
STATUTORY INSTRUMENTS

2019 No. 801

**EXITING THE EUROPEAN UNION
PATENTS**

The Patents (Amendment) (EU Exit) Regulations 2019

Made - - - - 4th April 2019

Coming into force in accordance with regulation 1

A draft of these Regulations has been approved by resolutions of both Houses of Parliament pursuant to paragraph 1(1) of Schedule 7 to the European Union (Withdrawal) Act 2018 ^{M1}.

The Secretary of State, in exercise of the powers conferred by section 8(1) of the European Union (Withdrawal) Act 2018, makes the following Regulations:

Marginal Citations

M1 [2018 c.16.](#)

PART 1

INTRODUCTORY

1. These Regulations may be cited as the Patents (Amendment) (EU Exit) Regulations 2019 and come into force on exit day.

Commencement Information

11 Reg. 1 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

*Status: This version of this Instrument contains provisions that are prospective.
Changes to legislation: There are currently no known outstanding effects for the The Patents (Amendment) (EU Exit) Regulations 2019. (See end of Document for details)*

PART 2

AMENDMENTS TO THE PATENTS ACT 1977

2. The Patents Act 1977 is amended follows.

Commencement Information

I2 Reg. 2 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

3. In section 128A (EU compulsory licences)—

- [^{F1}(a) in the heading for “EU compulsory”, substitute “Compulsory pharmaceutical”;
- (b) in subsection (1), for “an “EU compulsory”, substitute “a “compulsory pharmaceutical”];
- (c) in subsection (2)—
 - (i) for “EU compulsory”, substitute “ compulsory pharmaceutical ”;
 - (ii) “an EU compulsory”, substitute “a compulsory pharmaceutical”;
- (d) in subsection (5), for “an EU compulsory”, substitute “ a compulsory pharmaceutical ”.

F1 Reg. 3(a)(b) substituted (31.12.2020 immediately before IP completion day) by [The Intellectual Property \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1050\)](#), regs. 1(2), **27**

Commencement Information

I3 Reg. 3 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

PROSPECTIVE

^{F2}4.

F2 Reg. 4 omitted (31.12.2020 immediately before IP completion day) by virtue of [The Intellectual Property \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1050\)](#), regs. 1(2), **28**

PART 3

AMENDMENT TO THE COPYRIGHT, DESIGNS AND PATENTS ACT 1988

5.—(1) Section 281 (power of comptroller to refuse to deal with certain agents) of the Copyright, Designs and Patents Act 1988 ^{M2} is amended as follows.

(2) In subsection (5), for the words from the words “another” to the end, substitute “ a member State ”^{M3} .

Commencement Information

- I4** Reg. 5 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

Marginal Citations

- M2** [1988 c.48](#).
M3 Article 4 of [S.I. 2011/1043](#) provided that references to the European Union are substituted for references to the European Communities.

PART 4

AMENDMENTS TO THE PATENTS AND PLANT VARIETY RIGHTS (COMPULSORY LICENSING) REGULATIONS 2002

6. The Patents and Plant Variety Rights (Compulsory Licensing) Regulations 2002 ^{M4} are amended as set out in this Part.

Commencement Information

- I5** Reg. 6 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

Marginal Citations

- M4** [S.I. 2002/247](#)

7.—(1) Regulation 2 (interpretation) is amended as follows.

(2) In paragraph (1)—

- (a) omit the definition of “Community plant variety right”;
- (b) omit the definition of “Council Regulation”;
- (c) for the definition of “plant breeders' rights”, substitute—

[^{F3}“plant breeders’ right” means—

- (a) any right granted under, or having effect as if granted under, section 3 of the 1997 Act (including existing rights as defined by section 40(4) of that Act); and
- (b) any right which by virtue of regulation 3 of the Plant Breeders’ Rights (Amendment etc.) (EU Exit) Regulations 2019 is treated as if it were a plant breeders’ right granted in accordance with the 1997 Act and as if the variety were registered in accordance with regulations under section 18(1)(c) of the 1997 Act;”].

