Statutory Document No. 2019/0121

European Union and Trade Act 2019

EUROPEAN UNION AND TRADE ACT 2019 (DEFICIENCIES) (PATENTS) REGULATIONS 2019

Approved by Tynwald: 20 March 2019
Coming into Operation in accordance with regulation 2

The Council of Ministers makes the following Regulations under section 12(1) of the European Union and Trade Act 2019.

1 Title

These Regulations are the European Union and Trade Act 2019 (Deficiencies) (Patents) Regulations 2019.

2 Commencement

If approved by Tynwald[1] these Regulations come into operation on exit day.

3 Interpretation

In these Regulations, "exit day" has the same meaning as in the European Union and Trade Act 2019.

4 Amendment of the Patents (Plant Protection Products) Order 1999

(1) The Patents (Plant Protection Products) Order 1999[2] is amended as follows.

(2) In article 2 (application of Council Regulation 1610/96), after "law of the Island", insert --

> «, subject to –
>
> (a) the modification that the Island shall be treated as part of the United Kingdom; and
>
> (b) the modifications set out in the Schedule».

[1] Tynwald approval is required under section 12(1) of the European Union and Trade Act 2019
[2] SD 698/99

(3) Insert the Schedule contained in Schedule 1 to these Regulations as the Schedule to the Patents (Plant Protection Products) Order 1999.

(4) For the text of Regulation (EC) No. 1610/96 of 23rd July 1996 concerning the creation of a supplementary protection certificate for plant protection products in the Annex, substitute the text in Annex I to these Regulations.

5 Amendment of the European Union (Intellectual Property) (No. 2) Order 2013

(1) The European Union (Intellectual Property) (No. 2) Order 2013[3] is amended as follows.

(2) For article 3(4)(b) (application of EU instruments) substitute –

> "(b) the modifications set out in the Schedule."

(3) Insert the Schedule contained in Schedule 2 to these Regulations as the Schedule to the European Union (Intellectual Property) (No. 2) Order 2013.

(4) For the text of 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 in the Annex, substitute the text in Annex II to these Regulations.

6 Amendment of the Patents (Medicinal Products) Order 2014

(1) The Patents (Medicinal Products) Order 2014[4] is amended as follows.

(2) For article 3(3) (application of EU instruments) substitute –

> "**3 Application of EU instruments**
>
> (3) Regulation (EC) No 469/2009 shall apply to the Island subject to —
>
> (a) the modification that the Island shall be treated as part of the United Kingdom; and
>
> (b) the modifications set out in the Schedule."

(3) Insert the Schedule contained in Schedule 3 to these Regulations as the Schedule to the Patents (Medicinal Products) Order 2014.

(4) For the text of 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 in the Annex, substitute the text in Annex III to these Regulations.

[3] SD 0180/13

[4] SD 2014/0088

(5) This paragraph applies to –

(a) an application for an extension of the duration of a supplementary protection certificate, filed in accordance with Article 7 of Regulation (EC) No. 469/2009 as it forms part of the law of England and Wales, Scotland and Northern Ireland by virtue of section 3 of the European Union (Withdrawal) Act 2018 (of Parliament)[5] (as that Article has effect in the United Kingdom) but not determined before exit day; and

(b) an extension of the duration of such a certificate granted –

(i) before exit day; or

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

(6) Where paragraph (5) applies, Articles 1(e) and 13(3) of Regulation (EC) No. 469/2009 as it applies to the Island by virtue of the Patents (Medicinal Products) Order 2014 continue to apply without the amendments made by this Regulation and, for the purposes of Article 13(3), the reference in Article 36(3) of Regulations (EC) No. 1901/2006 to "all Member States) is to be read as a reference to "the United Kingdom and all Member States".

7 Construction

To avoid doubt, any retained EU law is to be construed and have effect subject to these Regulations.

MADE 28 FEBRUARY 2019

W GREENHOW
Chief Secretary

[5] 2018 c.16

SCHEDULE 1

[Article 4(3)]

SCHEDULE TO BE INSERTED INTO THE PATENTS (PLANT PROTECTION PRODUCTS) ORDER 1999

“SCHEDULE

[Article 2]

MODIFICATIONS TO COUNCIL REGULATION (EC) NO. 1610/96 AS IT APPLIES TO THE ISLAND

1. (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 of the United Kingdom;

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 as it forms part of EU law;

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 as it forms part of the law of England and Wales, Scotland and Northern Ireland by virtue of section 3 of the European Union (Withdrawal) Act 2018 (of Parliament).”.

2. 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 (of Parliament) (as it has effect in the Island), ‘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;

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

(d) as respects the Island, the High Court of Justice of the Isle of Man.

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.".

3. 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.".

4. 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.".

5. (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 (as it forms part of the law of England and Wales, Scotland and Northern Ireland by virtue of section 3 of the European Union (Withdrawal) Act 2018 (of Parliament));

(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.

6. (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;".

7. (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 (of Parliament) (as it has effect in the Island).".

8. (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;".

9. Omit Article 12 (annual fees).

10. 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".

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

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

(3) For subparagraphs (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 as it forms part of the law of England and Wales, Scotland and Northern Ireland by virtue of section 3 of the European Union (Withdrawal) Act 2018 (of Parliament). 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 (of Parliament) (as it has effect in the Island).".

12. 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".

13. In Article 16 (notification of lapse or invalidity), for "the authority referred to in Article 9(1)", substitute "the comptroller".

