

THE DRAFT PATENTS (COMPULSORY LICENSING AND SUPPLEMENTARY PROTECTION CERTIFICATES) REGULATIONS 2007

Introduction

1. This document seeks your comments on proposed changes to the Patents Act 1977 (“the 1977 Act”) relating to EC legislation on compulsory licences and on supplementary protection certificates (“SPCs”).

Background

2. Earlier this year, the UK Intellectual Property Office consulted widely on a fully modernised and consolidated draft of the Patents Rules¹. Proposals included new rules to implement recent EC Regulations on medicinal products for paediatric use and the compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.
3. A related proposal was to update existing rules on SPCs² and to incorporate them into the new Patents Rules.
4. The consultation document also referred to the Patents (Supplementary Protection Certificate for Medicinal Products) Regulations 1992 (S.I. 1992/3091) and the Patents (Supplementary Protection Certificate for Plant Protection Products) Regulations 1996 (S.I. 1996/3120). As the document explained, these are short instruments which state, in a very general way, that the provisions of the 1977 Act apply to SPCs. The document continued:

“We propose to replace these Regulations with a specific new provision within the Act itself (section 125B) which will state clearly which provisions in the Act apply to SPCs and which do not. It will also contain a few specific provisions in relation to SPCs, including to provide for the annual fee, and thus provide a clearer basis for the SPC provisions in the Rules. The draft section 125B will be made public once drafting has been completed.”

5. In light of this, the draft Regulations, which will insert new provisions into the 1977 Act, are attached to this document. Before finalising the drafting, we would be interested in your comments on the draft Regulations.

Summary

6. The draft Regulations are designed to:
 - set out more clearly than at present which provisions in the 1977 Act apply to SPCs and SPC applications

¹ The consultation closed in June but the consultation document remains available: www.ipo.gov.uk/consult-patentrules.pdf

² Currently separate legislation – the Patents (Supplementary Protection Certificate) Rules 1997 (S.I. 1997/64)

- provide a legal basis in the 1977 Act for the new rules implementing the EC Regulation on paediatric medicines
 - provide a legal basis in the 1977 Act for the new rules implementing the EC Regulation on compulsory licences, and in doing so set out clearly which provisions in the 1977 Act apply to compulsory licences granted under the EC Regulation.
7. In terms of SPCs there is intended to be no change to existing practice or policy, other than to implement the EC Regulation on paediatric medicines.

New section 128A – EU compulsory licences

8. New section 128A will deal with the application of the 1977 Act to EU compulsory licences. It lists those sections of the Act in which references to a licence or a right or proprietary interest under a patent are taken to include an EU compulsory licence. For example, it makes clear that references in section 38(1) to the continuation in force of licences after an entitlement dispute will include not only licences under the Act but licences granted under the EC Compulsory Licensing Regulation.
9. New section 128A also lists sections of the 1977 Act in which references to the Act itself are taken to include the EC Compulsory Licensing Regulation. For example, the reference in section 120 to the Office’s opening hours and business done “under this Act” will include business done under the provisions of the EC Compulsory Licensing Regulation.

New section 128B and Schedule 4A – SPCs

10. A new section 128B and Schedule 4A will similarly deal with the application of the 1977 Act to SPCs. Sections of the Act which have application to SPCs are identified in paragraph 1 of the Schedule. This also contains a set of general glosses which ensure that the applied provisions make sense for SPCs. Thus, for example, “patent” is glossed to mean “SPC”, and “specification” is glossed to mean the content of the SPC itself. A few very specific further glosses are contained in paragraph 4 of the Schedule.
11. As noted above, in making clear that certain sections of the Act apply to SPCs (with glosses), there is intended to be no change in policy or practice – just a more clear expression of the legal position. Thus, for example, it is made clear that the basis on which an SPC application may be amended is section 19(1), which is applied and glossed appropriately³.
12. Certain provisions concern provisional protection bestowed by the SPC application and have only been applied in circumstances where the patent concerned has expired while the SPC application is still pending. (If the SPC application takes effect immediately on expiry of the patent then there is no

³ In a provision which is applied to SPCs, any reference to a section of the Act which is not applied to SPCs has no effect. Thus, for example, the reference to section 76 in section 19(1), as applied to SPCs and glossed accordingly, has no effect.

need for provisional protection from the SPC application). This is set out in paragraph 2 of the Schedule.