- F3** Words in reg. 7(2)(c) substituted (31.12.2020 immediately before IP completion day) by [The Intellectual Property \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1050\)](#), regs. 1(2), **29**

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Changes to legislation: There are currently no known outstanding effects for the The Patents (Amendment) (EU Exit) Regulations 2019. (See end of Document for details)*

Commencement Information

I6 Reg. 7 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

8.—(1) Regulations 3 (applications) and 6 (grant) are amended as follows.

(2) Omit “or a Community plant variety right” and “or Community plant variety right” wherever they occur.

Commencement Information

I7 Reg. 8 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

9. In regulation 7 (conditions), omit paragraphs (4) and (5).

Commencement Information

I8 Reg. 9 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

10. Omit regulation 15 (Community plant variety rights).

Commencement Information

I9 Reg. 10 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

11. In regulation 16 (variation and revocation), omit paragraphs (4) to (7).

Commencement Information

I10 Reg. 11 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

12. In regulation 17, for paragraph (2), substitute—

“(2) Where a decision of the controllers relates to a compulsory patent licence or cross licence ordered to be granted under regulation 7(2) or 7(3), an appeal may be made to the court.”.

Commencement Information

I11 Reg. 12 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

13.—(1) Regulation 20 (extension of powers to make rules and regulations) is amended as follows.

(2) In paragraph (a), for “regulations 3(1) and 15(1)”, substitute “ regulation 3(1) ”.

(3) In paragraph (b)—

(a) for “regulations 8 and 16(4)” substitute “ regulation 8 ”; and

(b) for “regulations 9 and 16(5)”, substitute “ regulation 9 ”.

Commencement Information

I12 Reg. 13 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

14.—(1) Regulation 22 (application of existing rules and regulations) is amended as follows.

(2) In paragraph (1), for “regulations 7(2), 7(3) and 15(3)”, substitute “ regulation 7(2) and 7(3) ”.

(3) In paragraph (2), for “other than in relation to an application under regulation 15(1), and with any other necessary modifications”, substitute “ with any necessary modifications ”.

Commencement Information

I13 Reg. 14 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

15. In regulation 24, omit “or 15(1)”.

Commencement Information

I14 Reg. 15 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

16.—(1) Regulation 26 (application of 1977 and 1997 Acts) is amended as follows.

(2) In paragraph (1), in both places where it occurs, for “regulations 7(2), 7(3) and 15(3)”, substitute “ regulation 7(2) and 7(3) ”.

(3) In paragraph (3), for “regulations 15(1), 16(3) and 16(4)” substitute “ regulation 16(3) ”.

Commencement Information

I15 Reg. 16 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

*Status: This version of this Instrument contains provisions that are prospective.
Changes to legislation: There are currently no known outstanding effects for the The Patents (Amendment) (EU Exit) Regulations 2019. (See end of Document for details)*

PROSPECTIVE

Transitional provision

^{F4}17.

F4 Reg. 17 omitted (31.12.2020 immediately before IP completion day) by virtue of [The Intellectual Property \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1050\)](#), regs. 1(2), **30**

PART 5

AMENDMENTS TO THE PATENTS RULES 2007

- 18.**—(1) The Patents Rules 2007 ^{M5} are amended as follows.
- (2) In rule 85(1), omit from “, but not resident” to “the Civil Jurisdiction and Judgements Act 1982”.
- (3) In rule 103(4), for “another EEA state”, substitute “ an EEA state ”.
- (4) In Part 1 of Schedule 3—
- (a) in the entry relating to Article 5(c) of the Compulsory Licensing Regulation, for “EU compulsory”, substitute “ compulsory pharmaceutical ”; and
- (b) in the entries relating to Articles 6(1), 16(1) and 16(4), for “an EU compulsory”, substitute “ a compulsory pharmaceutical ”.

