EXPLANATORY MEMORANDUM TO

THE PATENTS (AMENDMENT) (EU EXIT) REGULATIONS 2019

2019 No. 801

1. Introduction

1.1 This explanatory memorandum has been prepared by the Intellectual Property Office, an Executive Agency of the Department for Business, Energy and Industrial Strategy, and is laid before Parliament by Act.

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

2.1 This instrument amends a number of pieces of legislation relating to the UK patent system, including retained EU law[1], to fix issues which will occur as a result of the UK's departure from the European Union, so that the law continues to work effectively.

Explanations

What did any relevant EU law do before exit day?

2.2 The relevant EU law being addressed in this instrument is:

- Regulation (EC) 469/2009 concerning the creation of a supplementary protection certificate for medicinal products and Regulation (EC) 1610/96 concerning the creation of a supplementary protection certificate for plant protection products ("the SPC Regulations");
- Regulation (EC) 816/2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems ("the Compulsory Licensing Regulation");
- The Patents and Plant Variety Rights (Compulsory Licensing) Regulations 2002 (SI 2002/247; "the Cross-licensing regulations");

As set out in more detail in paragraphs 7.6-7.7, 7.14, and 7.17 of this memorandum, this law:

- provides for the grant of a supplementary protection certification (SPC), setting out the requirements to be met, the scope of the granted right, the circumstances in which an SPC can lapse or be found invalid, and connects the operation of the SPC system to the national patent laws of the Member States;
- establishes a process for granting compulsory licences for the export of patented pharmaceuticals to countries with a public health need, as well as restrictions on their manufacture and distribution; and
- allows for compulsory licences to be granted where there is an overlap between a patent and a plant breeders' right held by two separate parties and agreement cannot be reached between the holders.

[1] As defined in section 6(7) of the European Union (Withdrawal) Act 2018.

Minor amendments are also being made to the Patents Act 1977 (c.37), the Patents Rules 2007 (SI 2007/3291) and the Copyright, Design and Patents Act 1988 (c.48).

Why is it being changed?

2.3 As noted in paragraph 7.2 of the memorandum, although most of the provisions of the relevant EU law will form part of domestic law on and after exit day without creating deficiencies in drafting and other absurdities, there are specific provisions which will not work. These would either prevent existing rights from functioning as they did before the UK's departure from the EU, or mean that new applications for those rights could not be made.

What will it now do?

2.4 Paragraphs 7.8-7.9, 7.15, and 7.18 set out the specific modifications but, broadly, the relevant EU law will continue to do the same things as it did prior to the UK's departure from the EU, preserving the status quo as far as is possible.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 The instrument contains provisions consequential to prospective statutory amendments. This matter is detailed in paragraphs 7.9 to 7.11, and Annex A contains relevant drafting.

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

3.2 The territorial application of this instrument includes Scotland and Northern Ireland.

3.3 The powers under which this instrument is made cover the entire United Kingdom (see section 24(1) of the European Union (Withdrawal) Act 2018) and the territorial application of this instrument is not limited either by the Act or by the instrument.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument is all of the United Kingdom.

4.2 The territorial application of this instrument is to all of the United Kingdom.

4.3 Certain elements of the legislation being amended by this instrument extend to the Isle of Man; however, the amendments themselves do not extend to the Isle of Man. Separate provision will need to be made, and the UK Government is working with the Isle of Man Government to ensure that appropriate legislation is enacted, in line with the constitutional arrangements with the Crown Dependency.

5. European Convention on Human Rights

5.1 The Minister of State for Universities, Science, Research and Innovation, Sam Gyimah has made the following statement regarding Human Rights:

"In my view the provisions of the Patents (Amendment) (EU Exit) Regulations 2018 are compatible with the Convention rights."

6. Legislative Context

6.1 These Regulations are made under section 8 of the European Union (Withdrawal) Act 2018. Section 2 of that Act saves domestic law which derives from EU legislation on exit day, whilst section 3 retains EU law which had direct effect in the UK on exit day as domestic law. Section 8 allows a Minister to make regulations to resolve any deficiencies in law that arise as a result of the UK's departure from the European Union.

6.2 The Patents Act 1977 and the Patents Rules 2007 are the principal legislation governing the patents system in the UK and give the Comptroller-General of Patents, Trade Marks and Designs ("the Comptroller") certain powers and duties relating to its operation. The Copyright, Design and Patents Act 1988 provides regulation of patent attorneys.