13. Just as for EU compulsory licences, sections of the 1977 Act are listed in which references to the Act itself are taken to include the EC Medicinal and Plant Protection SPC Regulations. See paragraph 3 of the Schedule.

14. Paragraph 5 of the Schedule will, in conjunction with the proposed Patents Rules, provide the basis for the SPC renewal fees⁴. This involves no change to the fees themselves, nor to the periods for payment.

Your comments are welcome

15. We are interested in your comments on the proposed new sections 128A and 128B of, and new Schedule 4A to, the 1977 Act. We are considering further the application of the provisions in square brackets in draft section 128A(3) and would be particularly interested in any comments you have in this regard.

16. This document is being made available on the Office's website, has been sent to certain of the Office's focus groups and specific interests, and has been sent to respondents to the consultation on the draft Patents Rules.

17. Please send comments on the draft Regulations by **31 October 2007** to:

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18. Please note that this is not intended to re-open consultation on the detailed implementation of the EC Regulations on paediatric medicines and compulsory licenses, nor re-open consultation on the inclusion of SPC rules within the new Patents Rules. These issues were covered by the Patents Rules consultation earlier this year and were subject to no adverse comment or criticism.

What happens next

19. The draft Regulations will be finalised in light of any comments and will be laid before Parliament to come into force at the same time as the new Patents Rules. The intention is that this will take place in December 2007.

⁴ The cross-references in draft rule 116 (as shown in the Patents Rules consultation document) will be updated to reflect the structure of proposed new Schedule 4A to the 1977 Act.

2007 No.

PATENTS

The Patents (Compulsory Licensing and Supplementary Protection Certificates) Regulations 2007

Made - - - - - ***

Laid before Parliament ***

Coming into force - - - - - ***

The Secretary of State has been designated for the purposes of section 2(2) of the European Communities Act 1972⁽⁵⁾ in relation to intellectual property (including both registered and unregistered rights)⁽⁶⁾.

The Secretary of State makes the following Regulations under the powers conferred by that section as read with paragraph 1A of Schedule 2 to that Act.

These Regulations make provision for a purpose mentioned in that section and it appears to the Secretary of State that it is expedient for certain references to Community instruments to be construed as references to those instruments as amended from time to time.

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Patents (Compulsory Licensing and Supplementary Protection Certificates) Regulations 2007.

(2) These regulations come into force on [...] 2007.

(3) These Regulations have the same extent as the Patents Act 1977⁽⁷⁾, except that they do not extend to the Isle of Man.

Amendments to the Patents Act 1977

2. —(1) The Patents Act 1977 is amended as follows.

(2) After section 128 insert—

“128A EU compulsory licences

(1) In this Act an “EU compulsory licence” means a compulsory licence granted under Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems (referred to in this Act as “the Compulsory Licensing Regulation”).

⁽⁵⁾ 1972 c. 68.

⁽⁶⁾ SI 2006/608.

⁽⁷⁾ 1977 c. 37.

(2) In the application to EU compulsory licences of the provisions of this Act listed in subsection (3)—

- (a) references to a licence under a patent,
 - (b) references to a right under a patent, and
 - (c) references to a proprietary interest under a patent,
- include an EU compulsory licence.

(3) The provisions referred to in subsection (2) are—

- sections 32 and 33 (registration of patents etc);
- section 37 (determination of right to patent after grant);
- section 38(1), (3), (4) and (5) (continuation in force of licences and other rights on transfer of patent);
- [section 41 (amount of compensation);]
- section 46(2) (notice of application for entry that licences are available as of right);
- [section 57(1) and (2) (right of third parties in respect of Crown use).]

(4) In the following provisions references to this Act include the Compulsory Licensing Regulation—

- sections 97 to 99B, 101 to 103, 105 and 107 (legal proceedings);
- section 119 (service by post);
- section 120 (hours of business and excluded days);
- section 121 (comptroller's annual report);
- section 123 (rules);
- section 124A (use of electronic communications);
- section 130(8) (disapplication of Part 1 of Arbitration Act 1996).

(5) In section 108 (licences granted by order of comptroller) the reference to a licence under section 11, 38, 48 or 49 includes an EU compulsory licence.

(6) References in this Act to the Compulsory Licensing Regulation are to that Regulation as amended from time to time.