Commencement Information

I16 Reg. 18 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

Marginal Citations

M5 [S.I. 2007/3291](#). [S.I. 2007/3291](#) has been amended on a number of occasions but only the amendments made by [S.I. 2009/546](#), [regulations 8](#) and 9 are relevant.

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.

*Status: This version of this Instrument contains provisions that are prospective.
Changes to legislation: There are currently no known outstanding effects for the The Patents (Amendment) (EU Exit) Regulations 2019. (See end of Document for details)*

Commencement Information

I17 Reg. 19 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

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;

[^{F5}**12.** ‘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];

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;

^{F6}**15.**”.

F5 Words in reg. 20(3) substituted (31.12.2020 immediately before IP completion day) by [The Intellectual Property \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1050\)](#), regs. 1(2), **31**

F6 Words in reg. 20(3) omitted (31.12.2020 immediately before IP completion day) by virtue of [The Supplementary Protection Certificates \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1471\)](#), regs. 1(2), **2(3)** (with reg. 7)

Commencement Information

I18 Reg. 20 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

PROSPECTIVE

^{F7}**21.**

F7 [Reg. 21](#) omitted (31.12.2020 immediately before IP completion day) by virtue of [The Intellectual Property \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1050\)](#), regs. 1(2), **32**

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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 [^{F8}GB or NI] authorization prior to being placed on the market as a plant protection product.”.

F8 Words in reg. 22 substituted (31.12.2020 immediately before IP completion day) by The Supplementary Protection Certificates (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1471), regs. 1(2), 2(4) (with reg. 7)

Commencement Information

I19 Reg. 22 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

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 [^{F9}GB or NI] 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 ^{F10}... authorization to place the product on the market as a plant protection product [^{F11}in the territory of England and Wales and Scotland or the territory of Northern Ireland as the case may be].”.

F9 Words in reg. 23 substituted (31.12.2020 immediately before IP completion day) by The Supplementary Protection Certificates (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1471), regs. 1(2), 2(5)(a) (with reg. 7)

F10 Word in reg. 23 omitted (31.12.2020 immediately before IP completion day) by virtue of The Supplementary Protection Certificates (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1471), regs. 1(2), 2(5)(b)(i) (with reg. 7)

F11 Words in reg. 23 inserted (31.12.2020 immediately before IP completion day) by The Supplementary Protection Certificates (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1471), regs. 1(2), 2(5)(b)(ii) (with reg. 7)

Commencement Information

I20 Reg. 23 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

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 [^{F12}GB or NI authorisation or both GB and NI authorisations] as referred to in Article 3(1)(b) [^{F13}and (d)]; and
- (v) the number and date of the earliest EEA authorization, the granting of which predates the granting of the [^{F14}GB or NI] authorization [^{F15}as referred to in Article 3(1)(b) and (d)];”.
- (3) For paragraph 8(1)(b) and (c), substitute—
- “(b) a copy of the [^{F16}GB or NI authorisation or both GB and NI authorisations] to place the product on the market, as referred to in Article 3(1)(b) [^{F17}and (d)], 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, [^{F18}Part A section 1, points 1.1 to 1.7 or Part B, Section 1 points 1.1 to 1.4.3];
- (c) where the product is the subject of one or more EEA authorizations granted prior to the [^{F19}GB or NI] authorization referred to in Article 3(1)(b) [^{F20}and (d)], 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.

