph applies when paragraph 7 does not apply.

(2) Where an application for a patent has been published, any person may request the comptroller to issue an authorisation certificate.

(3) Where the application has not been published, a person who has been notified in accordance with section 118(4) may request the comptroller to issue an authorisation certificate.

(4) A request must be made on Patents Form 8.

(5) Where the biological material has been deposited at an international depositary authority, the request must be accompanied by the relevant form required by the Budapest Treaty.

(6) Where the comptroller grants the request, he must send copies of the request and the certificate (and any form required by the Budapest Treaty) to—

(a) the applicant for, or the proprietor of, the patent;

(b) the depositary institution; and

(c) the person making the request.

The undertaking

5.—(1) A request made under paragraph 4 or 7 shall include an undertaking by the person making the request—

(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,

subject to the following sub-paragraphs.

(2) The applicant for, or the proprietor of, a patent may agree to limit the effect of the undertaking in a particular case.

(3) The undertaking shall cease to have effect—

(a) when the application for a patent is terminated or withdrawn (but it will continue to have effect if the application is reinstated or resuscitated); or

(b) when the patent ceases to have effect.

(4) Where a request is made—

(a) by a government department or any person authorised in writing by a government department; and

(b) for the purposes of using the patented invention for the services of the Crown,

no undertaking is required and any undertaking by the government department or the person so authorised shall not have effect.

(5) Where—

(a) a licence under the patent to which the undertaking relates is available as of right; or

(b) a compulsory licence in respect of the patent to which the undertaking relates has been granted,

any undertaking made shall have no effect to the extent necessary to give effect to any such licence.

Restriction of availability of biological material to experts

6.—(1) Where the first or the second condition is met (except in relation to Crown use), paragraph 7 applies until the end of the relevant period.

(2) The first condition is—

(a) the applicant requests on Patents Form 8A that a sample of the biological material should only be made available to an expert; and

(b) that request is made before the preparations for the application's publication have been completed by the Patent Office.

(3) The second condition is that, in relation to an international application for a patent (UK), the applicant made a reference to the deposited biological material in accordance with the Patent Co-operation Treaty.

(4) Where the first condition is met, the comptroller shall, when he publishes the application, include a notice that the provisions of paragraph 7 apply.

(5) In paragraph 6(1) "the relevant period" is—

(a) where the patent is granted, the period ending with the date on which the patent was granted; and

(b) where the application is terminated or withdrawn, twenty years beginning with the date of filing.

(6) Nothing in this or the following paragraph affects the rights under section 55 of any government department or any person authorised in writing by a government department.

Request for a sample to be made available to expert

7.—(1) A request for a sample to be made available to an expert must be made on Patents Form 8 and must include details of the expert.

(2) Where the biological material has been deposited at an international depositary authority, the request must be accompanied by any form required by the Budapest Treaty.

(3) The comptroller must send a copy of Patents Form 8 to the applicant for the patent.

(4) Before the end of the period of one month beginning with the date on which a copy of Patents Form 8 is sent by the comptroller, the applicant may give notice of his objection to the particular expert, and where he objects the comptroller shall determine the matter.

(5) Where—

(a) the applicant does not object to the sample being made available; or

(b) following an objection, the comptroller decides that the sample should be made available to the particular expert,

the comptroller must issue a certificate authorising the release of a sample to the expert.

(6) A copy of Patents Form 8 (and any form required by the Budapest Treaty) and any certificate issued under sub-paragraph (5) must be sent to—

(a) the applicant for the patent;

(b) the depository institution where the sample of the biological material is stored;

(c) the expert; and

(d) the person who made the request.

New deposits

8.—(1) This paragraph applies where the first, second or third circumstance occurs.

(2) The first circumstance is that the biological material ceases to be available at the depositary institution because it is no longer viable.

(3) The second circumstance is that—

(a) the depositary institution is, for any other reason, unable to supply the biological material; or

(b) the place where the biological material is deposited is no longer a depositary institution for that type of material (whether temporarily or permanently).

(4) The third circumstance is that the biological material is transferred to a different depositary institution.

(5) The first requirement and the second requirement shall be treated as having been complied with throughout the relevant period, if and only if—

(a) where the first or second circumstance occurs—

(i) a new deposit of biological material is made at the relevant depositary before the end of the relevant period, and

(ii) that deposit is accompanied by a statement, signed by the person making the deposit, that the biological material deposited is the same as that originally deposited; and

(b) in all circumstances, the applicant or proprietor, before the end of the relevant period, applies to the comptroller to amend the specification of the application for the patent, or the patent, so that it meets the second requirement.

(6) For the purposes of paragraph (5) "the relevant period" is the period beginning when the first, second or third circumstance occurs and ending—

(a) three months after the date on which the depositor is notified by the depositary institution that the first, second or third circumstance occurred; or

(b) where it expires later, three months after the date on which that circumstance is advertised in the journal.

(7) The relevant depositary is—

(a) where only the first circumstance occurs, the depositary institution where the original deposit was made; or

(b) in any other case, any depositary institution.