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Intellectual Property and Brexit (including provisions relevant to the Pharmaceutical Sector)

SEPTEMBER 2019

IP rights which are designated as applying across the EU (EU trade marks, Community plant variety rights, Community registered designs and Community unregistered designs) and those, qualification for which involves activity within the EU (such as sui generis database rights), are all at risk of termination in relation to the territory of the UK once the definition of 'EU' no longer includes the UK. However, the Withdrawal Agreement (**'WA'**) provides for replacement rights to be provided by the UK. Since the chances of the WA being approved by the House of Commons have decreased for various reasons, in addition, the UK Government has published its own set of no-deal technical notices stating that registered rights will be replaced with equivalent rights in the UK. The Government has also published statutory instruments confirming this. These will come into effect on exit day – at the end of the transition/implementation period after the UK leaves the EU if there is a "deal" in place, as is currently set out in the WA, or immediately, if the UK leaves the EU without a deal.

Table of Contents

Brexit statutory instruments – How IP will work after exit day (with or without a "deal")

Statutory instruments

The UK Government has now issued several draft statutory instruments which adapt UK IP legislation to take account of Brexit by amending references but also making provision for the various replacement rights or recognition of existing rights post-Brexit:

- European Union (Withdrawal) Act 2018
- European Union (Withdrawal) Act 2018 (Exit Day) (Amendment) Regulations 2019 (2019/718)
- Plant Breeders' Rights (Amendment etc.) (EU Exit) Regulations 2019
- Patents (Amendment) (EU Exit) Regulations 2019
- Intellectual Property (Exhaustion of Rights) (EU Exit) Regulations 2019
- Trade Marks (Amendment etc.) (EU Exit) Regulations 2019
- Horizon 2020 Framework Programme for Research and Innovation (EU Exit) Regulations 2019
- Intellectual Property (Copyright and Related Rights) (Amendment) (EU Exit) Regulations 2019
- Design Right (Semiconductor Topographies) (Amendment) (EU Exit) Regulations 2018 (2018/1052)
- Designs and International Trade Marks (Amendment etc.) (EU Exit) Regulations 2019 (2019/638)
- Customs (Enforcement of Intellectual Property Rights) (Amendment) (EU Exit) Regulations 2019 (2019/514)

These will come into force along with the other Brexit-related legislation, at the end of the transitional period provided for in the WA. For example, EU trade mark rights in the UK will be replaced by something to be called "a comparable trade mark (EU)" with the same priority date and all other administrative details, as the EUTM from which it originated.

The following rights existing at exit day (the day that Brexit takes effect) will be dealt with as follows:

- EU trade marks will become "comparable trade marks (EU)";
- Community registered designs will become "re-registered designs";
- Unregistered Community designs will become "continuing unregistered Community designs" (note: there will also be a new type of unregistered design right to replace unregistered Community design rights in the UK, known as the "supplementary unregistered design right");
- Community plant variety rights will be recognised in the UK as if they were UK PVRs;
- Geographical indications will have an entirely new UK regime; and
- Sui generis database rights will be recognised in the UK.

Trade marks

It is crucial to remember with trade marks that notwithstanding the UK leaving the EU, owners of EU trade marks will still have valid EU trade marks in the remaining EU states. Additionally, UK entities will still be able to apply for and register an EU trade mark which will cover all remaining EU member states. As such, UK entities will still have access to the Madrid System for enforcing trade marks, but only when it concerns marks subsisting in one or more EU27 country.

The picture is slightly different for those EU trade marks existing at exit day which currently subsist in the UK. In this regard, the UK Government has published the Trade Marks (Amendments etc.) (EU Exit) Regulations 2019, which will come into force on exit day. It has two main effects on the Trade Marks Act 1994 (**'TMA 1994'**). The first is to amend the TMA 1994 to make provision for EU trade marks to be treated as registered UK trade marks from exit day, and to include provisions about certain applications of EU trade marks before exit day. To cover this, a new Schedule 2A would be added to the TMA.

Existing EU Trade Marks ('EUTM')

With regards to EU Trade Marks that are currently registered in the EUTM register, in so far as they have effect in the UK, these are to be treated on and after exit day as UK registered trade marks but will be referred to as "a comparable trade mark (EU)". Such rights will be deemed registered as of the filing date of the corresponding EUTM. This is important, as there will be no publication of the new registration, and no new certificate will be issued. This means that sections 40(3) and 40(4) TMA will not apply to a comparable trade mark (EU).

Ownership of the UK element of the EUTM will not change once this right is automatically converted to a comparable trade mark (EU). Although there are likely to be delays due to the overwhelming amounts of marks to be

No deal – IP & Pharma

Should the UK leave the EU with no deal, ie not agree the **Withdrawal Agreement ('WA')** or any other arrangements, the Statutory Instruments (**'SIs'**) published by the UK Government will provide amendments to UK IP law to provide for the continued protection of EU-wide rights in the UK, just as they would at the end of the transition period if there were no further agreement in the interim. The difference is that, under a no-deal scenario, there will be no transition period.

No deal arrangements for IP rights effectively mirror the provisions set out in the WA in any case, as they provide for replacement of registered rights and the recognition of unregistered rights that are existing in the UK at the date the UK leaves the EU.

The main exception is for Geographical Indications: these will no longer be recognised in the UK if originating from the EU. The UK would set up its own geographical indication protection system. In either a no deal or withdrawal agreement situation, UK originating Geographical Indications would not apply in the EU post-Brexit.

Similarly the provision made in the WA for the exchange of information between the EMA and the MHRA would not be agreed and would need to be negotiated separately.

The UK Government has said that, in relation to exhaustion, if there is no deal "the UK looks forward to exploring arrangements on IP cooperation that will provide mutual benefits to UK and EU rights holders and we are ready to discuss issues the EU wishes to raise in the negotiations on our future relationship, including exhaustion of IP rights"; whereas the WA provides that IP rights that were exhausted both in the EU and in the UK before the end of the transition period under the conditions provided for by EU law shall remain exhausted both in the EU and in the UK post-transition. If there was no deal, this would mean that whilst exhaustion within the EU (as it is then constituted) will continue, the UK courts will be able to exercise local or international exhaustion as they see fit. Historically the UK has taken an international exhaustion approach pre-EU membership.

converted, the registrar has said that it will enter the details of the comparable trade mark (EU) in the UK register using the English language version of the goods or services used for the corresponding EUTM.

It will be possible for EUTM owners to opt out of the process, but if they do not, their trade mark rights in the UK will convert automatically to a comparable trade mark (EU). To opt out, the owner of an EUTM may at any time on or after exit day serve notice on the UK registrar that the EUTM is not to convert. This is subject to the following conditions on or after exit day:

- the comparable trade mark (EU) cannot have been put to use in the UK by the owner or with his consent;
- the comparable trade mark (EU) (or any right under it) cannot have been made subject of an assignment, licence, security interest or any other agreement or document except for an assent by an estate's personal representatives; and
- the comparable trade mark (EU) must not be subject of proceedings initiated by the proprietor or with his consent.

