EXPLANATORY MEMORANDUM TO

THE INTELLECTUAL PROPERTY (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2020

2020 No. 1050

1. Introduction

1.1 This explanatory memorandum has been prepared by the Intellectual Property Office (IPO), an executive agency of the Department for Business, Energy & 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 intellectual property (IP) legislation which were made in 2019 in preparation for a potential "no deal" exit from the EU and the expected retention of EU law as domestic law at that point. This legislation is listed in paragraph 6.3 and is referred to collectively as "the 2019 Regulations" in this memorandum.

2.2 As the UK has left the EU under the terms of the Withdrawal Agreement, the retention of EU law will now take place at the end of the transition period[1]. The provisions in this instrument reflect commitments made in the Withdrawal Agreement and ensure that the retained EU law will continue to function effectively, taking account of the transition period. They also deal with inoperabilities arising from new EU law which entered into force during the extended Article 50 period and correct some minor errors in the 2019 Regulations.

Explanations

What did any relevant EU law do before exit day?

2.3 In brief, and as explained further in paragraphs 7.7, 7.11, 7.15-7.16, and 7.25, the relevant EU law:

- provided a framework for the EU trade mark;
- established a system of EU-wide registered and unregistered designs;
- provided for a supplementary protection certificate (SPC) system for patented pharmaceuticals and agrochemicals;
- developed the principle of a regional regime for the exhaustion of IP rights; and
- established an IP right for databases.

2.4 As set out in more detail in paragraphs 7.8, 7.12, 7.17 and 7.26, these pieces of EU law were the subject of amendments by the 2019 Regulations, which, amongst other things:

[1] This point in time is defined in s.1A of the European Union (Withdrawal) Act 2018 as "IP completion day".

- created comparable UK intellectual property rights in place of EU trade marks, registered designs and unregistered designs which would have ceased to have protection on exit day, including rights which have been protected at an international level;
- enabled the filing of new UK applications for trade marks and designs where EU or international applications would have still been pending on exit day whilst retaining the relevant filing date;
- provided for the continued functioning of the SPC system;
- ensured that goods whose IP rights should be treated as exhausted remain so; and
- limited eligibility for new database rights to UK nationals while providing for continued protection of database rights held by EEA individuals and businesses that were in force on exit day.

2.5 After the 2019 Regulations were made, Regulation (EU) 2019/933 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products[2] introduced what is known as the "manufacturing waiver" to the SPC system. As explained further in paragraph 7.27, this enables third parties to manufacture SPC-protected products without requiring the consent of the SPC holder, but only for export outside the EU or for storing in the EU for sale on the EU market after the SPC has expired. Doing so will not infringe the SPC right.

Why is it being changed?

2.6 The 2019 Regulations do not reflect that there is now a transition period in which EU law continues to apply in the UK - if they came into force, they would retroactively make changes as from exit day; 31 January 2020. They also do not address the commitments made in the Withdrawal Agreement or provide fixes to any inoperabilities in new EU law which will be retained at the end of the transition period.

2.7 This last point applies to the manufacturing waiver specifically. The retained EU law would not be clear on how the waiver would apply in the UK after the transition period; there would be uncertainty about what actions third parties could take without infringing the SPC, and without prompting legal action from the rightsholder.

What will it now do?

2.8 For the most part, the changes ensure that the provisions of the 2019 Regulations will apply with effect from the end of the transition period as opposed to exit day. This will ensure that, in particular, any EU IP rights arising during that period will be properly protected in the UK going forward.

2.9 In relation to trade marks and designs, the changes also implement commitments contained in the Withdrawal Agreement so that, as set out in paragraphs 7.22-7.23, certain decisions taken by EU bodies or courts on the validity of such rights are recognised in the UK.