- F12** Words in [reg. 24\(2\)](#) substituted (31.12.2020 immediately before IP completion day) by [The Supplementary Protection Certificates \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1471\)](#), [regs. 1\(2\)](#), [2\(6\)\(a\)\(i\)](#) (with [reg. 7](#))
- F13** Words in [reg. 24\(2\)](#) inserted (31.12.2020 immediately before IP completion day) by [The Supplementary Protection Certificates \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1471\)](#), [regs. 1\(2\)](#), [2\(6\)\(a\)\(ii\)](#) (with [reg. 7](#))
- F14** Words in [reg. 24\(2\)](#) substituted (31.12.2020 immediately before IP completion day) by [The Supplementary Protection Certificates \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1471\)](#), [regs. 1\(2\)](#), [2\(6\)\(b\)\(i\)](#) (with [reg. 7](#))
- F15** Words in [reg. 24\(2\)](#) inserted (31.12.2020 immediately before IP completion day) by [The Supplementary Protection Certificates \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1471\)](#), [regs. 1\(2\)](#), [2\(6\)\(b\)\(ii\)](#) (with [reg. 7](#))
- F16** Words in [reg. 24\(3\)](#) substituted (31.12.2020 immediately before IP completion day) by [The Supplementary Protection Certificates \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1471\)](#), [regs. 1\(2\)](#), [2\(7\)\(a\)\(i\)](#) (with [reg. 7](#))
- F17** Words in [reg. 24\(3\)](#) inserted (31.12.2020 immediately before IP completion day) by [The Supplementary Protection Certificates \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1471\)](#), [regs. 1\(2\)](#), [2\(7\)\(a\)\(ii\)](#) (with [reg. 7](#))
- F18** Words in [reg. 24\(3\)](#) substituted (31.12.2020 immediately before IP completion day) by [The Intellectual Property \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1050\)](#), [regs. 1\(2\)](#), [33](#)
- F19** Words in [reg. 24\(3\)](#) substituted (31.12.2020 immediately before IP completion day) by [The Supplementary Protection Certificates \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1471\)](#), [regs. 1\(2\)](#), [2\(7\)\(b\)\(i\)](#) (with [reg. 7](#))
- F20** Words in [reg. 24\(3\)](#) inserted (31.12.2020 immediately before IP completion day) by [The Supplementary Protection Certificates \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1471\)](#), [regs. 1\(2\)](#), [2\(7\)\(b\)\(ii\)](#) (with [reg. 7](#))

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Changes to legislation: There are currently no known outstanding effects for the The Patents (Amendment) (EU Exit) Regulations 2019. (See end of Document for details)*

Commencement Information

I21 Reg. 24 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

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—

[^{F21}(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;]

(e) where there are EEA authorizations granted before [^{F22}any GB or NI authorisation provided under Article 8(1)(b)], the number and date of the earliest EEA authorization;”.

F21 Words in reg. 25(4) substituted (31.12.2020 immediately before IP completion day) by [The Supplementary Protection Certificates \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1471\)](#), regs. 1(2), **2(8)(a)** (with reg. 7)

F22 Words in reg. 25(4) substituted (31.12.2020 immediately before IP completion day) by [The Supplementary Protection Certificates \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1471\)](#), regs. 1(2), **2(8)(b)** (with reg. 7)

Commencement Information

I22 Reg. 25 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

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—

^{F23}“**6.**”

F23 Words in reg. 26(6) omitted (31.12.2020) by virtue of [The Supplementary Protection Certificates \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1471\)](#), regs. 1(2), **2(9)** (with reg. 7)

Commencement Information

I23 Reg. 26 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

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—

^{F24}(a)

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

“(e) where there are EEA authorizations granted before [^{F25}any authorisation provided under Article 8(1)(b)], the number and date of the earliest EEA authorization;”.

F24 Reg. 27(3)(a) omitted (31.12.2020 immediately before IP completion day) by virtue of The Supplementary Protection Certificates (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1471), regs. 1(2), 2(10) (with reg. 7)

F25 Words in reg. 27(3)(b) substituted (31.12.2020 immediately before IP completion day) by The Supplementary Protection Certificates (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1471), regs. 1(2), 2(11) (with reg. 7)

Commencement Information

I24 Reg. 27 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

28. Omit Article 12 (annual fees).

Commencement Information

I25 Reg. 28 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

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”.