An opt-out notice must identify the EUTM and any person who has an interest in the EUTM which had effect before exit day and that was recorded in the EUTM Register. However, the notice will be of no effect unless the EUTM owner certifies that such a person has been given not less than 3 months' notice of the owner's intention to opt out or is not affected at all (or consents to the opt-out if affected). Once an opt-out notice is served, then the comparable trade mark (EU) ceases to have effect in the UK from exit day and any details of the comparable trade mark (EU) will be removed from the UK register.

Comparable Trade Marks (EU)

Renewals: once a comparable trade mark (EU) is entered into the register, if it is meant to expire within 6 months from exit day, then the owner may renew the trade mark. However, if the owner fails to renew such a mark within those 6 months, then the registrar will notify the owner and the owner may renew the registration within 6 months from the date of the notice. If the trade mark is not renewed then, it will be removed from the UK register. If a comparable trade mark (EU) is removed because it is not renewed then the rules relating to restoration of a UK trade mark apply.

Relative grounds in opposition proceedings in case of non-use: It is currently the case that in UK opposition proceedings, an opponent can rely on its registration of an earlier trade mark. However, that earlier trade mark must have been put to genuine use in the UK within the five year period before the date on which the opposed application is published. Where the earlier mark is a comparable trade mark (EU), then if the five year period expires before exit day then use of the corresponding EU trade mark in the UK or the EU can be relied on. On the other hand, if exit day falls within the 5-year period then the use of the corresponding EU trade mark in the UK or the EU in the part of the period falling before exit day can be relied on.

Non-use as a defence in infringement proceedings: It is currently the case that the owner of a UK trade mark that is over 5 years old can only prevent infringement of its mark to the extent that the trade mark is not liable to revocation for non-use at the date that the infringement proceedings are brought. The defendant may request that the trade mark owner provide proof that during the 5 year period before the date of the commencement of the infringement proceedings the trade mark owner had made genuine use of its mark in the UK. Where the alleged infringement is of a comparable trade mark (EU), then if the five year period expires before exit day then the use of the corresponding EU trade mark in the UK or the EU can be relied on by the owner. On the other hand, if exit day falls within the 5-year period then the use of the corresponding EU trade mark in the UK or the EU in the part of the period falling before exit day can be relied on by the owner.

Non-use in the revocation of a comparable trade mark (EU): Section 46 of the TMA states that the registration of a UK trade mark may be revoked if: (i) it is not put to genuine use with 5 years from the date of registration; and (ii) use has been suspended for an uninterrupted period of 5 years; but (iii) the registration will not be revoked if use is commenced or resumed after the relevant 5 year period but before the application for revocation is made (ignoring any use made in the 3 months before the application for revocation).

Where the revocation an action against a comparable trade mark (EU), if the five year period expires before exit day then the use of the corresponding EU trade mark in the UK or the EU can be relied on by the owner. On the other hand, if exit day falls within the 5-year period then the use of the corresponding EU trade mark in the UK or the EU in the part of the period falling before exit day can be relied on by the owner. Similar provisions will apply to reliance on the use of EU trade marks in the EU, when the existence of an earlier comparable trade mark (EU) is relied on when seeking a declaration of invalidity of a UK trade mark registration.

Reputation of a comparable trade mark (EU): The reputation of a trade mark in the UK may be relied upon (i) to oppose a trade mark on relative grounds or (ii) to claim infringement of a trade mark that has a reputation in the UK. Where the reputation of a comparable trade mark (EU) is to be considered in respect of any time before exit day then the reputation of the corresponding EUTM in the EU may be considered.

Priority and seniority dates: The relevant date for determining the priority date of a comparable trade mark (EU) is the date from which priority is claimed for the corresponding EUTM (ie the date on which the application was filed in a Convention country which is the basis of the claim of priority). Seniority may be claimed from a UK trade mark from which the corresponding EUTM claimed seniority. Thus, if the senior trade mark is allowed to lapse the comparable trade mark (EU) continues to have the same rights as the owner would have had as if the UK senior mark had continued to be registered.

Rights associated with EUTMs

While the above paragraphs set out the position for the actual mark on the registry, questions remain as to what happens to related rights, such as assignments, licences, security interests, and the continuity of these related rights. We set out the status of these rights after exit day below.

Assignments of an existing EUTM not recorded on exit day: Where there is an assignment of an EUTM (or a right in it) but the assignment has not been registered at the EUIPO before exit day then, the assignee of the corresponding EUTM (or a right in it), or the owner of the comparable trade mark (EU), may apply to the UK registrar to record the assignment against the comparable trade mark (EU). The usual rules apply in relation to the effects of non-registration of the assignment, ie, the assignment is ineffective against a person with a conflicting interest in ignorance of the assignment; and no award of costs in infringement proceedings, unless the assignment was registered within 6 months of the date of the assignment.

Licences on an existing EUTM: Where an existing EUTM is subject to a licence before exit day which licenses the use of the EUTM in the UK and does not expire on exit day, then (subject to any agreement between the licensor and the licensee to the contrary) the licence continues to apply to the comparable

trade mark (EU) in the UK (subject to the terms of the licence as may be modified in order to be applicable in the UK).

Whether or not the licence has already been recorded against the EUTM then an application to register the licence against the comparable trade mark (EU) may be made to the UK registry by the licensee or the owner of the comparable trade mark (EU). If the licence had not been recorded against the EUTM before exit day, then the usual rules apply in relation to the effects of non-registration, ie, the licence is ineffective against a person with a conflicting interest in ignorance of the licence; the licensee does not have the statutory rights of a licensee in relation to infringement actions; and no award of costs in infringement proceedings unless the licence was registered within 6 months of the date of the licence. Where the licence has been recorded against the EUTM before exit day then the effects of non-registration do not apply until 12 months after exit day.

Security interests in an existing EUTM: Where an existing EUTM (or any right under it) is the subject of a security interest before exit day and the security interest does not terminate on exit day then reference to an EUTM in a document that creates security over the EUTM are to be read as including a reference to the comparable trade mark (EU). Whether or not the security interest has been recorded against the EUTM then an application to register the security interest may be made by the holder of the security interest over the comparable trade mark (EU) or the owner of the comparable trade mark (EU). It is foreseeable, as is usual with the registration of security interests, that the holder of the security interest will seek to ensure that registration is appropriately made.

If the security interest had not been recorded against the EUTM before exit day then the usual rules apply in relation to the effects of non-registration, ie, the security interest is ineffective against a person with a conflicting interest in ignorance of the security interest. Additionally, where the security interest has been recorded against the EUTM before exit day then the effects of non-registration do not apply until 12 months after exit day.

Continuity of rights: References to an existing EUTM in any document made before exit day shall, unless there is evidence that the document was not intended to have effect in the UK, be read on and after exit day as including references to a comparable trade mark (EU). Subject to any agreement to the contrary, if before exit day, the owner of an EUTM has consented to the use or other act relating to the EUTM which would infringe the comparable trade mark (EU) on or after exit day then the owner will be treated as having given consent to do that use or act in the UK on or after exit day.

