STATUTORY INSTRUMENTS

2020 No. 1471

The Supplementary Protection Certificates (Amendment) (EU Exit) Regulations 2020

Citation and commencement

1.—(1) These Regulations may be cited as the Supplementary Protection Certificates (Amendment) (EU Exit) Regulations 2020.

(2) This regulation and regulations 2 and 3 come into force immediately before IP completion day and regulations 4 to 7 come into force on IP completion day.

Amendments to the Patents (Amendment) (EU Exit) Regulations 2019

2.—(1) Part 6 of the Patents (Amendment) (EU Exit) Regulations 2019(**1**) (supplementary protection certificates for plant protection products – amendments to Regulation (EC) No 1610/96) is amended as follows.

(2) In the following paragraphs, a reference to an Article or a paragraph is to that of Regulation (EC) 1610/96(**2**) and a reference to a regulation is to a regulation of the Patents (Amendment) (EU Exit) Regulations 2019.

(3) In Article 1 (definitions), as amended by regulation 20(3), omit paragraph 15.

(4) In Article 2(b) (scope), as inserted by regulation 22, for "UK", substitute "GB or NI".

(5) In Article 3(1) (conditions for obtaining a certificate), as amended by regulation 23—

(a) in sub-paragraph (b), for "UK", substitute "GB or NI";

(b) in sub-paragraph (d)—

(i) omit "UK";

(ii) insert at the end "in the territory of England and Wales and Scotland or the territory of Northern Ireland as the case may be".

(6) In Article 8 (content of the application for a certificate), as amended by regulation 24(2)—

(a) in paragraph 1(a)(iv)—

(i) for "UK authorization", substitute "GB or NI authorisation or both GB and NI authorisations";

(ii) after "3(1)(b)", insert "and (d)";

(b) in paragraph (1)(a)(v)—

(i) for "UK", substitute "GB or NI";

(ii) after "authorization", in the second place it occurs, insert "as referred to in Article 3(1)(b) and (d)".

(7) In Article 8, as amended by regulation 24(3)—

(**1**) S.I. 2019/801, as amended by S.I. 2020/1050.

(**2**) EUR 1996/1610, as amended by S.I. 2019/801 and S.I. 2020/1050. This is a reference to the retained version of Regulation (EC) 1610/96. That retained version is online at http://www.legislation.gov.uk/eur/1996/1610/contents

(a) in paragraph (b)—

(i) for "UK authorization", substitute "GB or NI authorisation or both GB and NI authorisations";

(ii) after "3(1)(b)", insert "and (d)";

(b) in paragraph (c)—

(i) for "UK", substitute "GB or NI ";

(ii) after "3(1)(b)", insert "and (d)".

(8) In Article 9 (lodging of an application for a certificate), as amended by regulation 25(4)—

(a) for paragraph 2(d), substitute—

"(d) the number and date of the GB or NI authorisation or both a GB and a NI authorisation provided under Article 8(1)(b), the product identified in the authorisation and the territory in respect of which the authorisation has been granted or has effect as if granted";

(b) in paragraph (e), for "the UK authorisation", substitute "any GB or NI authorisation provided under Article 8(1)(b)".

(9) In Article 10 (grant of the certificate or rejection of the application), as amended by regulation 26, omit paragraph 6.

(10) In regulation 27(3), omit sub-paragraph (a) of that regulation.

(11) In Article 11(1)(e), as amended by regulation 27(3), for "the UK authorization", substitute "any authorisation provided under Article 8(1)(b)".

(12) In Article 14(1) (expiry of the certificate), as amended by regulation 30—

(a) at the end of paragraph (c), insert "or";

(b) in paragraph (d), for "the appropriate authorization or" substitute "all".

(13) In regulation 30, omit paragraph 4 of that regulation.

3.—(1) Part 8 of the Patents (Amendment) EU Exit Regulations 2019 (supplementary protection certificates for medicinal products – amendments to Regulation (EC) No 469/2009) is amended as follows.

(2) In the following paragraphs, a reference to an Article or a paragraph is to that of Regulation (EC) 469/2009(**3**) and a reference to a regulation is to a regulation of the Patents (Amendment) (EU Exit) Regulations 2019.

(3) In Article 1, in the definition of "UK authorisation" in paragraph (j) inserted by regulation 52(3), after "market", insert "in the United Kingdom".

(4) In Article 2 (scope), in paragraph (b), as inserted by regulation 54, after "UK", insert ", GB or NI".

(5) In Article 3 (conditions for obtaining a certificate), as inserted by regulation 54—

(a) in sub-paragraph (b), after "UK", insert ", GB or NI";

(b) in sub-paragraph (d)—

(i) after "UK", insert ", GB or NI";

(ii) insert at the end "in the territory of the United Kingdom, the territory of England and Wales and Scotland or the territory of Northern Ireland as the case may be".

(6) In Article 8 (content of the application for a certificate), as amended by regulation 55(2)—

(**3**) EUR 2009/469, as amended by S.I. 2019/801 and S.I. 2020/1050. This is a reference to the retained version of Regulation EUR 2009/469. That retained version is online at http://www.legislation.gov.uk/eur/2009/469/contents

(a) for paragraph 1(a)(iv), substitute—

"(iv) the number and date of the UK, GB or NI authorisation, or where there is more than one such authorisation, of each authorisation as referred to in Article 3(b) and (d);";

(b) in paragraph (1)(a)(v)—

(i) after "UK", insert ", GB or NI";

(ii) after "authorisation", in the second place it occurs, insert "as referred to in Article 3(b) and (d)".