6.3 The Plant Varieties Act 1997 and the Plant Breeders' Rights Regulations 1998 govern the operation of plant breeders' rights in the UK, and give the Controller of Plant Variety Rights certain powers and duties in that regard.

6.4 The Cross-licensing Regulations were made under section 2(2) of the European Communities Act 1972, and implement parts of Directive 98/44/EC on the legal protection of biotechnological inventions. The SPC Regulations and the Compulsory Licensing Regulations are directly effective EU legislation which have effect in UK law through section 2(1) of the European Communities Act 1972.

7. Policy background

What is being done and why?

7.1 A patent protects an invention and lets the owner of that patent take legal action against anyone who makes, uses, sells or imports that invention without the owner's permission – this is known as infringement of the patent. A patent can provide such protection for up to twenty years.

7.2 Although most aspects of UK patent law are domestic in origin, or derived from international treaties, there are certain areas which derive from EU law – in particular, from the EU instruments listed above. When the UK leaves the European Union, these instruments will be retained in UK law through the European Union (Withdrawal) Act. This will preserve the general principles of how they function, as well as most of the provisions in the form they are currently written. However, there are a number of references in the legislation which will not function correctly following our departure, which this instrument seeks to repair.

7.3 The modifications set out in this instrument are, where possible, drafted to retain the same intention as the original provisions, so that pre-existing case law of the Court of Justice of the European Union on the meaning and effect of the relevant provisions continues to apply.

The SPC Regulations

7.4 Before they can be sold to the public, medicinal products (human and veterinary) and plant protection products (pesticides, etc.) must be approved by regulatory bodies by way of a marketing authorisation. This process is often lengthy, as proper trials and tests must be carried out to demonstrate to the regulators that the product is safe and effective.

7.5 These products are frequently protected by patents. However, due to the requirement to complete the regulatory approval process, holders of such patents are often unable to benefit from the full period of protection they are entitled to. This affects the ability of innovative companies to recover the high costs of investment put into researching and developing the product in the first place.

7.6 The SPC Regulations provide a period of additional protection for such products after the expiry of a patent protecting them, under a Supplementary Protection Certificate (SPC). This can be for up to five years, depending on the length of time taken during the patent's lifetime to complete the regulatory approval process. SPCs provide the same rights to the holder as the patent does, but are a standalone intellectual property right.

7.7 Despite being set up by EU law, SPCs are national rights. An application for an SPC is made to the relevant national intellectual property office, and the granted SPC only provides protection in that country. The SPC Regulations set out the requirements to be met for an SPC to be granted, outline the circumstances in which an SPC can lapse or be found invalid, and connect the operation of the SPC system to the national patent laws of the Member States.

7.8 In order to ensure that the SPC system continues to operate effectively, this instrument makes changes to the SPC Regulations to:

- replace references to Member States and Member State discretion, as the UK will not be a Member State after Exit;
- ensure that the correct legal basis for UK marketing authorisations is recognised, as EU Directives will not be retained;
- expressly define the Intellectual Property Office as the designated authority for examination and grant of SPC applications, and UK courts as the route of appeal, to restate the law in a clearer way;
- clarify that proceedings for invalidating the SPC can be brought before the Comptroller or the UK courts;
- reflect Exit-related amendments being made to the legislation governing regulatory processes; and
- remove provisions setting out transitional arrangements for specific countries joining the European Union, as these will be redundant.

7.9 The instrument also makes changes to the SPC Regulations in relation to the "paediatric extension", a six-month extension of an SPC which is available for pharmaceuticals if the product has been tested for use with children.

7.10 The paediatric extension is granted under Article 36 of EU Regulation 1901/2006, to which the SPC Regulations refer. At exit, the Government will revoke and restate EU Regulation 1901/2006 through amendments to the Human Medicines Regulations 2012. Those amendments are made by the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019[2] under the powers of the Withdrawal Act, and the changes in this instrument are consequential on the revocation and restatement of Article 36.

7.11 At the time this instrument was laid, the amendments to the Human Medicines Regulations had not yet been approved by Parliament. So that Parliament was able to fully consider the effects of this instrument, the relevant drafting is provided as Annex

[2] SI 2019/775.

A to this memorandum, which reflects the form in which the provisions restating Article 36 were expected to be laid in draft. These amendments have now been made by the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019.