Trade mark litigation

If, on exit day there are proceedings pending in the UK courts which relate to an EUTM, then the EU Trade Mark Regulations 2017/1001 will continue to apply as if the UK were still a member state (not Arts 128(2) (4) (6) and (7) or 132 – which relate to counterclaims for revocation or of invalidity of an EUTM). In infringement proceedings, the UK court may grant an injunction to prevent use of the comparable trade mark (EU) in the UK. In proceedings that involve a counterclaim for revocation/declaration of invalidity, the UK court may revoke or make the declaration of invalidity in relation to the comparable trade mark (EU). If before exit day, there is an injunction in force that prohibits use of an EUTM in the UK, then the injunction continues to have effect in the UK subject to any order of the court to the contrary.

Registration and Renewal of Expired EUTMs

An EUTM that has expired within 6 months before exit day is to be treated as if it were an existing EUTM. Thus, a comparable trade mark (EU) derived from an EUTM which expired in the 6 months prior to Brexit can be entered onto the UK register but the mark will remain expired unless and until it is renewed. If an expired EUTM is renewed in accordance with Article 53 of the EUTM Regulation (2017/1001) (ie in the 6 months before expiry or the 6 months following expiry) then the UK registrar must renew the comparable trade mark (EU) for a period of 10 years to the same extent as the EUTM is renewed. (eg for the same good and services).

EUTM Applications

If an applicant has filed an application for an EUTM prior to exit day which has not been granted or refused prior to exit day then if the applicant (or his successor in title) files an application for an identical UK mark for some or all of the same goods or services within 9 months from exit day then the UK mark takes its application date or priority date (under Article 32 EUTM Regulation) from that for the equivalent EUTM. If an EUTM application claims seniority from a UK trade mark registration then a UK application which is based on the EUTM application can also claim that seniority, provided that the application for the UK mark is made within 9 months of exit day. The applicant will have to pay the filing fees for the UK trade mark application.

Restoration of EUTM and Applications

If an EUTM is removed from the EU register prior to exit day but is restored to the EUTM register after exit day then the owner of the EUTM may, within 6 months from the date of restoration, file at the UK registry a request that the EUTM is treated as an existing EUTM on exit day and is able to benefit from the provisions relating to comparable trade marks (EU). If an application for an EUTM has been refused before exit day and the application is restored on or after exit day and the applicant (or its successor in title) applies to register a UK trade mark for some or all of the same goods or services, then the application is treated as if the EUTM application was pending on exit day (and so can claim the same right to priority and or seniority as the EUTM) but the 9 month period for filing the UK application is calculated from the date of restoration.

Collective and Certification Marks

When collective marks or certification marks are filed at the EUIPO or the UK IPO then the relevant regulations of use of that collective or certification mark must also be filed. An EU collective mark or an EU certification mark which becomes a comparable trade mark (EU) will be treated as a UK collective mark or a UK certification mark as the case may be. The owner of such a comparable trade mark (EU) must, after notification from the UK registrar, file at the UK registry the regulations of use that had been filed at the EU IPO before exit day (with a translation to English if appropriate). If the regulations of use are not filed then the comparable trade mark (EU) will be removed from the register.

International Trade Marks Protected in the EU

Similar provisions apply to an international trade mark which is protected in the EU (Article 189(2) EUTM Regulation) as they do to EUTMs. Under the Designs and International Trade Marks (Amendment etc.) (EU Exit) Regulations 2019, the UK right is called a comparable trade mark (IR). The comparable trade mark (IR) is deemed to be registered in the UK from the date of registration of the international registration in the EUIPO if the EU was designated in the original international application filed at World Intellectual Property Organisation (**'WIPO'**) or, if a request for extension of the international registration to the EU was made subsequently to WIPO, from the date of the recordal of that request.

Other amendments

Amendments have also been made in relation to: payment of fees, amendments to the 1994 Act by removing references to the EU and amendments to the Trade Mark Rules 2008. Certain legislation is also revoked, including the EU Trade Mark Regulation 2017/1001.

Exhaustion of trade mark rights

IP rights are considered exhausted once they have been put on the market anywhere in the EEA by the rights holder or with its permission. Thus, the rights holder cannot rely on his IP rights to prevent movement of those goods within the EEA. After Brexit, the UK will no longer be part of the EEA and such exhaustion will not automatically apply, although the UK Government has suggested that it might continue to recognise IP rights in goods put on the EEA market as exhausted in the UK post Brexit in order to prevent these rights preventing the free movement of goods into the UK. However, the same is not true of the EU/EEA and it can be expected that rights owners in the EU/EEA will use their IP rights to prevent goods moving into the EEA from the UK.

Goods moving from the EEA to the UK: The UK will continue to recognise the EEA regional exhaustion regime from exit day, as per section 2 of the Intellectual Property (Exhaustion of Rights) (EU Exit) Regulations 2019/265. Goods placed on the market in the EEA after the UK has exited the EU will continue to be considered exhausted in the UK. Entities can continue to import goods into the UK that were first put on the market in the EEA without risk of a rights holder relying on its IP rights to prevent that importation. Thus, parallel imports from the EEA, where the goods have been first marketed by the rights holder or with its consent in the EEA, should be able to continue. This will be particularly relevant for the parallel import of pharmaceuticals from the EEA into the UK. The UK Government guidance initially indicated that the exhaustion of rights position for imports into the UK from the EEA would operate on a transitional basis. However, in the latest guidance there is no reference to a transitional period. It is not clear whether this exhaustion principle will continue into the future and if it does not, when the period would come to an end.

Goods moving from the UK to the EEA: The position in relation to the treatment of goods first put on the market in the UK, which are exported from the UK into the EEA, is not clear. The UK Government guidance states that businesses that wish to export IP-protected goods to the EEA that have already been legitimately put on the market in the UK may need the consent of the rights holder to do so.

The legislation: Section 2(1) of the Intellectual Property (Exhaustion of Rights) (EU Exit) Regulations 2019/265, states that anything which was, immediately before exit day, an enforceable EU right relating to the exhaustion of rights of the owner of an IP right under Arts 34 to 36 of the TFEU or Articles 11 to 13 of the Agreement on the EEA, and is retained EU law by virtue of section 4 of the European Union (Withdrawal) Act 2018, has the same effect on and after exit day, despite the UK not being a member state, as it had immediately before exit day. "Enforceable EU right" includes any right created or arising by or under the Treaties, and all remedies and procedures provided for by or under the Treaties which are given legal effect or are used in the UK without further enactment and such rights are recognised and available in UK domestic law and are enforced, allowed and followed accordingly (section 2(1) of the European Communities Act 1972).