2.10 In relation to the manufacturing waiver, as set out in paragraph 7.29, the retained law will allow third parties to manufacture SPC-protected products in the UK, without the

[2] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2019.153.01.0001.01.ENG

rightsholder's consent, either for export outside of the UK or EU or for stockpiling in the UK for sale in the UK or EU once the SPC has expired.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 This instrument corrects several drafting errors identified in the 2019 Regulations. In particular:

- regulation 3 fixes an error where a reference was retained to a schedule which was repealed in the same instrument;
- regulation 19(b) corrects a provision where the wrong type of unregistered design was named;
- regulation 23 fixes an error where the period in which no additional fees are due for renewing a converted EU registered design was set to expire, rather than begin, on a specific date; and
- regulation 25 fixes an error where a conflicting amendment was made to the underlying Act by two different sets of amending regulations.

Other provisions fix typographical errors.

3.2 The Department and the IPO have therefore followed the requirement in paragraph 4.7.6 of Statutory Instrument Practice to consult the SI Registrar, and the free issue procedure has been applied because of the length and mix of the new and correcting provisions.

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)

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

3.4 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.

5. European Convention on Human Rights

5.1 The Parliamentary Under Secretary of State (Minister for Science, Research and Innovation), Amanda Solloway MP, has made the following statement regarding Human Rights:

"In my view the provisions of the Intellectual Property (Amendment etc.) (EU Exit) Regulations 2020 are compatible with the Convention rights."

6. Legislative Context

6.1 These regulations are made primarily under section 8 of the European Union (Withdrawal) Act 2018 (EUWA). This 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, including in EU law which continues to form part of domestic law at

the end of the transition period under section 2 and 3 of the EUWA (namely the saving of EU-derived domestic legislation and the incorporation of direct EU legislation) and under section 4 (which relates to certain enforceable EU rights).

6.2 The European Union (Withdrawal Agreement) Act 2020 (WAA) amended the powers in section 8 EUWA to include the ability to deal with any deficiencies in law which arise as a result of the transition period. It also added section 8B, which allows a Minister to make regulations to implement the provisions set out in Part 3 of the Withdrawal Agreement. These Regulations are also made under section 8B.

6.3 As part of the Government's legislative programme to prepare for a "no deal" outcome, five statutory instruments relating to intellectual property were laid before Parliament in 2019 and approved (the 2019 Regulations)[3]. These instruments, which relied upon the power in section 8 EUWA, are:

- The Intellectual Property (Exhaustion of Rights) (EU Exit) Regulations 2019 (SI 2019/265; "the Exhaustion Regulations"),
- The Trade Marks (Amendment etc.) (EU Exit) Regulations 2019 (SI 2019/269; "the Trade Mark Regulations"),
- The Intellectual Property (Copyright and Related Rights) (Amendment) (EU Exit) Regulations 2019 (SI 2019/605; "the Copyright Regulations"),
- The Designs and International Trade Marks (Amendment etc.) (EU Exit) Regulations 2019 (SI 2019/638; "the Designs Regulations"), and
- The Patents (Amendment) (EU Exit) Regulations 2019 (SI 2019/801; "the Patents Regulations").

6.4 Parts 1 to 6 of these Regulations amend each of these instruments, whilst Parts 7 and 8 make new changes to the Patents Act 1977 and Regulation 469/2009.

7. Policy background

What is being done and why?

7.1 The UK has left the EU under the terms of the Withdrawal Agreement, and there is now a transition period until the end of 2020 while the UK and EU negotiate additional arrangements. The current rules on trade, travel, and business for the UK and EU continue to apply during the transition period.

7.2 The 2019 Regulations were drafted and designed to function in the event that the UK left the EU without an agreement being reached by exit day. They do not reflect the legal situation that now exists following the UK's entry into the Withdrawal Agreement. This instrument is needed to ensure that the law properly reflects the obligations in the Withdrawal Agreement, and to ensure that it otherwise works effectively at the end of the transition period.

7.3 Because the 2019 Regulations take a similar approach to the arrangements set out in the Withdrawal Agreement, the legislative gap between the two is minimal. This instrument will ensure that the arrangements set out in the Withdrawal Agreement are fully implemented.

