STATUTORY INSTRUMENTS

2001 No. 1412

PATENTS

The Patents (Amendment) Rules 2001

Made - - - -	*9th April 2001*
Laid before Parliament	*9th April 2001*
Coming into force - -	*6th July 2001*

The Secretary of State, in exercise of the powers conferred upon him by sections 123 and 125A of the Patents Act 1977[M1], after consultation with the Council on Tribunals pursuant to section 8(1) of the Tribunals and Inquiries Act 1992[M2], hereby makes the following Rules:—

Marginal Citations

M1 1977 c. 37.

M2 1992 c. 53.

Citation and Commencement

1. These Rules may be cited as the Patents (Amendment) Rules 2001 and shall come into force on 6th July 2001.

Amendment of the Patents Rules 1995

2. The Patents Rules 1995 [M3] are amended as set out in rules 3 to 8.

Marginal Citations

M3 S.I. 1995/2093 as amended by S.I. 1999/1092, **S.I**. 1999/1899 and S.I. 1999/3197.

3. In rule 17 —

(a) in the heading, for “Micro-organisms” substitute “ Biological material ”;

(b) in the rule, for “require for their performance the use of micro-organisms” substitute “ involve the use of or concern biological material ”.

4. In rule 26(1)(b), after "paragraph 1(2)(a)(ii)" insert " , 1(2)(a)(iii) ".

5. In rule 85(2), for "subparagraph (2)(a)(ii)" substitute " subparagraphs (2)(a)(ii) and (iii) ".

6. In rule 110(2), for "paragraph 4(2) of Schedule 2" substitute " paragraphs 5(2) and 5(4) of Schedule 2 ".

7. Patents Forms 8/77 and 8A/77 in Schedule 1 are replaced by Patents Forms 8/77 and 8A/77 in Schedule 1 to these Rules.

8. Schedule 2 is replaced by the provisions of Schedule 2 to these Rules.

Kim Howells
Parliamentary Under Secretary of State for
Competition and Consumer Affairs
Department of Trade and Industry

9th April 2001

SCHEDULE 1

Rule 7

Patents Form 8/77

Patents Act 1977
(Rule 17 and Schedule 2)

8/77

Request for a certificate authorising the release of a sample of biological material

(See the notes on the back of this form)

The Patent Office

Cardiff Road
Newport
South Wales
NP10 8QQ

1. Your reference:

2. Patent application or patent number

3. Full name of the or of each patent applicant or proprietor

4. Name of the depositary institution where the biological material is held
(see note (i))

5. Accession number and description of the deposit

6. Name and address of the or of each person making this request

7. Full name, address and postcode in the United Kingdom to which the certificate is to be sent

8. Name and address of the expert to whom the sample is to be released, if not the person named at part 6.
(see note (ii))

Patents Form 8/77

9. *To be signed by the expert if one has been nominated at part 8 (see note (f))*

If a sample of the requested biological material is released to me, I undertake not to make the biological material, or any material derived from it, available to any other person; and to use the biological material, or any material derived from it, only for experimental purposes relating to the subject matter of the invention.

Signature Date

10. *(see notes (e) & (f))*

I/We give the undertaking in part 9 above, if not already signed by the nominated expert, and declare that the specification of the application or patent identified in part 2 discloses an invention which requires for its performance the use of the biological material identified at part 5; and that, where the application has not yet been published, I am/we are entitled to receive information and inspect documents by virtue of Section 118(4) or (5).

I/We request a certificate authorising the release of a sample of the biological material.

Signature Date

11. Name and daytime telephone number of person to contact in the United Kingdom

Notes

a) If you need help to fill in this form or you have any questions, please contact the Patent Office on 08459 500 505.

b) Write your answers in capital letters using black ink or you may type them.

c) If the biological material is deposited with an International Depositary Authority under the Budapest Treaty, Form BP/12 should also be filled in and filed with this form.

d) Paragraph 3 of Schedule 2 to the Patents Rules 1995 allows an applicant for a patent to restrict availability of biological material to 'experts' until the patent is granted, by filing Patents Form 8A/77.

e) If you want to obtain a sample before publication of the application, by virtue of Section 118(4), a statutory declaration should also be furnished in accordance with Rule 96 of the Patents Rules 1995.

f) These undertakings are subject to the provisions of paragraphs 2(4) to 2(8) of Schedule 2 to the Patents Rules 1995.

g) Once you have filled in the form you must remember to sign and date it and if necessary have it signed and dated at part 9 by the nominated expert.