As a result, there are consequential amendments to the relevant IP statutes. For example, section 12 (1) of the Trade Marks Act 1994 will be amended to state that "a registered trade mark is not infringed by the use of the trade mark in relation to goods which have been put on the market in the United Kingdom or the European Economic Area under that trade mark by the proprietor or with his consent". Section 17(3) of the Trade Marks Act 1994 will be amended to state that "nothing in subsection (2) shall be construed as affecting the importation of goods which may lawfully be imported into the United Kingdom by virtue of anything which forms part of retained EU law as a result of section 3 or 4 of the European Union (Withdrawal) Act 2018". Similar amendments will be made to sections 7A(4) and 24G (5) of the Registered Designs Act 1949 and to Sections 18(2) and 27 (5) of the Copyright, Designs and Patents Act 1988 (**'CDPA'**).

Copyright

Brexit-related changes to copyright in the UK are dealt with by the Intellectual Property (Copyright and Related Rights) (Amendment) (EU Exit) Regulations 2019.

Although copyright law is not harmonised across EU, elements introduced through the Information Society Directive and other Directives which are already transposed into UK law will remain valid after exit day unless the UK Government choses to alter the law. Some key issues are that the country of origin principle will not include the UK, which means that separate clearance of rights will be required to broadcast in the UK, UK subscribers will no longer benefit from online content portability and that sui generis database rights will not arise in relation to databases created or owned by non-EEA entities/citizens. The UK Government is keen to negotiate some form of mutual recognition for broadcasting rights and continued portability. Member states have 24 months to implement the Directive on Copyright in the Digital Single Market 15 April 2019.

Copyright- Qualifying test: the EU legislative test to qualify for copyright protection is "author's own intellectual creation" where an element of creativity is required. However, old/current doctrine of UK courts is application of "labour, skill and judgment". The UK test is arguably easier to achieve. Some elements of the "intellectual creation" test are incorporated into UK law already (eg in statute in relation to copyright in databases (s.3A CDPA)) and in case law. There is a debate over which test will apply after exit day.

Sui generis database rights

Sui generis database rights only arise/exist in relation to databases created or owned by EEA entities/citizens under Article 11 Database Directive (confirmed in European Commission notice to stakeholders): "[the sui generis database right] ... "shall apply to database whose makers or right holders are nationals of a member state or who have their habitual residence in the territory of the Community. [...] Where such a company or firm has only its registered office in the territory of the Community, its operations must be genuinely linked on an ongoing basis with the economy of a [member state]."

In the UK Government's no-deal copyright guidance, the guidance for these database rights is that on a no-deal basis, only UK persons will be able to obtain new sui generis database rights in the UK. However, sui generis rights of EEA persons already in existence will remain recognised in the UK. On exit day, there will be no obligation for EEA states to provide database rights to UK nationals, residents, and businesses and UK owners of UK database rights may find that their rights are unenforceable in the EEA. In this regard, the UK Government has recommended that UK rights owners consider relying on other forms of protection, such as restrictive licensing agreements or copyright (where applicable), for their databases.

Geographical indications

Due to the nature of geographical indications (**'GIs'**), it is understandable that continuity of rights will be difficult to establish. The Government has published guidance stating

that on exit day, a new GI scheme will be introduced that will "broadly mirror the current EU regime and be no more burdensome to producers". Three new UK schemes, overseen by the Department for Environment, Food, and Rural Affairs, will be put in place, namely the Protected Designation of Origin (PDO), Protected Geographical Indication (PGI), and Traditional Specialties Guaranteed (TSG).

The issue more broadly is one of recognition. While current UK GIs would be automatically protected in the UK on exit day, producers of EU GIs will have to apply for protection under the new UK GI system. Additionally, although it is anticipated that current UK GIs will still be protected by the EU's GI schemes, the Government has admitted that "it is possible that the EU may not continue to protect UK GI products". The exception is with GIs produced anywhere on the entire island of Ireland. These will continue to be protected both in the UK and the EU, and include products such as Irish whiskey, Irish cream, or poteen.

If a UK producer wants to apply for an EU GI, then it will have to do so as a third country producer. This requires completion of the current application process, and additionally proving that the GI is protected in the UK. The UK Government's note indicated that it would assist with this. Alternatively, producers could take other steps such as applying for trade mark protection. It is important to note that there is currently no SI that covers GIs, and so it is crucial for producers to be alert to any new guidance issued by the Government.

Designs

Changes to the design regime in the UK necessitated by Brexit are covered by the Designs and International Trade Marks (Amendment etc.) (EU Exit) Regulations 2019 (2019/638). Below we set out the impact of exit day on both Registered Community Designs (**'RCDs'**) and Unregistered Community Designs (**'UCDs'**).

Registered Community Designs

If a design is registered on the RCD register, and published in the Community Design Bulletin before exit day, it will be treated as a UK registered design. It will be automatically entered on the UK register at no cost, and denominated a "re-registered design". The priority date and any other assessment dates will remain the same. The same applies to designs registered for the EU under the Hague System, although these will be denominated "re-registered international design" instead. The Hague System for the International Registration of Industrial Designs will remain open for UK businesses to access, as the UK has already ratified this agreement in its own right.

Just as with trade marks, design owners can opt out, at any time from exit day onwards, from the automatic conversion of its design rights. However, if the application for a design right is pending on exit day despite having a filing date, the rights holder will have to re-file its application at the UKIPO as a UK application within 9 months from the day after exit day. The new application will then be given the same filing date as the RCD application. The same applies if the RCD application is deferred.

Unregistered Community Designs

Like RCDs, UCDs created before the end of the transition period will automatically continue to have the benefit of a UK right post-Brexit, having the same level of protection in the UK as UCDs would have. These will be called "continuing community unregistered designs". This right will expire on the same day as it expires in the EU27, meaning that the last rights that are created will expire three years from exit day.

A new right, the "supplementary unregistered design" will fill the gap left by the unregistered community design right. It is important to note that a UK unregistered design is not exactly the same, hence the need for this new right. This new right will protect designs where they are disclosed in the United Kingdom or countries or territories that are designated by statutory instrument under powers inserted into the EU Design Regulation.

.eu Domain names

The registry for .eu domains (EURid) has published a notice setting out what will happen after Brexit to .eu domain names registered with the GB (Great Britain) or GI (Gibraltar) country code. Due to Article 20 of Regulation 2019/517 coming into force on 19 October 2019 (prior to Brexit), the following persons will be eligible to register .eu domain names:

- a Union citizen, independently of their place of residence;
- a natural person who is not a Union citizen and who is a resident of a Member State;
- an undertaking that is established in the Union; or
- an organisation that is established in the Union, without prejudice to the application of national law.