[3] An additional instrument, the Design Right (Semiconductor Topographies) (Amendment) (EU Exit) Regulations 2018 (SI 2018/1052), was made in 2018, but is not amended by this draft instrument.

7.4 As the 2019 Regulations were intended to take effect on exit day, they do not take account of the transition period, or that EU law now continues to apply until the end of that period. The WAA has deferred the coming into force of instruments made under the EUWA, including the 2019 Regulations, by glossing their commencement provisions so that they refer to IP completion day instead of exit day[4]. However, this change does not extend to other references to exit day in the 2019 Regulations (such as in transitional provisions). If those references are not updated when the 2019 Regulations come into force, the law will be changed retroactively and rights which currently exist may not be properly recognised.

7.5 In addition, the 2019 Regulations could only operate on the UK and EU law as it stood at the time they were made. Any new legislation, or any amendment to existing legislation, since that time needs to be accounted for and, if necessary, any inoperabilities addressed. As far as possible, the approach remains to ensure that the law which currently applies in the UK will continue to do so at the end of the transition period, to ensure continuity and certainty for businesses and rightsholders.

7.6 This instrument covers a number of different IP rights. The specific policy background to each is explored in more detail in the following sections.

Copyright and database rights

7.7 Database rights are a form of IP protection unique to EU law. They give database creators the right to prevent others copying or sharing the contents of their databases where a substantial investment has been made in obtaining, verifying or presenting the data. The right is automatic and unregistered; however, only databases made by EEA nationals, residents and businesses are eligible for the right.

7.8 Among other things, the Copyright Regulations amended the retained EU law on database rights so that only databases created by UK nationals, residents and businesses will be eligible for the right in the UK after exit day. However, it included a transitional provision (regulation 38) which ensured that any database rights existing before exit day would continue to be recognised for the remainder of their duration, including those made by EEA nationals, residents or businesses.

7.9 Article 58 of the Withdrawal Agreement requires the UK to continue to recognise any database rights which arose before the end of the transition period. As the Copyright Regulations only do so for database rights from EEA makers that existed before exit day, an amendment is needed to ensure any rights arising during the transition period are properly protected. Regulation 4 does this by changing the provision to cover any database right existing before IP completion day.

7.10 In addition, regulation 3 corrects an error in the Copyright Regulations in relation to orphan works (orphan works are copyright works where one or more rightsholders are unknown or cannot be found). A reference to Schedule ZA1 to the Copyright, Designs & Patents Act 1988 had been inadvertently retained in regulation 31(a), despite its deletion from that Act by an earlier provision of the Copyright Regulations.

Exhaustion of rights

7.11 IP rights are said to be "exhausted" if the IP-protected product has been first sold with the approval of the rightsholder. As a result, the rightsholder cannot use their IP rights to prevent the product being resold. In the EU, exhaustion occurs if the product is

[4] As provided in paragraph 1(1) of schedule 5 to the WAA.

lawfully sold anywhere in the EEA; the product can be resold freely within the EEA and the rightsholder cannot stop it moving between Member States even if they have IP rights in a particular country. This forms part of the principle of free movement of goods set out in the EU treaties.

7.12 The Exhaustion Regulations preserved the effect of the EEA exhaustion regime in the UK by reference to the retention of EU law and enforceable rights in the EUWA on exit day. This meant that the IP rights of any product lawfully sold in the EEA, either before or after exit day, would continue to be treated as having been exhausted in the UK.

7.13 Article 61 of the Withdrawal Agreement commits the UK and the EU to recognise that any IP rights which are exhausted before the end of the transition period will continue to be treated as such.

7.14 Regulation 6 replaces references to "exit day" in the Exhaustion Regulations with "IP completion day". This ensures that, although any products sold during the transition period would be correctly treated as exhausted under the existing provision, the rights which are enforceable are those which are available at the end of the transition period. This also provides legal certainty.