128B Supplementary protection certificates

(1) Schedule 4A contains provision about the application of this Act in relation to supplementary protection certificates and other provision about such certificates.

(2) In this Act a “supplementary protection certificate” means a certificate issued under—

- (a) Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, or
- (b) Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products.”.

(3) After Schedule 4 insert—

“SCHEDULE 4A

SUPPLEMENTARY PROTECTION CERTIFICATES

References to patents etc

1 (1) In the application to supplementary protection certificates of the provisions of this Act listed in sub-paragraph (2)—

- (a) references to a patent are to a supplementary protection certificate;

- (b) references to an application or the applicant for a patent are to an application or the applicant—
 - (i) for a supplementary protection certificate, or
 - (ii) for an extension of the duration of a supplementary protection certificate;
 - (c) references to the proprietor of a patent are to the holder of a supplementary protection certificate;
 - (d) references to the specification of a patent are to the content of a supplementary protection certificate;
 - (e) references to a patented product or a patented invention are to a product for which a supplementary protection certificate has effect;
 - (f) references to a patent having expired or having been revoked are to a supplementary protection certificate having lapsed or having been declared invalid;
 - (g) references to proceedings for the revocation of a patent are to proceedings—
 - (i) for a decision that a supplementary protection certificate has lapsed, or
 - (ii) for a declaration that a supplementary protection certificate is invalid;
 - (h) references to the issue of the validity of a patent include the issue of whether a supplementary protection certificate has lapsed or is invalid.
- (2) The provisions referred to in sub-paragraph (1) are—
- section 14(1), (9) and (10) (making of application);
 - section 19(1) (general power to amend application before grant);
 - sections 20A and 20B (reinstatement of applications);
 - section 21 (observations by third party on patentability);
 - section 27 (general power to amend specification after grant);
 - section 29 (surrender of patents);
 - sections 30 to 36, 37(1) to (3) and (5) to (9) and 38 (property in patents and applications, and registration);
 - sections 39 to 59 (employees' inventions, licences of right and compulsory licences and use of patented inventions for services of the Crown);
 - sections 60 to 71 (infringement);
 - section 74(1) and (7) (proceedings in which validity of patent may be put in issue);
 - section 75 (amendment of patent in infringement or revocation proceedings);
 - sections 103 and 105 (privilege for communications relating to patent proceedings);
 - section 108 (licences granted by order of comptroller);
 - sections 110 and 111 (unauthorised claim of patent rights or that patent has been applied for);
 - section 116 (immunity of department as regards official acts);
 - sections 117 to 118 (administrative provisions);
 - section 123 (rules);
 - section 130 (interpretation).

2 (1) In the case of the provisions listed in sub-paragraph (2), paragraph 1 applies in relation to an application for a supplementary protection certificate only if the basic patent expires before the certificate is granted.

- (2) The provisions referred to in sub-paragraph (1) are—
- section 20B(3) to (6A) (effect of reinstatement under section 20A);
 - section 55(5) and (7) (use of patented inventions for services of the Crown);
 - section 58(10) (disputes as to Crown use);
 - section 69 (infringement of rights conferred by publication of application);

section 117A(3) to (7) (effect of resuscitating a withdrawn application under section 117).

References to this Act etc

3 (1) In the provisions listed in sub-paragraph (2)—

- (a) references to this Act include the Medicinal Products Regulation and the Plant Protection Regulation, and
- (b) references to a provision of this Act include any equivalent provision of the Medicinal Products Regulation and the Plant Protection Regulation.

(2) The provisions referred to in sub-paragraph (1) are—

sections 20A and 20B (reinstatement of applications);
section 21 (observations by third party on patentability);
section 69 (infringement of rights conferred by publication of application);
section 74(1) and (7) (proceedings in which validity of patent may be put in issue);
sections 97 to 99B, 101 to 103, 105 and 107 (legal proceedings);
section 116 (immunity of department as regards official acts);
sections 117 and 118 to 121 (administrative provisions);
section 122 (Crown's right to sell forfeited articles);
section 123 (rules);
section 124A (use of electronic communications);
section 130 (interpretation).

Other references

4 (1) In the application of section 21(1) (observations by third party on patentability) in relation to supplementary protection certificates, the reference to the question whether the invention is a patentable invention is to the question whether the product is one for which a supplementary protection certificate may have effect.