This presents problems for many domain name holders in light of Brexit, regardless of whether that is under the WA or under a no-deal scenario. The following measures will be enforced by EURid in relation to those .eu domain names with GB or GI as the registrant's residence code:

- **New registrations**: From 1 November 2019, EURid will not allow the registration of any new domain name with GB or GI as the residence code, unless the registrant's citizenship country code is an EU27 member state.
- **.eu domain names with GB or GI as the registrant's residence country code on exit day**: GB and GI registrants will receive communications on both 24 October 2019 and 1 November 2019 of their non-compliance with the .eu regulatory framework. They will be given the opportunity until 1 January 2020 to comply with the framework – EURid's notice contains examples of actions which can be taken by GB and GI registrants. On 1 January 2020, those who do not demonstrate compliance with the .eu regulatory framework will be deemed ineligible to hold a .eu domain name and their domain name will be withdrawn.
- **.eu domain names with GB or GI as the registrant country code on WHOIS but are on hold on exit day**: if there is a legal court case pending, these domain names will remain unregistered until judgment. As of 1 January 2020, however, they will be suspended and cease to function. The rules mentioned above in relation to the registrant's residence country code apply to these domain names as well, with the difference that EURid will withdraw the domain name as soon as practicable after having received a final court decision.
- **.eu domain names with GB or GI as the registrant country code on WHOIS but in quarantine status on exit day**: no transfers from quarantine will be possible between 1 November 2019 and 1 January 2020, unless the registrant has a citizen country code of an EU27 member state. Transfer to a registrant not in GB or GI will remain possible.

For any EU citizens which have a registered domain name, they will have to ensure that their registration data is updated to comply with the eligibility criteria of Article 20 of Regulation 2019/517. Similarly, any UK citizens that are resident in an EU27 member state will remain eligible for an .eu domain name on the basis of the Article 20 criteria. It is therefore crucial for domain name holders to act quickly and resolutely to ensure that their domains are not withdrawn from the register.

Patents

European patents and UK national patents

UK designated European patents (**'EPs'**) will continue to apply in the UK and will still be able to be applied for at the European Patent Office. UK entities will be able to apply for European patents as normal for any designations. Nationally granted UK patents will also be available.

The UPC

The main impact on patent litigation will be on the establishment of the Unified Patent Court (**'UPC'**) and whether the UK can continue to be part of this new patent litigation system for European patents and the new unitary patent (**'UP'**), post-Brexit. The UK has now ratified the UPC Agreement so all that is needed for the new system to commence is for Germany to ratify also. Germany's ratification has been delayed by a complaint about the UPC Agreement in the German Constitutional Court.

Opinions vary on whether the UK could continue as part of the UPC system once it is no longer an EU member state, but this is largely dependent on whether the Court of Justice of the EU (**'CJEU'**) would accept a non-EU state's involvement and whether the UK would accept the role of the CJEU in relation to references from the UPC on EU law matters.

Pan-European enforcement post-Brexit

Even if the UK is not in the EU (and not in the UPC system), UK businesses with European patents designated to participating EU member states will still be able to use the new UPC system (unless they have chosen to opt these patents out of its jurisdiction), and will of course be able to apply for UPs – although the latter will not cover the non-participating States (Spain, Croatia & Poland), nor any non-EU European Patent Convention States (eg Turkey, Switzerland, Norway), for which European patents will still be available but which will all need to be litigated nationally as they will be outside the jurisdiction of the UPC.

The UPC has advantages (central enforcement) and disadvantages (central revocation) for patentees and their competitors alike. Assuming that the UPC does go live, UK businesses with UPs and EPs will still be able to use the UPC for enforcement in other EU participating countries, whether the UK is in or out of the EU. However given concerns about how the UPC will operate in the early years and the quality of the early decisions made by it, some patent proprietors will choose to opt-out their European patents from the UPC system. As a result, business is still likely to pursue litigation in countries across Europe (including the UK) outside of the UPC system.

See the jurisdiction and opt-out page of our UPC and UP hub on our website for more information on the UPC and our article on considerations for opt-out published in Managing IP Magazine, as well as our PLC Magazine article on preparing your patent portfolio for the advent of the UPC and the UP which are also listed on our UPC and UP hub.

Pan-European enforcement strategies will remain important post-Brexit and post the introduction of the UPC. Indeed, current or future pan-European patent litigation strategy will still involve multiple courts and supranational management of disputes, whether or not the UPC goes ahead and with or without the UK's participation given that Spanish, Polish and Croatian designated European patents will also be outside the UPC's jurisdiction, and UPs will not have effect in these jurisdictions. Further, nationally granted patents will continue to be litigated locally.

Thus it will still be critical to have advisers who are expert in handling multiple cross-border disputes and managing local lawyers in jurisdictions within Europe or beyond.

Unitary patents

Once the UPC is established, applications for UPs will be able to be made via the EPO system (a designation of unitary effect will be able to be requested at the time of grant). Should the new system be established before the UK has left the EU or whilst it is still effectively part of the EU legal systems through some transitional arrangement, the unitary patents will cover the UK during that period. However once any Brexit transition period is over (or at Brexit if no transition agreement is in place) any granted UPs will no longer apply to the UK. In such circumstances it is likely that the UK Government would provide some sort of replacement right, as is planned currently under the draft WA for the other registered rights (see above).

There is no provision made in the WA for creating equivalent rights to replace UP rights should the UPC come into effect (and UPs therefore become available) prior to the end of the Brexit transition period, which is December 2020 under the current WA, although an extension may be granted. The UPC itself needs to be in place before UPs can be granted. It seems that UPs were not included in the WA as it was far from clear that the new patent system would be up and running before the end of the transition period since, for instance, the German ratification of the UPC Agreement being dependent on both constitutional court and parliamentary decisions.

The EMA

With the UK poised to leave the EU, the European Medicines Agency (**'EMA'**) moved from London to Amsterdam in early March 2019. However, it is crucial that the UK and the rest of the EU remain in step in terms of the ability to get pharmaceutical and medicinal products to market efficiently in both jurisdictions post-Brexit, whilst relying upon common clinical study data, as well as monitoring patient safety. The Medicines and Healthcare products Regulatory Agency (**'MHRA'**) will take many of the regulatory responsibilities in the UK currently dealt with by the EMA, and the MHRA has committed itself to maintaining a good relationship with the relocated EMA (see below).

Supplementary Protection Certificates

Supplementary Protection Certificates (**'SPCs'**) are UK national rights granted by the Intellectual Property Office (**'IPO'**) under rules determined by an EU Regulation. The WA will have the effect that all EU law applying to the UK at the day before Brexit will remain as UK law going forward unless and until this is changed by the Government or Parliament. This will mean that SPCs on UK designated patents can continue and can be granted by the IPO post-Brexit, although transitional arrangements are expected.

Post-Brexit or on a no-deal scenario, the UK will be able to award SPCs on the same or some other basis as under the, by then, parallel EU system. However, the SPC application must relate to a patent valid in the UK and a Marketing Authorisation (**'MA'**) which allows products to be sold in the UK. The WA sets out a provision for dealing with pending applications for SPCs in the United Kingdom, stating that Regulation (EC) No 1610/96 of the European Parliament and of the Council and Regulation (EC) No 469/2009 of the European Parliament and of the Council shall apply in respect of applications for SPCs for plant protection products, for medicinal products, or applications for the extension of the duration of such certificates, submitted to an authority in the United Kingdom before the end of the transition period where the administrative procedure for the grant of the certificate concerned or of the extension of its duration was ongoing at the end of the transition period" and that any certificate granted pursuant to this "shall provide for the same level of protection as that provided for in Regulation (EC) No 1610/96 or Regulation (EC) No 469/2009".

