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(**1**).

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:

## PART 1

### INTRODUCTORY

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

## PART 2

### AMENDMENTS TO THE PATENTS ACT 1977

**2.** The Patents Act 1977 is amended follows.

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

(a) in the heading for "an "EU compulsory", substitute "a "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".

(**1**) 2018 c.16.

**4.** In paragraph 1 of Schedule A1 (derogation from patent protection in respect of biotechnological inventions), in the definition of "Council Regulation", at the end, insert, "as it had effect immediately before exit day".

## 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(**2**) is amended as follows.

(2) In subsection (5), for the words from the words "another" to the end, substitute "a member State"(**3**).

## 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(**4**) are amended as set out in this Part.

**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—

> ""plant breeders' right" means 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);".

**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.

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

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

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

**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.".

(**2**) 1988 c.48.
(**3**) Article 4 of S.I. 2011/1043 provided that references to the European Union are substituted for references to the European Communities.
(**4**) S.I. 2002/247

**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".

**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".

**15.** In regulation 24, omit "or 15(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)".

**Transitional provision**

**17.**—(1) In this regulation "former regulations" means the Patents and Plant Variety Rights (Compulsory Licensing) Regulations 2002 without the amendments made by these Regulations.

(2) The former regulations continue to apply for the purposes of—

(a) any application pursuant to regulation 15 made but not determined before exit day; and

(b) a cross licence granted—

(i) before exit day pursuant to regulation 15; or

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

# PART 5

## AMENDMENTS TO THE PATENTS RULES 2007

**18.**—(1) The Patents Rules 2007(**5**) 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".

(**5**) 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.

**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.".

# 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.

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

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

**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).

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

**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,".

**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.

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

**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.".

**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".

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

**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.

**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,".

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

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

# PART 8

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

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

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

(2) In paragraph (e) for "Article 36 of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use", substitute "regulation 58A(3) of the Human Medicines Regulations 2012(**6**)".

(3) After paragraph (e) insert—

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

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

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

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

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

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

(ii) regulation 4(3) of, and Schedule 1 to, the Veterinary Medicines Regulations 2013(**7**).".

**53.** After Article 1(interpretation), insert—

*"Article 1A*

*Meaning of 'court'*

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

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

**3.** In any other case, 'court' means—

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

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

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

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

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

*"Article 2*

*Scope*

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

(a) protected by a patent; and

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

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

*Article 3*

*Conditions for obtaining a certificate*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(4) In paragraph 1(d)—

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

(b) omit paragraph (ii).

(5) Omit paragraph (4).

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

(2) For paragraph 1 substitute—

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

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

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

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

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

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

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

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

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

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

(6) Omit paragraph 5.

(7) After paragraph 6, insert—

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

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

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

(3) In paragraph 1—

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

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

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

**59.** Omit Article 12 (annual fees).

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

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

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

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

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

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

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

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

(4) After paragraph 1, insert—

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

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

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

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

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

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

**65.** Omit Article 18 (appeals).

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

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

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

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

**Transitional provision**

**69.**—(1) This regulation applies to—

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

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

(i) before exit day; or

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

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

(3) Where paragraph (1) applies—

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

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

*Chris Skidmore*
Minister of State
Department for Business, Energy and Industrial Strategy

4th April 2019

## 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.