Patents Form 8A/77

Patents Act 1977
(Rule 17 and Schedule 2)

8A/77

Notice of the intention to restrict the availability of samples of biological material to experts

(See the notes on the back of this form)

The Patent Office

Cardiff Road
Newport
South Wales
NP10 8QQ

1. Your reference

2. Patent application number
(If you know it)

3. Full name, address and postcode of the or of each applicant

4. Name of the depositary institution where the biological material is held

5. Accession number and description of the deposit

6. I am/we are the applicant(s) named in part 3 above and give notice that samples of the biological material identified in part 5 above should be available only to experts as set out in paragraph 3 of Schedule 2 to the Patents Rules 1995.

Signature Date

7. Name and daytime telephone number of person to contact in the United Kingdom

Patents Form 8A/77

Patents Form 8A/77

Notes

a) If you need help to fill in this form or you have any questions, please contact the Patent Office on 08459 500505.

b) Write your answers in capital letters using black ink or you may type them.

c) In order to be effective, this form must be filed before the Patent Office has completed the preparations for publishing your application under Section 16(1) of the Patents Act 1977.

d) The restriction will not be effective after the grant of a patent on the application or after 20 years from the date of filing the application in the circumstances set out in paragraph 3(2)(b)(ii) of Schedule 2 to the Patents Rules 1995.

e) Once you have filled in this form you must remember to sign and date it.

f) For details of the fee and ways to pay, please contact the Patent Office.

Patents Form 8A/77

SCHEDULE 2 Rule 8

"SCHEDULE 2 Rule 17

BIOLOGICAL MATERIAL

Applications

1.—(1) The specification of an application for a patent, or of a patent, for an invention which involves the use of or concerns biological material:

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

(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, the biological material has been deposited in a depositary institution which is able to furnish a sample of the biological material; and

(ii) the name of the depositary institution and the accession number of the deposit are given in the specification of the application; and

(iii) where the biological material has been deposited by a person other than the applicant, the name and address of the depositor are stated in the application and a document is filed satisfying the comptroller that the depositor has authorised the applicant to refer to the deposited material in the application and has given his unreserved and irrevocable consent to the deposited material being made available to the public in accordance with this Schedule; 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 paragraph 5 below applies, a further condition that a new deposit has been made in accordance with that paragraph and the applicant or proprietor has made the request referred to in subparagraph (2)(b) of that paragraph within the period referred to in subparagraph (2) or, if applicable, (4) of that paragraph.

(3) Where the information specified in subparagraph (2)(a)(ii) or (iii) 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 a request is made by the applicant to the comptroller to publish the application before the end of the period prescribed for the purposes of section 16(1), on or before the date of that 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 biological material (including a deposit which is to be treated as having always been available by virtue of paragraph 5(2) below) is from time to time deposited making the biological material available on receipt of the comptroller's certificate authorising the release to the person who is named therein as a person to whom the biological material may be made available and who makes a valid request therefor to the institution.

General availability of biological material

2.—(1) Save where paragraph 3 below has effect, a request may be made to the comptroller to issue a certificate authorising a depositary institution to make available a sample of biological material—

(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 (notwithstanding revocation or cancellation of the patent).

(2) A request under subparagraph (1) above shall be made on Patents Form 8/77 (which shall be filed in duplicate together, in the case of biological material which is deposited under the Budapest Treaty with an international depositary authority, with the form provided for by the Regulations under that Treaty).

(3) On receipt of a valid request under subparagraph (1) above, the comptroller shall send copies of the form or forms lodged with him under subparagraph (2) 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.

(4) 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 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, otherwise than for experimental purposes relating to the subject matter of the invention,

and both undertakings shall have effect—

(i) 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, during any period for which the patent is in force and during the period of six months referred to in section 25(4).

(5) For the purposes of enabling any act specified in section 55 to be done in relation to the biological material for the services of the Crown, the undertakings specified in subparagraph (4) 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

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

(6) An undertaking given pursuant to subparagraph (4) above may be varied by way of derogation by agreement between the applicant or proprietor and the person by whom it is given.

(7) Where, in respect of a patent to which an undertaking given pursuant to subparagraph (4) above 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.

(8) In subparagraph (4) above, references to material derived from deposited biological material are references to material so derived which exhibits those characteristics of the deposited biological material essential for the performance of the invention.

Restriction of availability of biological material to experts

3.—(1) Subject to subparagraph (3) 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 biological material should be made available only to an independent 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:

(i) until the grant of the patent; or, where applicable,

(ii) for 20 years from the date on which the patent application was filed if the application for the 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,

issue any certificate authorising release of a sample otherwise than under paragraph 4 below.

(3) Where 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 biological material 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 subparagraph (1) above and subparagraph (2)(a) above shall not apply.

Request for a sample to be made available to an expert

4.—(1) Where the availability of samples is restricted to independent experts by paragraph 3 above, any person wishing to have a sample of the biological material 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 biological material which 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 subparagraph (4) of paragraph 2 above and the provisions of that paragraph relating to undertakings shall also apply to the undertakings given by the expert.