With regards to the six-month paediatric extensions granted by EU Regulation 1901/2006, the availability of this extension will be dependent on equivalent provisions being introduced into UK law.

The extension application process will remain broadly the same, and the requirements will be the same. The key difference will be that the SPC holder will not need to provide MA evidence across different EEA states. If an extension has already been granted at the IPO or the application is pending, the existing requirement of showing MAs in all relevant EEA states will be needed.

There has been no provision made under the Unitary Patent Regulation (1257/2012) for 'unitary SPCs', nor under the UPC Agreement. It appears that SPCs on unitary patents will therefore need to be obtained through separate applications in each country for which protection is required (as currently for EPs). The Patents Regulation will however follow the jurisdiction of the UPC over SPCs if that ever falls into place in the future.

However any assessment of the validity of an SPC (on either an EP or a UP) will be made by the UPC unless the EP involved has been opted out. It is possible that there may be some sort of unitary SPC available in the future but this would require a central administrative body and further legislation and so is unlikely to be in place if the UK exits, with no deal, nor even shortly before the end of the Brexit transition period if there is one.

Licensing

Although there is provision in the WA for the EU to be 'understood' as including the UK in any interpretation of EU law during the transition period, the same does not directly apply to individual contractual and other arrangements and nothing is agreed as to how to approach this post-Brexit. The effect of the territory of a licence being specified as the 'EU' or whether a licence of EU-wide right covers the replacement right in the UK post-transition, will be a matter of contractual interpretation. For clarity, those who license (in or out) EU-wide IP rights or have the EU as a designated territory in any agreement where the UK is a key territory, should take every opportunity to ensure that all parties are in agreement as to what this means during the transition period and importantly beyond. New agreements should provide specifically for the effect of Brexit.

Pharmaceutical sector provisions

Whilst the WA sets out a transitional period during which the status quo would prevail, for those involved in the supply of medicines to UK markets, there is little else in it to confirm the post-Brexit position for the pharmaceutical sector.

The WA does deal with marketing authorisations however, which are referred to under Art 45 as "making available of information in relation to past authorisation procedures for medicinal products". The WA provides that the UK should provide marketing authorisation dossiers to the EMA without delay, "upon reasoned request", on medicinal products which have been authorised by the UK before the end of the transition period, where that dossier is necessary for the EMA's assessment of a marketing authorisation application. There is provision for supply to the UK of such dossiers on medicinal products authorised before the end of transition for the purpose of the UK assessing marketing authorisation applications, but only to the extent that the UK's legislative requirements replicate the circumstances set out in relevant the EU Directives.

The WA does not make provision for patents or the UPC, nor for pharmaceutical regulatory issues. However, following repeated non-binding indicative Commons votes against a no-deal Brexit scenario, the WA being voted down for a third time on 29 March 2019, and Theresa May's announcement that she would resign as Prime Minister, there is a real risk that the UK will leave the EU without a deal. In that light, the Government and its regulatory agencies have published the guidance below for what happens on exit day, ie, after a transition period or on a no-deal Brexit scenario.

Regulation of medicines and clinical trials

Medicines

Market Authorisations ('MA'): Most human medicines on the UK market have a UK MA obtained via the national, decentralised (**'DCP'**) or mutual recognition (**'MRP'**) routes, however a subset including most novel medicines and biosimilars, and some generics, come to market via the centralised MA route. Any existing centralised MA granted by the EMA will automatically (without a fee) convert to a UK MA on exit day (called "grandfathering"), subject to the possibility of the MA holder opting out of having a UK MA. However, to support the ongoing regulation of these converted EU MAs, the MHRA requires certain "baseline data" to be submitted by the MA holders within a year of Brexit.

Current MAs: A difficult issue is what happens to granted MAs and MA applications for generic or biosimilar medicines which are based on the data from a Reference Medicinal Product (**'RMP'**), where that RMP does not have a UK MA. In this situation, the underlying data for the RMP held by the EMA or relevant authority of a non-UK reference member state will no longer be available to the MHRA after exit day.

The MHRA guidance confirms that granted MAs for generic products which are based on a RMP authorised in the EU would remain valid after Brexit. However, eligible RMPs for new UK MA applications are only those which have a granted UK MA, including those converted to UK MAs upon Brexit, or which had a centralised MA pre Brexit but where the MA holder opted out of the conversion to a UK MA (all subject to regulatory exclusivity). Therefore, where there is no eligible RMP for the UK, generic and biosimilar companies will need to file a complete set of regulatory data to the MHRA to obtain a UK MA.

Pending MA applications: There is guidance from the MHRA on how MA applications filed via the centralised, MRP or DCP routes which are pending on exit day will be treated. With regards to pending centralised MA applications, the MHRA does not hold supporting data for applications made to the EMA, so applicants will need to submit an application and supporting dossier to the MHRA. Procedures that have been completed with a positive opinion from the EMA's Committee for Medicinal Products for Human Use (**'CHMP'**) and are awaiting a European Commission decision will be determined "as soon as practicable" by the MHRA; in other cases, the MHRA will need to make an assessment, the timetable of which will vary depending on the stage the EMA assessment has reached.

For pending DCP or MRP applications, where the process is in the final 30 day national phase, the procedure for UK grant will continue as normal. Where applications have not reached this decision phase on exit day, the MHRA will take over the UK assessment under the national procedure. Where the UK is a concerned member state (**'CMS'**) (rather than a reference member state (**'RMS'**)), given the MHRA will not have access to the data, there is likely to be delay to the process. Where the UK is the RMS, there may be delay to the remaining (non-UK) applications to enable a new RMS to be allocated.

MHRA assessment routes: The MHRA has also issued guidance on three new routes of assessment of UK MA applications. The first is the "Targeted assessment process" for granting UK equivalents to pending centralised MAs where there is a positive assessment from the CHMP already published. The other two are for new UK MA applications (commencing post-Brexit). The "Accelerated Assessment pathway" is aimed at products containing new active substances, including biologics, for which the MHRA will reach its opinion on approvability within 150 days. The "Rolling Review route" is a new route with details yet to be finalised, but the concept is that the MA applicant would submit data in an iterative, ongoing process as it becomes available, linked to modular assessment, with a final assessment in a single phase following submission of the last module (and any updated previous modules).

The centralised procedure for UK-based applicants: What of granted, pending and future applications for centralised MAs by UK-based applicants? The EMA has published a Q&A on the functioning of the centralised procedure post a no-deal Brexit. It states that for granted or pending centralised MAs, UK MA holders/applicants should transfer their MA/application to an entity established in the EEA before Brexit. Granted centralised MAs that relied on an RMP with a UK MA will remain valid after Brexit; in future such MA applications should rely on an RMP authorised in the EEA.

Timeline and packaging: There are two main action points for MA Holders following exit day – one concerns the storage of medicines for contingency purposes, and the other concerns the MA Holders' pharmacovigilance systems.