(2) In the application of section 69(2) (conditions for infringement of rights conferred by publication of application) to supplementary protection certificates, the condition in paragraph (b) is that the act would, if the certificate had been granted on the date of the publication of the application, have infringed not only the certificate as granted but also the certificate for which the application was made.

Fees

5 A supplementary protection certificate does not take effect unless—

- (a) the prescribed fee is paid before the end of the prescribed period, or
- (b) the prescribed fee and any prescribed additional fee are paid before the end of the period of six months beginning immediately after the prescribed period.

Interpretation

6 (1) Expressions used in this Act that are defined in the Medicinal Products Regulation or the Plant Protection Regulation have the same meaning as in that Regulation.

(2) References in this Act to, or to a provision of, the Medicinal Products Regulation or the Plant Protection Regulation are to that Regulation or that provision as amended from time to time.

7 In this Act—

- (a) “the Medicinal Products Regulation” means Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, and
- (b) “the Plant Protection Regulation” means Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products.”.

Amendments to the Patents and Plant Variety Rights (Compulsory Licensing) Regulations 2002

3.—(1) The Patents and Plant Variety Rights (Compulsory Licensing) Regulations 2002⁽⁸⁾ are amended as follows.

(2) In regulation 2(1)—

(a) for the definition of “Patents Fees Rules” substitute—

““Patents (Fees) Rules” means the Patents (Fees) Rules 2007⁽⁹⁾”; and

(b) for the definition of “Patents Rules” substitute—

““Patents Rules” means the Patents Rules 2007⁽¹⁰⁾”.

(3) In regulation 22(2), omit the words “in rule 71(1) of the Patents Rules and”.

Revocations

4. The following instruments are revoked—

(a) the Patents (Supplementary Protection Certificate for Medicinal Products) Regulations 1992⁽¹¹⁾; and

(b) the Patents (Supplementary Protection Certificate for Plant Protection Products) Regulations 1996⁽¹²⁾.

Triesman

Parliamentary Under Secretary of State for Intellectual Property and Quality
Department for Innovation, Universities and Skills

Date

⁽⁸⁾ S.I. 2002/247

⁽⁹⁾ S.I. []

⁽¹⁰⁾ S.I. []

⁽¹¹⁾ S.I. 1992/3091.

⁽¹²⁾ S.I. 1996/3120.

EXPLANATORY NOTE

(This note is not part of the Order)

These Regulations make provision to give effect to Community legislation in relation to compulsory licences and supplementary protection certificates.

The European Parliament and Council adopted Regulation (EC) No 816/2006 of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems (“Compulsory Licensing Regulation”). The Compulsory Licensing Regulation implements a Decision of 30 August 2003 of the General Council of the World Trade Organisation (WTO) on the implementation of paragraph 6 of the Doha Declaration of 14 November 2001 on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and Public Health. TRIPS is an integral part of the Agreement establishing the WTO signed at Marrakesh on 15 April 1994.

Regulation 2(2) applies certain procedural provisions of the Patents Act 1977 in relation to applications and other proceedings under the Compulsory Licensing Regulation. The Regulations do not purport to implement provisions of the Compulsory Licensing Regulation that are directly applicable and thus already enforceable in relation to UK patents.

These Regulations also give effect to changes made to the supplementary protection certificate regime by Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004.

This is done by regulation 2(2) and 2(3), which also re-implement Council Regulation (EEC) No 1768/92 and Regulation (EC) No 1610/96 of the European Parliament and of the Council, concerning supplementary protection certificates for medicinal products and plant protection products. Regulation 4 then revokes the Patents (Supplementary Protection Certificate for Medicinal Products) Regulations 1992 and the Patents (Supplementary Protection Certificate for Plant Protection Products) Regulations 1996 which implemented the relevant provisions of Council Regulation 1768/92 and Regulation 1610/96 respectively.

Regulation 3 amends the Patents and Plant Variety Rights (Compulsory Licensing) Regulations 2002 which implemented Article 12 of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological measures (OJ No. L 213, 30.7.98, p.13). These changes are needed to replace the references in those Regulations to the Patent Rules 1995 and the Patents (Fees) Rules 1997 by references to the new Patents Rules 2007 and Patents (Fees) Rules 2007.