Trade marks, registered designs and unregistered designs

7.15 Trade marks and designs are intellectual property rights that distinguish the goods or services from one trader to another, or protect the appearance of a product, respectively. EU law provides for EU-wide trade marks, registered and unregistered designs, the first two of which are granted by the EU Intellectual Property Office (EUIPO). These rights will cease to apply in the UK when it is no longer treated as an EU Member State, although they continue to have effect during the transition period.

7.16 EU-wide protection of trade marks and registered designs can also be obtained by applying through the World Intellectual Property Organisation and designating the territories in which protection is sought. International trade marks and designs designating the EU will also cease to apply in the UK when it is no longer treated as an EU Member State.

7.17 The Trade Mark Regulations and the Designs Regulations provided for comparable rights to be granted under UK law for any EU trade marks or designs, or international rights designating the EU, that were in force on exit day. They also enabled new UK applications to be filed where an application for an EU right was pending on exit day, retaining the original filing date of the EU application.

7.18 Articles 54-57 and 59 of the Withdrawal Agreement require the UK to take these measures for EU rights in force, and applications pending, at the end of the transition period. This instrument therefore amends the Trade Mark Regulations and the Designs Regulations so that the grant of comparable rights and the right to file replacement applications both operate with effect from IP completion day, rather than exit day.

7.19 Failing to do so would mean that any EU rights which were granted during the transition period would not be converted and could potentially be lost - this could be as many as 200,000 rights.

7.20 The amendments in Parts 4 and 5 make the necessary substitutions.

7.21 In addition, some minor errors found in the two sets of regulations have been corrected. Regulation 19(b) provides a fix so that UK "design courts" correctly have exclusive jurisdiction over converted EU unregistered designs. Regulation 23 corrects an error in the Designs Regulations so that the period where no additional fees would be due on top of the applicable fee to renew a converted EU registered design is correctly set at six months, instead of one day as originally, inadvertently, drafted. Regulation 25 corrects a conflict of amendments between the Design Regulations and the Exhaustion Regulations.

7.22 Third parties can challenge the registration of an EU trade mark or registered design at the EUIPO, or as a counterclaim in infringement actions heard before courts designated as EU courts in Member States; the right may be cancelled or reduced in scope if the challenge is successful. Article 54(3) of the Withdrawal Agreement requires the UK to honour decisions made by the EUIPO, the CJEU on appeal from the EUIPO, or Member State courts on cancellation actions which were in progress at the end of the transition period, and to apply the decision to the comparable UK right. This means that successful parties will not need to launch a separate cancellation action in the UK. There is an exception where the grounds for revocation/invalidity would not apply if considered under UK law.

7.23 Regulations 9(b)(ii) and 11 (for trade marks) and 21(c)(ii) and 24 (for registered designs) provide for the IPO to take account of cancellation decisions on the EU rights, to determine if the exception applies based on evidence from the rightsholder, and to take action on the comparable right. A right of appeal is provided against the decision of the IPO on whether the exception applies.

Patents and supplementary protection certificates

7.24 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.

7.25 Supplementary protection certificates (SPCs) provide a period of additional protection for patented medicines and agrochemicals, to compensate for the need for lengthy regulatory approval procedures during the patent lifetime before the product can be sold and research investment recouped. The SPC gives the approved product the same rights and protection as the patent, subject to the same limitations, for up to five years after the patent expires. SPCs are provided by EU Regulations but operate as individual national rights.

7.26 The Patents Regulations, amongst other things, ensured that the retained EU SPC Regulations would continue to function as domestic law, replacing references to EU regulatory legislation with their UK equivalents and ensuring that the method for calculation of an SPC's duration would remain the same. The provisions of the Patents Regulations do not, in general, refer to "exit day", and so do not need changing to be able to work correctly when brought into force at the end of the transition period.