The storage of medicines for contingency purposes is covered by the Medicines Supply Contingency Programme (**'MSCP'**). The Department of Health and Social Care (**'DHSC'**) has identified pharmaceutical products imported from the EU and EEA that may be vulnerable to a no-deal Brexit, and populated the MSCP with these products. The DHSC is working with stakeholders to ensure that the UK has an additional 6 weeks' supply of medicines in case import routes from the EU and EEA are affected.

MA holders have been notified by email of the process by which they will have to store 6 weeks' supply of medicines. MA holders have been sent a password-protected response template pre-populated with those medicines that the DHSC considers to be within the scope of the MSCP, and the stakeholder's preparedness to stockpile and re-route these products. The MSCP will ensure that patients needing vital treatment imported from the EU/EEA will not be put at a major disadvantage if there is a no-deal Brexit scenario on 31 October 2019, or following any extension.

The other important action point for UK MA Holders, including those with 'grandfathered' MAs after exit day, is the need to have an appropriately qualified person responsible for pharmacovigilance (**'UK QPPV'**) and a UK pharmacovigilance system master file (**'UK PSMF'**). The UK QPPV should reside and operate in the UK. This is specified in the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 at regulation 182(2). The UK QPPV is responsible for establishing and maintaining the MA Holder's pharmacovigilance system for UK authorised products. For those MA holders with grandfathered MAs, there is a temporary 21-month exemption from regulation 182(2) under which EU/EEA MA Holders can find a UK QPPV for their UK authorised products.

MA Holders will also have to maintain and make available upon request a UK PSMF to describe its pharmacovigiliance system in the UK. The UK PSMF must be kept electronically or physically by the MA Holder, and be registered with the MHRA.

All UK MAs, including those that go through the 'grandfathering' process, must include a summary of the holder's pharmacovigilance system. Any applications to update the summary of pharmacovigilance system (**'SPS'**) in the MA should be made via MHRA Submissions (see our guidance on this below).

Additionally, for any MA holders who have been issued a grandfathered UK MA, as per the process outlined above, within 21 months of being issued the grandfathered UK MA, the MA holder will have to establish and register a UK presence for its MA. This means submitting to the MHRA the name and address of the MA holder or representative; the UK number for the MA; and the name and address of the product manufacturer from the batch release. After that, within 33 months of being issued the UK MA, all stock released to the market must be in compliant packaging.

Any changes that MA holders want to make to the below after the transition period or a no-deal Brexit will require the following action:

- **Changes to labelling or patient information leaflet ('PIL')**: MA Holder should submit full colour mock-up as part of variation submission.
- **Changes to name and address of MA holder and/or manufacturer for batch release**: MA Holders will need to submit notification under the 'Better Regulation of Medicines Initiative' basis (program running since 2014).
- **Changes to statutory information or pack design**: if it is not consequential to a change in Summary of Product Characteristics (**'SmPC'**), the MA holder will need to submit artwork for full assessment to Product Information Quality Units.

- **Multi-language packs**: the MHRA will continue to allow these, provided that the entirety of information is UK-compliant.

Batch Testing Medicines and Vaccines and Blood Products

The MHRA's general policy on this point is to ensure that products only need to undergo one approval process for batch testing. There are two main issues relevant to note:

- **Leaving the EMA**: the UK Government has said that in the event of no deal it would continue to accept batch testing of human medicines carried out in certain countries (yet to be named by the MHRA but to include at least initially EU and EEA countries and third countries with which the EU has a mutual recognition agreement). The UK will also continue to accept batch testing of substances in medical trials (**'IMPs'**) manufactured in the EU and EEA states.
- **Requirement to have a Qualified Person**: for human medicines and IMPs, those manufactured in the UK (or a third country and imported direct into the UK) would still require a UK-based qualified person (**'QP'**) to certify batches and ensure compliance with MA and good manufacturing practice (**'GMP'**) guidance. Where manufacture occurs in a third country, but importation is from certain countries (yet to be identified by the MHRA, but to include initially EU and EEA countries), certification, release and assurance of compliance with MA and GMP guidelines will be recognised, if conducted by a QP based in that listed country, without the need for further certification. There would be at least 2 years notice for any changes to this arrangement.

With regards to vaccine and blood products, once the UK leaves the EU, MA holders will no longer be able to benefit from mutual recognition of batch certificates and release from another Official Medicines Control Laboratory (**'OMCL'**). The OMCL in the UK is the National Institute for Biological Standards and Control (**'NIBSC'**). After exit day, in the UK, before placing a batch of vaccine or blood products into the market, in addition to batch testing by the NIBSC, the MHRA must be notified using the Market Information Form.

In a no-deal scenario, the NIBSC will the stand-alone National Control Laboratory, and certification before a batch of biological medicines is placed on the market will be required from the NIBSC. However, to ease transition, if a batch has an EU-equivalent certificate or a certificate from a country with whom the UK has a mutual recognition agreement, it will not need NIBSC certification. In any case, the MA Holder will have to send samples, documentation, and all protocols for batches to be marketed, and the NIBSC will decide whether it will need to undertake full testing or whether it can rely on the equivalent certificate provided.

Clinical trials

The general message is that arrangements will be made with the aim of minimising the disruption to clinical trials. The UK will also seek to "align where possible" with the EU Clinical Trials Regulation when it comes into force.

As above, once the UK leaves the EU, it will also cease to participate in the European regulatory network for clinical trials, and regulatory responsibilities would shift to the MHRA. Any existing approvals for clinical trials (both regulatory and ethics) will be recognised after exit day without the need to re-apply. Consultation undertaken on the basis of a no-deal scenario proposed the introduction of a UK contact point for the trial sponsor, but industry stakeholders considered that contacting any relevant sponsor or investigator in the UK would be acceptable. Where trials are pan-European, sponsors or legal representatives must however be based in the EU.

Transparency provisions will be aligned with those currently operating in the EU to eliminate any need for companies to duplicate disclosure efforts. In this regard, the MHRA Website and UK Clinical Trials Gateway will continue to serve as the repositories for any trial information for the public, patients, researchers, and clinicians. Additionally, there are new EU Clinial Trials Regulations (536/2014) that will come into force after Brexit, but the Government's guidance is to align where possible and as soon as possible with these Regulations subject to parliamentary approvals.

Orphan medicines

The Government's policy on orphan drug designation, which is given during development and re-assessed at MA grant stage, is to ease the transition for any orphan drugs on the central EU authorisation system. The orphan criteria will remain similar, but UK-specifics will be incorporated to reflect the fact that the UK has left the EU. Designation criteria is crucial for stakeholders, as orphan drug designation is assessed both during development and at MA grant stage. At that point, it is then reassessed. It may therefore be the case that the holder of a European orphan drug designation facing reassessment may need to meet the UK-only criteria. The criteria will be based on:

- prevalence of the rare disease in the UK – not more than 5 in 10,000;
- availability of satisfactory alternative treatment methods in the UK; and
- significant benefit of the product for the treatment, prevention or diagnosis of a life-threatening or chronically debilitating disease.