The Compulsory Licensing Regulation

7.12 Where a patent owner is not considered to be meeting demand for the invention in the country where the patent exists, and is not prepared to license the patent to interested parties on reasonable terms, it is possible for a compulsory licence to be granted. This allows someone else to make or use the invention to meet the demand in that country without infringing the patent.

7.13 The Agreement on Trade-Related Aspects of Intellectual Property Rights ("the TRIPS Agreement") forms part of the rules of the World Trade Organisation (WTO). It includes a requirement that members must ensure that compulsory patent licences are limited to allowing manufacture in, and for, the country in question. In 2003, the WTO General Council adopted a Decision which enabled WTO members to waive this requirement for certain inventions if they chose to do so. Specifically, this was done for patent-protected medicines made for export to countries with a specific public health need and which do not have a sufficient manufacturing base to meet that need. This Decision has since been incorporated into the TRIPS Agreement by ratified amendment (Article 31*bis*).

7.14 As a WTO member in its own right, the EU established the Compulsory Licensing Regulation to meet the commitment to the Decision and to facilitate the wider public health objective of enabling access to medicines in the developing world. To ensure that the system continues to function upon the UK's departure from the European Union, the Compulsory Licensing Regulation must continue to operate effectively.

7.15 In order to meet that objective, this instrument makes changes to:

- reflect that the UK will not be a Member State after Exit;
- expressly define the Intellectual Property Office as the competent authority for receiving applications for compulsory pharmaceutical licences, and UK courts as the route of appeal, to restate the law in a clearer way;
- remove references to the involvement of the European Commission, conferring instead certain functions on the Secretary of State, as those arrangements will no longer exist;
- ensure that restrictions on reimportation of the licensed product can continue to be enforced, as the UK and EU markets will be distinct; and
- provide a new identifier for these licences, as the current identifier will no longer be appropriate.

The Cross-licensing regulations

7.16 Innovations relating to new types of plants can be protected by patents, but also potentially by plant breeders' rights. These can be a UK right granted by the Animal and Plant Health Agency (an executive agency of the Department for Environment, Food & Rural Affairs) under the Plant Varieties Act 1997, or a Community plant variety right granted by the Community Plant Variety Office under EU Regulations. Because patents and plant breeders' rights have different purposes and scopes of protection, it is possible for an overlap to exist, where the holder of a patent would be unable to exploit their right without infringing the plant breeders' right, and vice versa.

7.17 Directive 98/44/EC on the legal protection of biotechnological inventions requires EU Member States to provide for compulsory licences to be granted where there is an overlap between a patent and a plant breeders' right and agreement could not be reached between the holders. It also allows for cross-licensing in the other direction. This enables holders of one type of right to benefit from their innovations without interference from the other. This requirement was implemented by the Cross-licensing regulations.

7.18 When the United Kingdom leaves the European Union, Community plant variety rights will no longer have effect in the United Kingdom. Instead, existing such rights will be converted into UK plant breeders' rights by way of the Plant Varieties Act 1997 (the subject of a DEFRA instrument). As a result, this instrument makes changes to the Cross-licensing regulations to:

- ensure that the types of right eligible for cross-licensing can accommodate the conversion;
- prevent a Community plant variety right from being used in the future as a basis for requesting a compulsory licence on an overlapping UK patent, as this would no longer be appropriate; and
- remove a provision allowing for the grant of a cross licence for a UK patent to a holder of a Community plant variety right where the Community Plant Variety Office has granted a compulsory licence to the holder of the patent, as this arrangement involving an EU entity would not apply to the UK.

Other amendments

7.19 The Patents Act includes an exception for farmers to use their harvest of certain crops for further planting without infringing any patent on them. This relies on certain definitions in EU law which set conditions on how the exception works. The instrument makes changes so that the definitions can continue to function in the UK.

7.20 There are additional, minor changes needed to the Patents Rules and the Copyright, Designs and Patents Act to reflect that the UK will no longer be a Member State.

8. European Union (Withdrawal) Act/Withdrawal of the United Kingdom from the European Union

8.1 This instrument is being made using the power in section 8 of the European Union (Withdrawal) Act 2018 in order to address failures of retained EU law to operate effectively or other deficiencies arising from the withdrawal of the United Kingdom from the European Union. In accordance with the requirements of that Act the Minister has made the relevant statements as detailed in Part 2 of the Annex to this Explanatory Memorandum.