7.27 In July 2019 - during the extended Article 50 period - the EU introduced a new exception to the rights provided by an SPC. This "manufacturing waiver" allows third parties to manufacture SPC-protected medicinal products, without needing the permission of the SPC holder. The product can only be manufactured for export to countries outside the EU where protection does not exist or has expired, or (in the

final 6 months of the SPC term) for storing the product in the Member State of making ("stockpiling"), ready for sale in the EU when the corresponding SPC expires. Acts which are necessary for the manufacture of the product, its export or storage, are also permitted as these too would otherwise infringe the protection provided by the SPC. The product must be specifically labelled with an "EU export" logo so it can be identified as having been made under the waiver; this is intended to prevent illicit diversion of the product back onto the EU market.

7.28 Article 60 of the Withdrawal Agreement requires that any applications for an SPC which are pending at the end of the transition period should be considered in accordance with the EU law in force at that time, and any SPC granted based on those applications should provide for the same level of protection provided for in EU law. This will now need to include the manufacturing waiver.

7.29 Regulations 40-43 and the accompanying Schedule make additional amendments to Regulation 469/2009 to fix inoperabilities in the manufacturing waiver legislation and make consequential amendments to other legislation. These maintain the scope of the waiver so that third parties can manufacture SPC-protected products in the UK, without the rightsholder's consent, either for export outside of the UK or EU or (in the final 6 months of the SPC term) for stockpiling in the UK for sale in the UK or EU once the SPC has expired. This means that the scope of the waiver within the UK will remain essentially unchanged at the end of the transition period.

7.30 Paragraph 3(d) of the Schedule changes the labelling requirement so that the product must be identified with "UK export" wording; this allows it to be distinguished from one made in the EU under its waiver. Paragraph 3(k) provides a power to further regulate the form and manner of that wording by negative statutory instrument, whilst a transitional provision in regulation 43 ensures that any product which has already been manufactured under the waiver does not require relabelling. The provision also preserves the effect of any notification of intention to use the waiver filed before the end of the transition period; as regulation 42 amends the Patents Rules 2007 to designate a specific form for such notifications after 1 January 2021.

7.31 Beyond the manufacturing waiver, Article 60 of the Withdrawal Agreement also applies to applications to extend the duration of an SPC for a medicine which has been tested for paediatric use; regulation 37 updates transitional provisions in the Patents Regulations so that they apply to applications pending at the end of the transition period, as well as extensions already granted.

7.32 In addition, some small changes have been made to other provisions of the Patents Regulations, to correct minor typographical errors and update cross-references to other domestic law. Regulation 29 ensures that plant breeders' rights which have been converted from Community plant variety rights are able to be cross-licensed. Regulations 28 and 39 replace a provision which preserved pre-exit day EU legislation with a cross-reference to equivalent domestic definitions.

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. The instrument is also made under the powers in section 8B of that Act in order to implement provisions in Part 3 of the Withdrawal

Agreement. 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 relevant legislation is planned at present. Informal consolidated texts of domestic intellectual property legislation are publicly available for free on the gov.uk website[5]. 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 relation to the manufacturing waiver, a public call for views was issued, seeking feedback on draft legislation to fix the inoperabilities in the EU law in the event of a "no deal" outcome[6]. The call for views was open from 5 July 2019 to 9 August 2019. In addition, meetings were held with major representative bodies from the innovative pharmaceutical industry, the manufacturers of generic pharmaceuticals, and the patent attorney profession during the period to discuss the proposed draft.

10.2 Six responses were received before the call for views closed, from representative organizations of rightsholders, pharmaceutical innovators, legal representatives, and the generics industry. All of the respondents were in favour of ensuring the proper functioning of the waiver and avoiding legal uncertainty. Most of the respondents highlighted the importance of preserving the status quo regarding the territory to which export could take place; the consultation draft would have allowed manufacture for export to any country outside the UK. Other issues raised included the requirement for a logo or other indication on the packaging for medicines intended for export and the need for transitional arrangements.

10.3 In response to the feedback received, the Government made changes to the drafting of the provisions to maintain the current markets for export and stockpiling, to provide powers to allow for additional labelling requirements if necessary, and to include additional transitional arrangements covering use of forms and the use of the pre-existing labelling requirements on any products manufactured before the end of the transition period. The drafting was then incorporated into this instrument.