(7) In Article 8(1), as amended by regulation 55(3)—

(a) in paragraph (b)—

(i) after "UK", insert ", GB or NI authorisation or, where there is more than one such authorisation, of each";

(ii) after "3(b)" insert "and (d)";

(b) in paragraph (c)—

(i) after "UK", insert ", GB or NI";

(ii) after "3(b)" insert "and (d)".

(8) In Article 9 (lodging of an application for a certificate), as amended by regulation 56(4)—

(a) for paragraph 2(d), substitute—

"(d) the number and date of the UK, GB or NI authorisation or, where there is more than one such authorisation, each authorisation provided under Article 8(1)(b), the product identified in the authorisation or each authorisation and the territory in respect of which the authorisation has been granted or has effect as if granted";

(b) in paragraph (e), for "the UK authorisation", substitute "any UK, GB or NI authorisation provided under Article 8(1)(b)".

(9) In Article 10 (grant of the certificate or rejection of the application for a certificate) as amended by regulation 57, omit paragraph 7.

(10) In Article 11 (publication), as amended by regulation 58(3)—

(a) for paragraph (d), insert—

"(d) the number and date of the UK, GB or NI authorisation or, where there is more than one such authorisation, of each authorisation provided under Article 8(1)(b) or Article 13A(1), the product identified in the authorisation and the territory in respect of which the authorisation has been granted or has effect as if granted;";

(b) in paragraph (e), for "the UK authorisation", substitute "any UK, GB or NI authorisation provided under Article 8(1)(b)".

(11) In Article 14(1) (expiry of the certificate), as amended by regulation 61—

(a) at the end of sub-paragraph (c), insert "or";

(b) in sub-paragraph (d), for "the appropriate authorisation or" substitute "all UK, GB and NI".

(12) In regulation 61, omit paragraph (4) of that regulation.

Amendments to Regulation (EC) 1610/96

4. Regulation (EC) 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 Part 1 of the Schedule.

Amendments to Regulation (EC) 469/2009

5. Regulation (EC) 469/2009 of the European Parliament and of the Council of 6th May 2009 concerning the supplementary protection certificate for medicinal products is amended as set out in Part 2 of the Schedule.

Amendment to the Patents Rules 2007

6. In the Patents Rules 2007(**4**), in rule 116A, as inserted by regulation 42 of the Intellectual Property (Amendment etc.) (EU Exit) Regulations 2020(**5**)—

(a) the existing text is numbered as paragraph 1;

(b) after paragraph 1, insert—

"(2) Notifications under Article 13A of Regulation (EC) 1610/96 and Article 13A of Regulation (EC) 469/2009 must be made on Patents Form SP6.".

Transitional provisions

7.—(1) Where an application for an authorisation is made before IP completion day under—

(a) Directive 2001/83/EC(**6**) of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use,

(b) Directive 2001/82/EC(**7**) of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products, or

(c) Regulation (EC) No 1107/2009(**8**) of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market,

but the authorisation is not granted until on or after IP completion day, these Regulations apply to any application for a supplementary protection certificate made in respect of the authorisation.

(2) These Regulations apply to an application for a supplementary protection certificate made on or after IP completion day in respect of a UK authorisation granted or having effect as if granted before IP completion day.

(3) The former regulations continue to apply to an application for a supplementary protection certificate made, but not determined, before IP completion day in respect of a UK authorisation granted or having effect as if granted before IP completion day.

(4) Where on or after IP completion day a UK authorisation granted or having effect before IP completion day is withdrawn and replaced with a GB authorisation and a NI authorisation, any certificate granted in respect of the UK authorisation does not lapse.

(5) For the purposes of paragraphs (2), (3) and (4), "UK authorisation" means an authorisation granted or having effect as if granted under—

(a) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use,

(b) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products, or

(c) Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market,

(**4**) S.I. 2007/3291, as by S.I. 2011/2052; there are other amending instruments but none are relevant.
(**5**) S.I. 2020/1050.
(**6**) OJ L311, 28.11.2001, p.67.
(**7**) OJ L311, 28.11.2001, p.1.
(**8**) OJ L309, 24.11.2009, p.1.

and references to a UK, GB or NI authorisation, where they occur in these Regulations (but not including this regulation) are to be treated as meaning a "UK authorisation" as defined in this paragraph.

(6) For the purposes of paragraphs (4) and (7)—

(a) "GB authorisation" has the meaning ascribed to it in paragraph 15 of Article 1 of Regulation (EC) 1610/96, as amended by regulation 4 of, and paragraph 2 of the Schedule to, these Regulations, and paragraph (ja) of Article 1 of Regulation (EC) 469/2009 as amended by regulation 5 of, and paragraph 9 of the Schedule to, these Regulations; and

(b) "NI authorisation" has the meaning ascribed to it in paragraph 16 of Article 1 of Regulation (EC) 1610/96, as amended by regulation 4 of, and paragraph 2 of the Schedule to, these Regulations and paragraph (jb) of Article 1 of Regulation (EC) 469/2009 as amended by regulation 5 of, and paragraph 9 of the Schedule to, these Regulations.

(7) For the purposes of paragraph (4), where the former regulations apply to a "UK authorisation" as defined in paragraph (5), the UK authorisation includes a GB authorisation and NI authorisation in combination.

(8) For the purposes of this regulation, "former regulations" means Regulation (EC) 1610/96 and Regulation (EC) 469/2009 without the amendments made by these Regulations but including the amendments made by the Patents (Amendment) (EU Exit) Regulations 2019 and the Intellectual Property (Amendment etc.) (EU Exit Regulations) 2020.

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