9. Consolidation

9.1 No consolidation of the Patents Act, Patents Rules, or the Copyright, Designs and Patents Act is planned at present. Informal consolidated texts of this legislation are publicly available for free on the gov.uk website. The Intellectual Property Office is considering whether informal consolidation of the retained EU law as amended by this instrument will be necessary.

10. Consultation outcome

10.1 In order to ensure that the changes being made would work in practice for users of the system, and would not result in any unintended consequences, the Intellectual Property Office held informal discussions with a small group of selected individuals with expertise in the relevant areas, or in patent law generally, to get feedback on the legal drafting of the instrument. Participants were provided with a draft of the instrument in advance.

10.2 All of the participants were generally in favour of the goal and purpose of the instrument; issues that were raised included: whether the "Bolar exception" (which allows use of a patented product as part of comparative medicinal testing, as set out in Section 60(5)(i) of the Patents Act) required modification, whether the definition of "market" in the SPC Regulations was sufficiently clear in the context it is used, and whether the restatement of certain provisions fully corresponded with the previous wording. These were considered when preparing the final draft regulations.

11. Guidance

11.1 A technical notice, outlining preparations stakeholders may need to take in the unlikely event that the UK leaves the European Union without an agreement in place, was published in September 2018[3]. The Intellectual Property Office expects to provide additional guidance to reflect the contents of this instrument once it has been approved by Parliament.

12. Impact

12.1 There is no, or no significant, impact on business, charities or voluntary bodies.

12.2 There is no, or no significant, impact on the public sector.

12.3 An Impact Assessment has not been prepared for this instrument because, as it is designed to maintain the status quo, it imposes no new obligations or burdens on private, public or third sector bodies and does not require re-familiarisation. There are no changes to the operational procedures of applying and granting for affected rights and licences, and therefore no disruption to businesses. Similarly, transition costs will be limited or zero as it has been communicated that the status quo shall continue. The impacts therefore fall below the threshold for a formal impact assessment; a de minimis assessment was carried out.

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses.

13.2 No specific action is proposed to minimise regulatory burdens on small businesses.

13.3 The basis for the final decision on what action to take to assist small businesses is that, as the purpose of the instrument is to maintain the status quo, it introduces no new burdens to small businesses that need to be mitigated.

[3] https://www.gov.uk/government/publications/patents-if-theres-no-brexit-deal

14. Monitoring & review

14.1 The approach to monitoring of this legislation is, because the instrument makes no substantive changes, to assess the changes made in the course of normal departmental business.

14.2 As this instrument is made under the EU Withdrawal Act 2018, no review clause is required.

15. Contact

15.1 Michael Warren at the Intellectual Property Office, Telephone: 01633 813988 or email: Michael.Warren@ipo.gov.uk can be contacted with any queries regarding the instrument.

15.2 Liz Coleman (Divisional Director, Policy, Legal and Informatics Division) at the Intellectual Property Office can confirm that this Explanatory Memorandum meets the required standard.

15.3 Sam Gyimah, Minister of State for Universities, Science, Research and Innovation, at the Department for Business, Energy and Industrial Strategy can confirm that this Explanatory Memorandum meets the required standard.

Annex A

Paediatric rewards

58A.—(1) This paragraph applies if—

(a) an application to which regulation 50A[4] applies, and in relation to which there is an agreed paediatric investigation plan, is granted by the licensing authority; and

(b) the licensing authority is satisfied that the material provided by the applicant pursuant to regulation 50A(3) complies with the agreed paediatric investigation plan.

(2) Where paragraph (1) applies, the licensing authority must—

(a) include in the UK marketing authorisation a statement to the effect that it is satisfied as set out in paragraph (1)(b); and

(b) ensure that the results of all studies referred to in the paediatric investigation plan are included in the summary of product characteristics and, if the licensing authority considers that the information would be useful to patients, in the package leaflet.

(3) Where paragraph (1) applies, the holder of a patent or supplementary protection certificate covering the medicinal product to which the application relates is entitled to a six month extension of the period referred to in Articles 13(1) and 13(3) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products.

(4) Paragraph (3) does not apply if the grant of the application referred to in paragraph (1)(a)—

(a) relates to a new paediatric indication; and

(b) entitles the holder of the UK marketing authorisation to a one year extension of the ten year period referred to in regulation 51(2), in accordance with regulation 51(3) and (4).

[4] Regulation 50A will require that certain applications for marketing authorisation must include the results of a paediatric investigation plan.