10.4 The Government response to the call for views was published on 13 July 2020[6]; publication was initially delayed because the ratification of the Withdrawal Agreement made it necessary to reassess the drafting of both the response and the legislation itself. The Government's focus on prioritising communications relating to coronavirus necessitated a further delay.

10.5 As the other changes were largely technical and minor in nature, in line with Cabinet Office principles on consultation, a formal public consultation was not considered to be useful in determining the Government's approach on drafting. Informal views on the drafting of those changes were sought from relevant stakeholders; in particular, the provisions on cancelling trade marks and designs were provided to representative organisations and key users of the trade mark and design systems for comment and to

[5] https://www.gov.uk/topic/intellectual-property/law-practice
[6] https://www.gov.uk/government/consultations/supplementary-protection-certificate-waiver-no-deal-legislation

familiarise them with the proposed approach. Responses generally approved of the drafting of the legislation.

11. Guidance

11.1 Guidance was published in January 2020 on the effect of the transition period on intellectual property rights, how the law will change at the end of that period, and what preparations businesses may need to make[7]. The Intellectual Property Office expects to update that 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 the changes being made are largely technical in nature. The Government's assessment is that the combined policy impacts of this instrument fall below the threshold for a formal impact assessment; a de minimis assessment has been carried out. The instrument will update existing EU Exit regulations that were designed for a 'no deal' outcome to account for the transition period and the obligations of the Withdrawal Agreement, and address inoperabilities in the retained EU SPC Waiver Regulation arising as a result of EU Exit. In both cases, the changes will ensure that existing legislation continues to operate in the same way as before. As the status quo is being maintained, it imposes no new obligations or burdens on private, public or third sector bodies and does not require re-familiarisation; the changes are therefore not expected to result in costs for businesses.

12.4 Where this instrument departs from the status quo is in implementing Article 54(3) of the Withdrawal Agreement, under which the UK is obliged to recognise the outcome of cancellation proceedings against EU-level registered rights that are underway as of the end of the transition period. The impact of this is expected to be a small saving for businesses, as separate cancellation proceedings will not need to be prosecuted in both territories. This provision is expected to impact only around 1200 registered rights.

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 principal purpose of the instrument is to maintain the status quo, it introduces no new burdens to small businesses that need to be mitigated.

14. Monitoring & review

14.1 The approach to monitoring of this legislation is to assess the effect of the changes being made as part of the course of normal departmental business.

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

[7] https://www.gov.uk/government/news/intellectual-property-and-the-transition-period

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 James Porter, Deputy Director at the Intellectual Property Office can confirm that this Explanatory Memorandum meets the required standard.

15.3 Amanda Solloway MP, Parliamentary Under Secretary of State at the Department for Business, Energy & Industrial Strategy can confirm that this Explanatory Memorandum meets the required standard.

Annex

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 23(1) or jointly exercising powers in Schedule 2 to create a criminal offence	Set out the 'good reasons' for creating a criminal offence, and the penalty attached.
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 14, 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 15, 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 Parliamentary Under Secretary of State (Minister for Science, Research and Innovation), Amanda Solloway MP, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view the Intellectual Property (Amendment etc.) (EU Exit) Regulations 2020 do no more than is appropriate".

1.2 This is the case because the changes ensure compliance with the specific provisions of the Withdrawal Agreement, and only correct deficiencies to the extent necessary to maintain the continued functioning of the intellectual property system at the end of the transition period.

2. Good reasons

2.1 The Parliamentary Under Secretary of State (Minister for Science, Research and Innovation), Amanda Solloway MP, 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 it is critical to implement the commitments agreed in the Withdrawal Agreement and to ensure that EU law retained at the end of the transition period functions effectively as domestic law.

3. Equalities

3.1 The Parliamentary Under Secretary of State (Minister for Science, Research and Innovation), Amanda Solloway MP, 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 Parliamentary Under Secretary of State (Minister for Science, Research and Innovation), Amanda Solloway MP, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In relation to the draft instrument, I, Amanda Solloway 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.