(2) The comptroller shall send a copy of Patents Form 8/77 filed under subparagraph (1) above to the applicant for the patent and shall specify the period within which the applicant may object, in accordance with subparagraph (3) below, to a sample of the biological material being made available to the expert.

(3) Unless, within the period specified by the comptroller under subparagraph (2) 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 biological material being made available to the expert and gives his reasons for his objection, the comptroller shall send a copy of any form lodged with him under subparagraph (1)(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.

(4) Where, in accordance with subparagraph (3) 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, independence 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 subparagraph (3) above a copy of any form lodged with him under subparagraph (1)(a) above and of his certificate authorising the release of the sample to the expert.

(5) Before making a decision in accordance with subparagraph (4) above, the comptroller shall afford the applicant and the requester the opportunity of being heard.

(6) If the comptroller decides under subparagraph (4) 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.

(7) Nothing in this paragraph or paragraph 3 above shall affect the rights under section 55 of any government department or any person authorised in writing by a government department.

New deposits

5.—(1) This paragraph applies where—

(a) biological material ceases to be available from the institution with which it was deposited because—

(i) the biological material is no longer viable, or

(ii) for any other reason the institution is unable to supply samples, or

(b) the depositary institution—

(i) ceases to be a depositary institution for the purposes of this Schedule, either entirely or for the kind of biological material to which the deposited sample belongs, or

(ii) discontinues, temporarily or permanently, the performance of its functions as regards deposited biological material,

and no sample of the biological material has been transferred to another depositary institution, from which it continues to be available.

(2) An interruption in availabilty of the biological material shall be deemed not to have occurred if within a period of three months from the date on which the depositor was notified of the interruption by the depositary institution—

(a) the depositor (or applicant or proprietor if different) makes a new deposit of a sample of that biological material; and

(b) the applicant or proprietor makes a request for amendment of the specification under section 19 or section 27, as the case may be, so as to indicate the accession number of the new deposit and, where applicable, the name of the depositary institution with which the deposit was made.

(3) In the case provided for in subparagraph (1)(a)(i) above, the new deposit shall be made with the depositary institution with which the original deposit was made; in the cases provided for in subparagraphs 1(a)(ii) and 1(b), it may be made with another depositary institution.

(4) Where, in a case to which subparagraph (1)(b) applies, no notification of the interruption of availability of the biological material from the depositary institution is received by the depositor within six months from the date of such event, the three-month period referred to in subparagraph (2) shall begin on the date on which this event is announced in the Journal.

(5) Any new deposit shall be accompanied by a statement signed by the person making the deposit certifying that the sample of biological material newly deposited is of the same biological material as was the sample originally deposited.

Transitional Provisions

6.—(1) In relation to an application for a patent filed before 7th January 1991, rule 17 of the Patents Rules 1982 [M4] shall continue to have effect notwithstanding its revocation by rule 123(3) of the Patents Rules 1990 [M5].

Interpretation of Schedule

7.—(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 biological material 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."

Marginal Citations

M4 S.I. 1982/717, to which there are no relevant amendments.

M5 S.I. 1990/2384, to which there are no relevant amendments.

EXPLANATORY NOTE

(This note is not part of the Rules)

These Rules amend the Patents Rules 1995 (S.I. 1995/2093 as amended by S.I. 1999/1092, S.I. 1999/1899 and S.I. 1999/3197 ("the 1995 Rules") in order to implement Articles 13 and 14 of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions ("the Directive"). Articles 13 and 14 of the Directive concern the deposit, access and re-deposit of biological material. Amendment is also made to the 1995 Rules to more closely align them with the parallel regulations on deposit of biological material under the European Patent Convention. The following amendments are made:

a) Rules 3, 4, 5 and 6 make consequential changes to references and terminology in the 1995 Rules,

b) Rule 7 substitutes updated versions of forms 8/77 and 8A/77 for those forms currently in Schedule 1 to the 1995 Rules,

c) Rule 8 substitutes a new Schedule 2 to the 1995 Rules.Schedule 2 to the 1995 Rules contains detailed provisions dealing with the deposit, access and re-deposit of biological material.

A regulatory impact assessment is available, copies of which have been placed in the libraries of both Houses of Parliament. Copies of the assessment are also available from the Intellectual Property Policy Directorate of the Patent Office, Room 3B38, Concept House, Cardiff Road, Newport NP10 8QQ.

Changes to legislation:
The Patents (Amendment) Rules 2001 is up to date with all changes known to be in force on or before 03 December 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

– Instrument rev by S.I. 2007/3291 rule 120sch 6