Commencement Information

I26 Reg. 29 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

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—

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- “(c) if the prescribed annual fee is not paid in time; [^{F26}or]
- (d) if and as long as the product covered by the certificate may no longer be placed on the market following the withdrawal of [^{F27}all] 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.”.

^{F28}(4)

F26 Word in [reg. 30\(3\)](#) inserted (31.12.2020 immediately before IP completion day) by [The Supplementary Protection Certificates \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1471\)](#), [regs. 1\(2\), 2\(12\)\(a\)](#) (with [reg. 7](#))

F27 Word in [reg. 30\(3\)](#) substituted (31.12.2020 immediately before IP completion day) by [The Supplementary Protection Certificates \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1471\)](#), [regs. 1\(2\), 2\(12\)\(b\)](#) (with [reg. 7](#))

F28 [Reg. 30\(4\)](#) omitted (31.12.2020 immediately before IP completion day) by virtue of [The Supplementary Protection Certificates \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1471\)](#), [regs. 1\(2\), 2\(13\)](#) (with [reg. 7](#))

Commencement Information

I27 [Reg. 30](#) in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

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 ”.

Commencement Information

I28 [Reg. 31](#) in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

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

Commencement Information

I29 [Reg. 32](#) in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

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

Commencement Information

I30 [Reg. 33](#) in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see [reg. 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.”

Commencement Information

I31 Reg. 34 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

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

Commencement Information

I32 Reg. 35 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

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

Commencement Information

I33 Reg. 36 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

PART 7

COMPULSORY LICENSING OF PHARMACEUTICAL PATENTS - AMENDMENTS TO REGULATION (EC) NO 816/2006

37. 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 is amended as set out in this Part.

Commencement Information

I34 Reg. 37 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

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

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

Status: This version of this Instrument contains provisions that are prospective.
Changes to legislation: There are currently no known outstanding effects for the The Patents (Amendment) (EU Exit) Regulations 2019. (See end of Document for details)

Commencement Information

I35 Reg. 38 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

39.—(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;”.

(3) After paragraph (4), insert—

“(5) “patent” means “a patent under the Patents Act 1977;

(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”.

(4) Omit Article 3 (competent authority).

Commencement Information

I36 Reg. 39 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

40. In Article 4 (eligible importing countries), for “Commission”, substitute “United Kingdom”.

Commencement Information

I37 Reg. 40 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

41.—(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;”.

Commencement Information

I38 Reg. 41 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

42.—(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.

Commencement Information

I39 Reg. 42 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

43. In Article 8 (verification), for “Commission”, wherever it occurs, substitute “ United Kingdom ”.

Commencement Information

I40 Reg. 43 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

44.—(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.”.

Commencement Information

I41 Reg. 44 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

45.—(1) Article 12 (notification) is amended as follows.

(2) For “Member State”, substitute “ Secretary of State ”.

(3) Omit “through the intermediary of the Commission”.

Commencement Information

I42 Reg. 45 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

46. In Article 13 (prohibition of importation), in paragraph 1, for “Community”, substitute “ United Kingdom ”.

*Status: This version of this Instrument contains provisions that are prospective.
Changes to legislation: There are currently no known outstanding effects for the The Patents (Amendment) (EU Exit) Regulations 2019. (See end of Document for details)*

Commencement Information

I43 Reg. 46 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

- 47.**—(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.

Commencement Information

I44 Reg. 47 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

- 48.**—(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,”.

Commencement Information

I45 Reg. 48 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

- 49.** Omit Articles 17 to 19. (appeals, safety and efficacy of medicinal products and review)

Commencement Information

I46 Reg. 49 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

- 50.** After Article 20 (entry into force), omit “This Regulation shall be binding in its entirety and directly applicable in all Member States”.

Commencement Information

I47 Reg. 50 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

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.

Commencement Information

I48 Reg. 51 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

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 ^{M6}”.

