Draft Regulations laid before Parliament under paragraph 1(1) of Schedule 7 to the European Union (Withdrawal) Act 2018 for approval by resolution of each House of Parliament

DRAFT STATUTORY INSTRUMENTS

2018 No. XXXX

EXITING THE EUROPEAN UNION
PATENTS

The Patents (Amendment) (EU Exit) Regulations 2018

Made - - - - ***

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 2018 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";

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

(ii) "an EU compulsory", substitute "a compulsory pharmaceutical";

(d) in subsection (5), for "an EU compulsory", substitute "a compulsory pharmaceutical".

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**) 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

"(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.".

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

(**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.

(b) in the entries relating to Articles 6(1), 16(1) and 16(4), for "an EU compulsory", substitute "a compulsory pharmaceutical".

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;".