14. In Article 17 (appeals), omit paragraph 1.

15. 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 (of Parliament) (as it has effect in the Island)) shall apply to the certificate.".

16. Omit Articles 19 and 20 (transitional provisions).

17. After Article 21 (entry into force), omit "This Regulation shall be binding in its entirety and directly applicable in all Member States.".

SCHEDULE 2

[Article 5(3)]

SCHEDULE TO BE INSERTED INTO THE EUROPEAN UNION (INTELLECTUAL PROPERTY) (NO. 2) ORDER 2013

"SCHEDULE

[Article 3(4)]

MODIFICATIONS TO COUNCIL REGULATION (EC) NO. 816/2006 AS IT APPLIES TO THE ISLAND

1. (1) Article 1 (scope) is amended as follows.

(2) For "Member States", substitute "The competent authority".

2. (1) Article 2 (definitions) is amended as follows.

(2) For the definition of "competent authority" in paragraph (4), substitute –

> "'competent authority' for the purposes of Articles 1 to 11, 16 and 17 means the Comptroller-General of Patents, Designs and Trade Marks of the United Kingdom;".

(3) After paragraph (4), insert—

> "(5) "patent" means "a patent under the Patents Act 1977 (of Parliament) (as it has effect in the Island);
>
> (6) "supplementary protection certificate" means a supplementary protection certificate issued under 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 as it forms part of the law of England and Wales, Scotland and Northern Ireland by virtue of section 3 of the European Union (Withdrawal) Act 2018 (of Parliament).".

(4) Omit Article 3 (competent authority).

3. In Article 4 (eligible importing countries), for "Commission", substitute "United Kingdom".

4. (1) Article 5 (extension to least-developed and developing countries which are not members of the WTO) is amended as follows.

(2) In paragraph (a), for "Commission", substitute "Secretary of State".

(3) In paragraph (c), omit "or on its own initiative if national law allows the competent authority to act on its own initiative,".

5. (1) Article 6 (application for a compulsory licence) is amended as follows.

(2) For paragraph 1, substitute—

> "1. Any person may submit an application for a compulsory licence under this Regulation to the competent authority in a case where that person's intended

activities of manufacture and sale for export are covered by a patent or a supplementary protection certificate.".

(3) In paragraph 2, for "each application", substitute "the application made to the competent authority".

(4) Omit paragraph 4.

6. In Article 8 (verification), for "Commission", wherever it occurs, substitute "United Kingdom".

7. (1) Article 10 (compulsory licence conditions) is amended as follows.

(2) In paragraph 5, for "Member States", substitute "United Kingdom".

(3) In paragraph 8, omit "or on its own initiative, if national law allows the competent authority to act on its own initiative.".

8. (1) Article 12 (notification) is amended as follows.

(2) For "Member State", substitute "Secretary of State".

(3) Omit "through the intermediary of the Commission".

9. In Article 13 (prohibition of importation), in paragraph 1, for "Community", substitute "United Kingdom".

10. (1) Article 14 (action by customs authorities) is amended as follows.

(2) In paragraph 1—

(a) for "Community" substitute "United Kingdom"; and

(b) omit "Member States shall ensure that a body has the authority to review whether such importation is taking place".

(3) In paragraph 2, for "national provisions on", substitute "the law relating to".

(4) In paragraph 3, for "Community", substitute "United Kingdom".

(5) In paragraph 4, omit ", in accordance with national legislation,".

(6) Omit paragraph 6.

11. (1) Article 16 (termination or review of the licence) is amended as follows.

(2) In paragraph 2, for "through the intermediary of the Commission", substitute "by the Secretary of State".

(3) In paragraph 3, omit—

(a) "or any other body appointed by the Member State"; and

(b) "or by another body appointed by the Member State,".

12. Omit Articles 17 to 20 (appeals, safety and efficacy of medicinal products, review, entry into force).

13. After Article 20 (entry into force), omit "This Regulation shall be binding in its entirety and directly applicable in all Member States.".

SCHEDULE 3

[Article 6(2)]

SCHEDULE TO BE INSERTED INTO THE PATENTS (MEDICINAL PRODUCTS) ORDER 2014

"SCHEDULE

[Article 3(3)]

MODIFICATIONS TO COUNCIL REGULATION (EC) NO. 469/2009 AS IT APPLIES TO THE ISLAND

1. (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[6] (of Parliament)".

(3) After paragraph (e) insert—

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

(g) "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;

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

(i) '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[7] (of Parliament); or

(ii) regulation 4(3) of, and Schedule 1 to, the Veterinary Medicines Regulations 2013[8] (of Parliament).".

2. 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

[6] SI 2012/1916

[7] SI 2012/1916

[8] SI 2013/2033

(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 (as that Article has effect in the United Kingdom)[9], 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.".

3. Omit Articles 7 to 12.

4. (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[10] (of Parliament)".

5. Omit Articles 14 to 21 and 23.

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

[9] Article 7 of Regulation (EC) No. 469/2006 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificates for medicinal products as it forms part of the law of England and Wales, Scotland and Northern Ireland by virtue of section 3 of the European Union (Withdrawal) Act 2018 (of Parliament).

[10] SI 2012/1916

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Patents (Plant Protection Products) Order 1999,the European Union (Intellectual Property) (No. 2) Order 2013 and the Patents (Medicinal Products) Order 2014, in order to address deficiencies arising from the withdrawal of the United Kingdom from the European Union in relation to patents and connected areas including supplementary protection certificates.