(3) After paragraph (e) insert—

“(f) ‘comptroller’ means the Comptroller-General of Patents, Designs and Trade Marks;

[^{F29}(g) ‘court’ means—

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

(ii) as respects Scotland, the Court of Session;

(iii) as respects Northern Ireland, the High Court in Northern Ireland;]

(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 [^{F30}in the United Kingdom] as a medicinal product granted [^{F31}or having effect as if 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

^{M7}”.

F29 Words in [reg. 52\(3\)](#) substituted (31.12.2020 immediately before IP completion day) by [The Intellectual Property \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1050\)](#), regs. 1(2), [34\(a\)](#)

Status: This version of this Instrument contains provisions that are prospective.
Changes to legislation: There are currently no known outstanding effects for the The Patents (Amendment) (EU Exit) Regulations 2019. (See end of Document for details)

- F30** Words in [reg. 52\(3\)](#) inserted (31.12.2020 immediately before IP completion day) by [The Supplementary Protection Certificates \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1471\)](#), [regs. 1\(2\), 3\(3\)](#) (with [reg. 7](#))
- F31** Words in [reg. 52\(3\)](#) inserted (31.12.2020 immediately before IP completion day) by [The Intellectual Property \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1050\)](#), [regs. 1\(2\), 34\(b\)](#)

Commencement Information

- I49** [Reg. 52](#) in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

Marginal Citations

- M6** [S.I. 2012/1916](#). Regulation 58A is inserted by [S.I. 2019/775](#), [reg. 64](#).
- M7** [S.I. 2013/2033](#).

PROSPECTIVE

^{F32}**53.**

- F32** [Reg. 53](#) omitted (31.12.2020 immediately before IP completion day) by virtue of [The Intellectual Property \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1050\)](#), [regs. 1\(2\), 35](#)

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 [^{F33}, GB or NI] 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 [^{F34}, GB or NI] 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 [^{F35}, GB or NI] authorisation to place the product on the market as a medicinal product [^{F36}: 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].”.

- F33** Words in [reg. 54](#) inserted (31.12.2020 immediately before IP completion day) by [The Supplementary Protection Certificates \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1471\)](#), regs. 1(2), **3(4)** (with [reg. 7](#))
- F34** Words in [reg. 54](#) inserted (31.12.2020 immediately before IP completion day) by [The Supplementary Protection Certificates \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1471\)](#), regs. 1(2), **3(5)(a)** (with [reg. 7](#))
- F35** Words in [reg. 54](#) inserted (31.12.2020 immediately before IP completion day) by [The Supplementary Protection Certificates \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1471\)](#), regs. 1(2), **3(5)(b)(i)** (with [reg. 7](#))
- F36** Words in [reg. 54](#) inserted (31.12.2020 immediately before IP completion day) by [The Supplementary Protection Certificates \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1471\)](#), regs. 1(2), **3(5)(b)(ii)** (with [reg. 7](#))

Commencement Information

- I50** Reg. 54 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

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

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

[^{F37}(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);]

(v) the number and date of the earliest of any EEA authorisation, the granting of which predates the granting of the UK [^{F38}, GB or NI] authorisation [^{F39}as referred to in Article 3(b) and (d)];”.

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

“(b) a copy of the UK [^{F40}, GB or NI authorisation or, where there is more than one such authorisation, of each] authorisation to place the product on the market, as referred to in Article 3(b) [^{F41}and (d)], 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 [^{F42}, GB or NI] authorisation referred to in Article 3(b) [^{F43}and (d)], 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).

