STATUTORY INSTRUMENTS

2019 No. 801

The Patents (Amendment) (EU Exit) Regulations 2019

PART 8

SUPPLEMENTARY PROTECTION CERTIFICATES FOR MEDICINAL PRODUCTS – AMENDMENTS TO REGULATION (EC) No 469/2009

51. Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products is amended as follows.

52.—(1) Article 1 (interpretation) is amended as follows.

(2) In paragraph (e) for "Article 36 of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use", substitute "regulation 58A(3) of the Human Medicines Regulations 2012(**1**)".

(3) After paragraph (e) insert—

"(f) 'comptroller' means the Comptroller-General of Patents, Designs and Trade Marks;

(g) 'court' is to be interpreted in accordance with Article 1A;

(h) "EEA authorisation" means an authorisation to place a medicinal product on the market which has effect in an EEA state in accordance with Directive 2001/83/EC or Directive 2001/82/EC;

(i) 'patent' means a patent which has effect in the United Kingdom;

(j) 'UK authorisation' means, in relation to a product, an authorisation to place that product on the market as a medicinal product granted in accordance with—

(i) Part 5 of the Human Medicines Regulations 2012; or

(ii) regulation 4(3) of, and Schedule 1 to, the Veterinary Medicines Regulations 2013(**2**).".

53. After Article 1(interpretation), insert—

"Article 1A

Meaning of 'court'

1. In this Regulation the expression 'court' is to be interpreted in accordance with this Article.

2. In a case where the basic patent is subject to the jurisdiction of the Unified Patent Court by virtue of Schedule A4 to the Patents Act 1977, 'court' means the Unified Patent Court.

3. In any other case, 'court' means—

(**1**) S.I. 2012/1916. Regulation 58A is inserted by S.I. 2019/775, reg. 64.
(**2**) S.I. 2013/2033.

(a) as respects England and Wales, the High Court;

(b) as respects Scotland, the Court of Session; and

(c) as respects Northern Ireland, the High Court in Northern Ireland.

4. The reference in paragraph 2 to the Unified Patent Court is to the court created under the Agreement on a Unified Patent Court made in Brussels on 19th February 2013.".

54. For Articles 2 (scope) and 3 (conditions for obtaining a certificate), substitute—

"Article 2

Scope

A product may, under the terms and conditions provided for in this Regulation, be the subject of a certificate if it is—

(a) protected by a patent; and

(b) the subject of a UK authorisation prior to being placed on the market as a medicinal product.

Article 3

Conditions for obtaining a certificate

Where an application is submitted under Article 7, a certificate shall be granted if, at the date of submission of that application—

(a) the product is protected by a basic patent in force;

(b) there is a valid UK authorisation to place the product on the market;

(c) the product has not already been the subject of a certificate;

(d) the authorisation referred to in point (b) is the first UK authorisation to place the product on the market as a medicinal product.".

55.—(1) Article 8 (content of application for a certificate) is amended as follows.

(2) For paragraph 1(a)(iv), substitute—

"(iv) the number and date of the UK authorisation as referred to in Article 3(b); and

(v) the number and date of the earliest of any EEA authorisation, the granting of which predates the granting of the UK authorisation;".

(3) For paragraph 1(b) and (c), substitute—

"(b) a copy of the UK authorisation to place the product on the market, as referred to in Article 3(b), in which the product is identified, containing in particular the number and date of the authorisation and the summary of the product characteristics listed in Article 11 of Directive 2001/83/EC, Article 14 of Directive 2001/82/EC, Part 2 to Schedule 8 of the Human Medicines Regulations 2012 or Part 1 of Schedule 1 to the Veterinary Medicines Regulations 2013;

(c) where the product is the subject of one or more EEA authorisations granted prior to the UK authorisation referred to in Article 3(b), the applicant must provide in relation to the earliest of any such EEA authorisations—

(i) information regarding the identity of the product thus authorised;

(ii) information regarding the legal provision under which the authorisation procedure took place; and

(iii) a copy of the notice publishing the authorisation in the appropriate official publication;".

(4) In paragraph 1(d)—

(a) in paragraph (i), for "Article 36(1) of Regulation (EC) No 1901/2006" substitute "regulation 58A(2)(a) of the Human Medicines Regulations 2012"; and

(b) omit paragraph (ii).

(5) Omit paragraph (4).

56.—(1) Article 9 (lodging of an application for a certificate) is amended as follows.

(2) For paragraph 1 substitute—

"**1.** An application for a certificate (or an extension of the duration of a certificate) shall be lodged with the comptroller.".

