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STATUTORY INSTRUMENTS

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**2007 No. 3293**

**PATENTS**

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

*Made* - - - - *19th November 2007*  
*22nd November*  
*Laid before Parliament* *2007*  
*Coming into force* - - *17th December 2007*

The Secretary of State has been designated for the purposes of section 2(2) of the European Communities Act 1972<sup>(1)</sup> in relation to intellectual property (including both registered and unregistered rights)<sup>(2)</sup>.

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 17th December 2007.

(3) These Regulations have the same extent as the Patents Act 1977<sup>(3)</sup>, 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

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(1) 1972 c. 68.  
(2) SI 2006/608.  
(3) 1977 c. 37.

products for export to countries with public health problems<sup>(4)</sup> (referred to in this Act as “the Compulsory Licensing Regulation”).

(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 (effect of transfer etc of patent under section 37), apart from subsection (2) and subsections (3) to (5) so far as relating to subsection (2);
- 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) (rights 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<sup>(5)</sup>, 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<sup>(6)</sup>.”.

(3) After Schedule 4 insert—

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<sup>(4)</sup> OJ No L 157, 9.6.2006, pl.

<sup>(5)</sup> OJ No L 182, 2.7.92, pl.

<sup>(6)</sup> OJ No L 198, 8.8.96, p30.

“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 text of a supplementary protection certificate;
- (e) references to a patented product or an invention (including 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 of this Act 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 of this Act listed in sub-paragraph (2)—
- (a) references to this Act include the Medicinal Products Regulation and the Plant Protection Products Regulation, and
  - (b) references to a provision of this Act include any equivalent provision of the Medicinal Products Regulation and the Plant Protection Products 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) 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 Products 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 Products 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 Products 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(7) 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(8);”; and
- (b) for the definition of “Patents Rules” substitute—  
““Patents Rules” means the Patents Rules 2007(9);”.

(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(10); and
- (b) the Patents (Supplementary Protection Certificate for Plant Protection Products) Regulations 1996(11).

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(7) [SI 2002/247](#).  
(8) [SI 2007/3292](#).  
(9) [SI 2007/3291](#).  
(10) [SI 1992/3091](#).  
(11) [SI 1996/3120](#).

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**Status:** This is the original version (as it was originally made). UK  
Statutory Instruments are not carried in their revised form on this site.

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19th November 2007

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

## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

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”) (OJ No L 157, 9.6.2006, p1). 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 which is published in OJ L 336, 23.12.94, p1.

Regulation 2 amends the Patents Act 1977 to apply certain procedural provisions of that Act 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.

Regulation 2 also amends the Patents Act 1977 to make it clear how that Act applies in relation to supplementary protection certificates for medicinal and plant protection products. It also gives 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 (OJ No L 378, 27.12.2006, p1).

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, p13). These changes are needed to replace the references in those Regulations to the Patents Rules 1995 (SI 1995/2093) and the Patents (Fees) Rules 1998 (SI 1998/1778) by references to the new Patents Rules 2007 (SI 2007/3291) and Patents (Fees) Rules 2007 (SI 2007/3292).

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 supplemented the relevant provisions of Council Regulation 1768/92 on a supplementary protection certificate for medicinal products and Council Regulation 1610/96 on a supplementary protection certificate for plant protection products respectively.

An impact assessment has been prepared and copies placed in the libraries of both Houses of Parliament. Copies of the assessment are also available from Patents Legal Section, Concept House, Cardiff Road, Newport NP10 8QQ.