Status: This version of this Instrument contains provisions that are prospective.
Changes to legislation: There are currently no known outstanding effects for the The Patents (Amendment) (EU Exit) Regulations 2019. (See end of Document for details)

- F37** Words in [reg. 55\(2\)](#) substituted (31.12.2020 immediately before IP completion day) by [The Supplementary Protection Certificates \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1471\)](#), regs. 1(2), **3(6)(a)** (with [reg. 7](#))
- F38** Words in [reg. 55\(2\)](#) inserted (31.12.2020 immediately before IP completion day) by [The Supplementary Protection Certificates \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1471\)](#), regs. 1(2), **3(6)(b)(i)** (with [reg. 7](#))
- F39** Words in [reg. 55\(2\)](#) inserted (31.12.2020 immediately before IP completion day) by [The Supplementary Protection Certificates \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1471\)](#), regs. 1(2), **3(6)(b)(ii)** (with [reg. 7](#))
- F40** Words in [reg. 55\(3\)](#) inserted (31.12.2020 immediately before IP completion day) by [The Supplementary Protection Certificates \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1471\)](#), regs. 1(2), **3(7)(a)(i)** (with [reg. 7](#))
- F41** Words in [reg. 55\(3\)](#) inserted (31.12.2020 immediately before IP completion day) by [The Supplementary Protection Certificates \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1471\)](#), regs. 1(2), **3(7)(a)(ii)** (with [reg. 7](#))
- F42** Words in [reg. 55\(3\)](#) inserted (31.12.2020 immediately before IP completion day) by [The Supplementary Protection Certificates \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1471\)](#), regs. 1(2), **3(7)(b)(i)** (with [reg. 7](#))
- F43** Words in [reg. 55\(3\)](#) inserted (31.12.2020 immediately before IP completion day) by [The Supplementary Protection Certificates \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1471\)](#), regs. 1(2), **3(7)(b)(ii)** (with [reg. 7](#))

Commencement Information

- I51** Reg. 55 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

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—

[^{F44}(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];

(e) where there are authorisations granted in the EEA before [^{F45}any UK, GB or NI authorisation provided under Article 8(1)(b)], the number and date of the earliest EEA authorisation;”.

- F44** Words in [reg. 56\(4\)](#) substituted (31.12.2020 immediately before IP completion day) by [The Supplementary Protection Certificates \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1471\)](#), regs. 1(2), **3(8)(a)** (with [reg. 7](#))
- F45** Words in [reg. 56\(4\)](#) substituted (31.12.2020 immediately before IP completion day) by [The Supplementary Protection Certificates \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1471\)](#), regs. 1(2), **3(8)(b)** (with [reg. 7](#))

Commencement Information

I52 Reg. 56 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

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—

^{F46cc}7.”.

F46 Words in [reg. 57\(7\)](#) omitted (31.12.2020 immediately before IP completion day) by virtue of [The Supplementary Protection Certificates \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1471\)](#), regs. 1(2), **3(9)** (with [reg. 7](#))

Commencement Information

I53 Reg. 57 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

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) [^{F47} 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) for sub-paragraph (e), substitute—

“(e) where there are EEA authorisations granted before [^{F48} any UK, GB or NI authorisation provided under Article 8(1)(b)], the number and date of the earliest EEA authorisation;”.

F47 Words in [reg. 58\(3\)\(a\)](#) substituted (31.12.2020 immediately before IP completion day) by virtue of [The Supplementary Protection Certificates \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1471\)](#), regs. 1(2), **3(10)(a)** (with [reg. 7](#))

F48 Words in [reg. 58\(3\)\(b\)](#) substituted (31.12.2020) by [The Supplementary Protection Certificates \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1471\)](#), regs. 1(2), **3(10)(b)** (with [reg. 7](#))

*Status: This version of this Instrument contains provisions that are prospective.
Changes to legislation: There are currently no known outstanding effects for the The Patents (Amendment) (EU Exit) Regulations 2019. (See end of Document for details)*

Commencement Information

I54 Reg. 58 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

59. Omit Article 12 (annual fees).

Commencement Information

I55 Reg. 59 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

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”.

Commencement Information

I56 Reg. 60 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

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; [^{F49}or]

(d) if and as long as the product covered by the certificate may no longer be placed on the market following the withdrawal of [^{F50}all UK, GB and NI] 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.”.

