STATUTORY INSTRUMENTS

2019 No. 801

The Patents (Amendment) (EU Exit) Regulations 2019

PART 6

SUPPLEMENTARY PROTECTION CERTIFICATES FOR PLANT PROTECTION PRODUCTS – AMENDMENTS TO REGULATION (EC) No 1610/96

- 19. 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 is amended as set out in this Part.
 - **20.**—(1) Article 1 (definitions) is amended as follows.
 - (2) In paragraph 1(c), omit "Council or Commission".
 - (3) After paragraph 10, insert—
 - "11. 'comptroller' means the Comptroller-General of Patents, Designs and Trade Marks;
 - 12. 'court' is to be interpreted in accordance with Article 1A;
 - **13.** 'EEA authorization' means an authorization to place a plant protection product on the market which has effect in an EEA state in accordance with Regulation (EC) No 1107/2009;
 - **14.** 'patent' means a patent which has effect in the United Kingdom;
 - **15.** 'UK authorisation' means an authorisation to place a plant protection product on the market granted by the Secretary of State under Regulation (EC) No 1107/2009.".
 - **21.** After Article 1, insert—

"Article 1A

Meaning of court

- 1. In this Regulation, '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—
 - (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.** In this Article, 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.".

22. For Article 2, substitute—

"Article 2

Scope

A plant protection 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 authorization prior to being placed on the market as a plant protection product.".
- 23. For Article 3(1), substitute—
 - "1. Where an application is submitted under Article 7, a certificate shall be granted if at the date of submission of the application—
 - (a) the product is protected by a basic patent in force;
 - (b) there is a valid UK authorization to place the product on the market;
 - (c) the product has not already been the subject of a certificate;
 - (d) the authorization referred to in (b) is the first UK authorization to place the product on the market as a plant protection product.".
- **24.**—(1) Article 8 (contents of the application for a certificate) is amended as follows.
- (2) For paragraph 1(a)(iv), substitute—
- "(iv) the number and date of the UK authorization as referred to in Article 3(1)(b); and
 - (v) the number and date of the earliest EEA authorization, the granting of which predates the granting of the UK authorization;".
- (3) For paragraph 8(1)(b) and (c), substitute—
 - "(b) a copy of the UK authorization to place the product on the market, as referred to in Article 3(1)(b), in which the product is identified, containing in particular the number and date of the authorization and the summary of the product characteristics listed in Commission Regulation 283/2013, Part A, section 1, points 1 to 7 or Part B, Section 1 points 1 to 5;
 - (c) where the product is the subject of one or more EEA authorizations granted prior to the UK authorization referred to in Article 3(1)(b), the applicant must provide in relation to the earliest of any such EEA authorizations—
 - (i) information regarding the identity of the product thus authorised;
 - (ii) information regarding the legal provision under which the authorization procedure took place; and
 - (iii) a copy of the notice publishing the authorization in the appropriate official publication or, failing such a notice, any other document proving that the authorization has been issued, the date on which it was issued and the identity of the product authorized."
- (4) Omit paragraph 2.
- **25.**—(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 shall be lodged with the comptroller."

- (3) In the introductory words of paragraph 2, for "authority referred to in paragraph 1" substitute "comptroller".
 - (4) For sub-paragraphs (d) and (e) of paragraph 2, substitute—
 - "(d) the number and date of the UK authorization and the product identified in that authorization;
 - (e) where there are EEA authorizations granted before the UK authorization, the number and date of the earliest EEA authorization;".
 - **26.**—(1) Article 10 (grant of the certificate or rejection of the application) 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) Omit paragraph 5.
 - (6) At the end of the Article, insert—
 - "6. References in this Article to a "prescribed fee" are to a fee prescribed under section 123 of the Patents Act 1977.".
 - **27.**—(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 "authorization" where it first occurs;
 - (b) for sub-paragraph (e), substitute—
 - "(e) where there are EEA authorizations granted before the UK authorization, the number and date of the earliest EEA authorization;".
 - 28. Omit Article 12 (annual fees).
- **29.** In paragraph 1 of Article 13 (duration of the certificate), for "the Community", substitute "the area comprising the European Economic Area and the United Kingdom".
 - **30.**—(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 authorization or authorizations to place on the market in accordance with Article 28 of Regulation 1107/2009. 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.".

- **31.** In paragraph (2) of Article 15 (invalidity of certificate), for "the body responsible under national law for the revocation of the corresponding basic patent" substitute "the comptroller or the court".
- **32.** In Article 16 (notification of lapse or invalidity), for "the authority referred to in Article 9(1)", substitute "the comptroller".
 - **33.** In Article 17 (appeals), omit paragraph 1.
 - 34. In Article 18 (procedure), for paragraph 1 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."
 - 35. Omit Articles 19 and 20 (transitional provisions).
- **36.** After Article 21 (entry into force), omit "This Regulation shall be binding in its entirety and directly applicable in all Member States."