(3) In the introductory words of paragraph 2, for "the authority referred to in paragraph 1", substitute "the comptroller".

(4) For sub-paragraphs (d) and (e) of paragraph 2, substitute—

"(d) the number and date of the UK authorisation and the product identified in that authorisation;

(e) where there are authorisations granted in the EEA before the UK authorisation, the number and date of the earliest EEA authorisation;".

57.—(1) Article 10 (grant of the certificate or rejection of the application for a certificate) is amended as follows.

(2) In paragraphs 1 to 3, for "the authority referred to in Article 9(1)", substitute "the comptroller".

(3) In paragraph 2, after "in this Regulation", insert "or any prescribed fee is not paid".

(4) In paragraph 3, after "Article 8", insert "or the prescribed fee relating to the application has not been paid".

(5) In paragraph 4, for "the authority", substitute "the comptroller".

(6) Omit paragraph 5.

(7) After paragraph 6, insert—

"**7.** References in this Article to a "prescribed fee" are to a fee prescribed under section 123 of the Patents Act 1977.".

58.—(1) Article 11 (publication) is amended as follows.

(2) In paragraphs 1 and 2, for "the authority referred to in Article 9(1)" substitute "the comptroller".

(3) In paragraph 1—

(a) in sub-paragraph (d) insert "UK" before "authorisation" where it first occurs;

(b) for sub-paragraph (e), substitute—

"(e) where there are EEA authorisations granted before the UK authorisation, the number and date of the earliest EEA authorisation;".

59. Omit Article 12 (annual fees).

60.—(1) Article 13 (duration of the certificate) is amended as follows.

(2) In paragraph 1, for "the Community", substitute "the area comprising the European Economic Area and the United Kingdom".

(3) In paragraph 3, for "Article 36 of Regulation (EC) No 1901/2006", substitute "regulation 58A of the Human Medicines Regulations 2012".

61.—(1) Article 14 (expiry of the certificate) is amended as follows.

(2) The existing text is numbered as paragraph 1.

(3) For sub-paragraphs (c) and (d) of the renumbered paragraph 1, substitute—

"(c) if the prescribed annual fee is not paid in time;

(d) if and as long as the product covered by the certificate may no longer be placed on the market following the withdrawal of the appropriate authorisation or authorisations to place on the market. The comptroller may decide on the lapse of the certificate either of the comptroller's own motion or at the request of a third party.".

(4) After paragraph 1, insert—

"**2.** In this Article, "prescribed" means prescribed by rules made under section 123 of the Patents Act 1977.".

62. In paragraph 2 of Article 15 (invalidity of the certificate), for "before the body responsible under national law for the revocation of the corresponding basic patent" substitute "the comptroller or the court".

63.—(1) Article 16 (revocation of an extension of the duration) is amended as follows.

(2) In paragraph 1, for "Article 36 of Regulation (EC) No 1901/2006", substitute "regulation 58A(3) of the Human Medicines Regulations 2012".

(3) In paragraph 2, for "the body responsible under national law for the revocation of the corresponding basic patent", substitute "the comptroller or the court".

64. For references in Article 17 (notification of lapse or invalidity) to "the authority referred to in Article 9(1)", substitute "the comptroller".

65. Omit Article 18 (appeals).

66. For paragraph 1 of Article 19 (procedure), substitute—

"**1.** In the absence of procedural provisions in this Regulation, the procedural provisions applicable to the corresponding basic patent (as modified by section 128B of, and Schedule 4A to, the Patents Act 1977) shall apply to the certificate.".

67. Omit Articles 20 (enlargement of the Community) and 21 (transitional provisions).

68. After Article 23 (entry into force), omit "This Regulation shall be binding in its entirety and directly applicable in all Member States."

Transitional provision

69.—(1) This regulation applies to—

(a) An application for an extension of the duration of a certificate, filed in accordance with Article 7 but not determined before exit day; and

(b) An extension of the duration of a certificate granted—

(i) before exit day; or

(ii) after exit day, pursuant to an application falling within sub-paragraph (a);

(2) Where this regulation applies, Articles 1(e), 8(1)(d), 13(3), and 16(1) of Regulation 469/2009 continue to apply without the amendments made by these Regulations.

(3) Where paragraph (1) applies—

(a) Article 8(1)(d)(ii) is to be read as if, for the words "all other Member States", there were substituted "all Member States";

(b) Articles 13(3) and 16(1) are to be read as if, for the words "all Member States" in Article 36(3) of Regulation 1901/2006, there were substituted "the United Kingdom and all Member States".