^{F51}(4)

F49 Word in reg. 61(3) inserted (31.12.2020 immediately before IP completion day) by The Supplementary Protection Certificates (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1471), regs. 1(2), 3(11)(a) (with reg. 7)

F50 Words in reg. 61(3) substituted (31.12.2020 immediately before IP completion day) by The Supplementary Protection Certificates (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1471), regs. 1(2), 3(11)(b) (with reg. 7)

F51 Reg. 61(4) omitted (31.12.2020 immediately before IP completion day) by virtue of The Supplementary Protection Certificates (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1471), regs. 1(2), 3(12) (with reg. 7)

*Status: This version of this Instrument contains provisions that are prospective.
Changes to legislation: There are currently no known outstanding effects for the The Patents (Amendment) (EU Exit) Regulations 2019. (See end of Document for details)*

Commencement Information

I57 Reg. 61 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

62. In paragraph 2 of Article 15 (invalidity of the certificate), for “^{F52}... the body responsible under national law for the revocation of the corresponding basic patent” substitute “ the comptroller or the court ”.

F52 Word in [reg. 62](#) omitted (31.12.2020 immediately before IP completion day) by virtue of [The Intellectual Property \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1050\)](#), regs. 1(2), [36](#)

Commencement Information

I58 Reg. 62 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

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 ”.

Commencement Information

I59 Reg. 63 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

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

Commencement Information

I60 Reg. 64 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

65. Omit Article 18 (appeals).

Commencement Information

I61 Reg. 65 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

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

*Status: This version of this Instrument contains provisions that are prospective.
Changes to legislation: There are currently no known outstanding effects for the The Patents (Amendment) (EU Exit) Regulations 2019. (See end of Document for details)*

“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.”.

Commencement Information

I62 Reg. 66 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

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

Commencement Information

I63 Reg. 67 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

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

Commencement Information

I64 Reg. 68 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1

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 [^{F53}IP completion day]; and
- (b) An extension of the duration of a certificate granted—
 - (i) before [^{F53}IP completion day]; or
 - (ii) after [^{F53}IP completion day], pursuant to an application falling within subparagraph (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”.

F53 Words in [reg. 69](#) substituted (31.12.2020 immediately before IP completion day) by [The Intellectual Property \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1050\)](#), regs. 1(2), [37](#)

Status: This version of this Instrument contains provisions that are prospective.
Changes to legislation: There are currently no known outstanding effects for the The Patents (Amendment) (EU Exit) Regulations 2019. (See end of Document for details)

Commencement Information

I65 Reg. 69 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Department for Business, Energy and Industrial
Strategy

Chris Skidmore
Minister of State

Status: This version of this Instrument contains provisions that are prospective.
Changes to legislation: There are currently no known outstanding effects for the The Patents (Amendment) (EU Exit) Regulations 2019. (See end of Document for details)

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers in section 8(1) of the European Union (Withdrawal) Act 2018 (c.18) in order to address failures of retained EU law to operate effectively and other deficiencies arising from the withdrawal of the United Kingdom from the European Union in relation to patents and connected areas including supplementary protection certificates.

Part 1 of the Regulations contains introductory provisions.

Part 2 of the Regulations makes amendments to the Patents Act 1977.

Part 3 of the Regulations makes an amendment to the Copyright, Designs and Patents Act 1988.

Part 4 makes amendments to the Patents and Plant Variety Rights (Compulsory Licensing) Regulations 2002.

Part 5 of the Regulations makes an amendment to the Patents Rules 2007.

Part 6 of the Regulations makes amendments to 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.

Part 7 makes amendments to 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.

Part 8 of the Regulations amends 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.

An impact assessment has not been produced for this instrument as no, or no significant, impact on the private or voluntary sector is foreseen.

Status:

This version of this Instrument contains provisions that are prospective.

Changes to legislation:

There are currently no known outstanding effects for the The Patents (Amendment) (EU Exit) Regulations 2019.