Annex B

Statements under the European Union (Withdrawal) Act 2018

Part 1

Table of Statements under the 2018 Act

This table sets out the statements that may be required under the 2018 Act.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraphs 3(3), 3(7) and 17(3) and 17(7) of Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) to make a Negative SI	Explain why the instrument should be subject to the negative procedure and, if applicable, why they disagree with the recommendation(s) of the SLSC/Sifting Committees
Appropriate-ness	Sub-paragraph (2) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	A statement that the SI does no more than is appropriate.
Good Reasons	Sub-paragraph (3) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	Explain the good reasons for making the instrument and that what is being done is a reasonable course of action.
Equalities	Sub-paragraphs (4) and (5) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	Explain what, if any, amendment, repeals or revocations are being made to the Equalities Acts 2006 and 2010 and legislation made under them. State that the Minister has had due regard to the need to eliminate discrimination and other conduct prohibited under the Equality Act 2010.
Explanations	Sub-paragraph (6) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2 In addition to the statutory obligation the Government has made a political commitment to include these statements alongside all EUWA SIs	Explain the instrument, identify the relevant law before exit day, explain the instrument's effect on retained EU law and give information about the purpose of the instrument, e.g., whether minor or technical changes only are intended to the EU retained law.
Criminal offences	Sub-paragraphs (3) and (7) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9, and	Set out the 'good reasons' for creating a criminal offence, and the penalty attached.

		23(1) or jointly exercising powers in Schedule 2 to create a criminal offence	
Sub-delegation	Paragraph 30, Schedule 7	Ministers of the Crown exercising sections 10(1), 12 and part 1 of Schedule 4 to create a legislative power exercisable not by a Minister of the Crown or a Devolved Authority by Statutory Instrument.	State why it is appropriate to create such a sub-delegated power.
Urgency	Paragraph 34, Schedule 7	Ministers of the Crown using the urgent procedure in paragraphs 4 or 14, Schedule 7.	Statement of the reasons for the Minister's opinion that the SI is urgent.
Explanations where amending regulations under 2(2) ECA 1972	Paragraph 13, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA	Statement explaining the good reasons for modifying the instrument made under s. 2(2) ECA, identifying the relevant law before exit day, and explaining the instrument's effect on retained EU law.
Scrutiny statement where amending regulations under 2(2) ECA 1972	Paragraph 16, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA	Statement setting out: a) the steps which the relevant authority has taken to make the draft instrument published in accordance with paragraph 16(2), Schedule 8 available to each House of Parliament, b) containing information about the relevant authority's response to— (i) any recommendations made by a committee of either House of Parliament about the published draft instrument, and (ii) any other representations made to the relevant authority about the published draft instrument, and, c) containing any other information that the relevant authority considers appropriate in relation to the scrutiny of the instrument or draft instrument which is to be laid.

Part 2

Statements required when using enabling powers under the European Union (Withdrawal) 2018 Act

1. Appropriateness statement

1.1 The Minister of State for Universities, Science, Research and Innovation, Sam Gyimah has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view the Patents (Amendment) (EU Exit) Regulations 2018 does no more than is appropriate".

1.2 This is the case because: the instrument maintains the existing systems set out in EU legislation. The amendments only make changes which are needed to ensure their continued functioning, and do not change current policy.

2. Good reasons

2.1 The Minister of State for Universities, Science, Research and Innovation, Sam Gyimah has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view there are good reasons for the provisions in this instrument, and I have concluded they are a reasonable course of action".

2.2 These are: that the provisions are needed to ensure the continuing operation of the supplementary protection certificate system at the point of Exit, to ensure the UK continues to meet commitments it has made under the TRIPS Agreement, and to reflect changes to the types of plant variety right eligible for cross-licensing. As set out in paragraph 7.2 of the Memorandum, without these provisions, the legislation will not function correctly.

3. Equalities

3.1 The Minister of State for Universities, Science, Research and Innovation, Sam Gyimah has made the following statement(s):

"The draft instrument does not amend, repeal or revoke a provision or provisions in the Equality Act 2006 or the Equality Act 2010 or subordinate legislation made under those Acts."

3.2 The Minister of State for Universities, Science, Research and Innovation, Sam Gyimah has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In relation to the draft instrument, I, Sam Gyimah have had due regard to the need to eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010.".

4. Explanations

4.1 The explanations statement has been made in section 2 of the main body of this explanatory memorandum.