A drug successfully designated as an orphan drug will benefit from a 10-year data exclusivity period equivalent to that currently enjoyed at the centralised EU level. However, the Government will review this within two years following exit day to ensure that the UK orphan drug market remains competitive. For those products that have a running data exclusivity period at the EU level, exclusivity will continue to apply in the UK automatically post-Brexit.

Medical devices

As with MAs, if the UK leaves the EU without a deal, the UK would cease participating in the European regulatory network for medical devices, and the MHRA would take on sole responsibility for the UK market. Essentially, the Government's guidance attempts to ensure that the transition under a no-deal Brexit will be as smooth as possible.

Any medical devices or in-vitro devices (**'IVD'**) placed on the UK market must be registered with the MHRA. In turn, the MHRA will only register manufacturers with a registered place of business in the UK. For non-UK manufacturers, they will have to have a UK Responsible Person (see below) registering their device at the MHRA. According to the guidance, the MHRA is aware of the potentially high volume of applications, and will have a corresponding grace period to ensure that manufacturers comply with registration processes.

This includes a new role, known as a UK Responsible Person, for non-UK manufacturers to allow them to carry out tasks in relation to the manufacturers' obligations regarding their medical devices. This includes registering with the MHRA prior to placing the device on the market, and other responsibilities such as classifying the device, meeting safety and performance requirements, meeting increased clinical evidence requirements, and meeting vigilance reporting timescales.

Provisions for Medicine Suppliers, Importers, and Exporters

Provisions for Suppliers

The Government's primary aim is to ensure that medicines can be imported into and exported out of the country on exit day. Although such contingency plans were put in place by stakeholders prior to 29 March 2019, the updated guidance looking towards the Brexit date of 31 October 2019, assuming there is no further Article 50 extension, affords more flexibility to stakeholders than before. The guidance stresses that no-deal preparedness plans should concern the ability to re-route freight, stockpile medicines, and meet new customs and border requirements. The Government will be contacting suppliers to seek assurances with regards to these.

The Government will be supporting stakeholders accordingly with their contingency plans. The key message is that the approach is for the pharmaceutical sector and the public sector to work together to ensure the continuity of the supply of medicines to the UK. The support mechanisms include, but are not limited to:

- Government-sponsored 'Express Freight Services' to provide a solution to those products that cannot be re-routed by way of a 24-hour small consignment delivery or two-to-four-day pallet delivery service; and
- setting up a National Supply and Disruption Response (**'NSDR'**) unit within the DHSC.

Provisions for Importers and Exporters

With regards to Certificates of Pharmaceutical Products (**'CPP'**) issued for exporters (licensed or unlicensed), the MHRA will be able to issue a CPP for any grandfathered centrally authorised product (see above for the grandfathering process) on existing timescales. However, if a CPP is being sought for the first time relating to a grandfathered product, only the normal service of 10 days will be available. The 2-day expedited service will not be available. Mandatory baseline data must be submitted two days prior to the CPP request, and CPP applicants should email the MHRA Certificates team when the application is the first relating to a grandfathered product.

Additionally, exporters, and importers alike, will need a UK Economic Operator Registration and Identification (**'EORI'**) number starting with GB in order to trade in and out of the UK. Government guidance notes that it may take up to three days to obtain an EORI, so applicants should factor in this time-period well before exit day.

Certain products, known as drug precursor chemicals due to their nature of being used to produce illicit drugs are controlled by the Home Office. The Home Office has a list so that companies can verify whether their product would fall under this regime. If the relevant products are drug precursor chemicals, no changes will impact existing licensing and registration requirements if handling these solely within the UK or trading with non-EU countries. If trading with EU countries, importers and exporters should consider applying for a domestic licence or registration. It takes approximately 12 to 16 weeks to process the licence and ensure that any entities named on the licence are checked by the Disclosure and Barring Service (**'DBS'**).

Submitting regulatory information on medicinal products

The MHRA is making adequate preparations to ensure that if there is a no-deal scenario, regulatory and notification information can be easily submitted. There are two new sites that have been devised by the MHRA to ensure a smooth transition in submitting information:

- **MHRA Submissions:** this will be accessed by all pharmaceutical companies making regulatory submissions, medicine clinical trial sponsors, e-cigarette producers, and brokers of medical products.
- **MHRA Gateway:** for any users wishing to submit Individual Case Study Reports (**'ICSRs'**) and Suspected Unexpected Serious Adverse Reactions (**'SUSARs'**). A user must be registered for MHRA Submissions first before registering for MHRA Gateway.

There is detailed guidance from the Government on how companies can gain access to MHRA Submissions, including three helpful videos on user registration, addition of a new user, and addition of an external user. There are also two reference guides that cover "Gaining Access to MHRA Submissions" and "Managing users on MHRA Submissions". To ensure access to MHRA Submissions from exit day, companies can begin the process for gaining access to the site by an initial company administrator. This person can then, following the videos/guides above, provide access to both internal and external colleagues. There are also video demos and reference guides for submissions to MHRA Gateway.

Horizon 2020 funding

If there is no deal, the Government says it has taken steps to provide continued support for research and innovation currently being funded through this EU project fund. The Government will guarantee funding in most cases relating to successful bids submitted by UK participants before the UK exits the EU, for the full duration of the project. Funding will only be for UK participants however. Where UK participants are leading consortia of non-UK parties and would normally be distributing the Horizon 2020 funds, the Government will seek to discuss with the EU Commission how best to address this. Also for discussion is the impact of any change in status of the UK from a member state to a third country on compliance issues with Horizon 2020 rules. The UK Government's guarantee additionally covers funding for successful bids, where UK organisations are able to participate as a third country in competitive EU grant programmes. This extension runs from exit day until the end of 2020. Third country participation does not extend to some Horizon 2020 funding, including European Research Council (**'ERC'**) grants, some Marie Sklodowska-Curie Actions and the SME instrument.

The Government is considering what other measures may be necessary to support UK research and innovation in the event that the guarantee and the extension are required.

Looking beyond 2020, the UK remains committed to ongoing collaboration in research and innovation and wants to work with the EU on a mutually beneficial outcome.

Actions for businesses and other stakeholders: UK Research & Innovation will be developing systems to ensure payments to beneficiaries of Horizon 2020 funding can continue. Current UK recipients of Horizon 2020 funding will soon be invited to provide initial data about project(s) on a portal hosted on GOV.UK. The guidance states that the portal will remain open after the UK leaves the EU, so that UK applicants can continue to register, as and when, they are informed that their bid has been successful. More information on the portal is available on the UKRI webpage.

The Withdrawal Agreement

There is still a chance, however small, that the WA will be approved by Parliament before exit day. With a change of prime minister and, as a result, possibly government policy, some parts of the WA may be re-negotiated with the EU. However, it appears unlikely that the IP provisions in the WA would change substantially. In this light, we set out below a summary of the provisions in the WA on intellectual property. The basic premise is that EU-wide rights will be replaced or recognised in the UK and provision has been made for pending applications, including for SPCs. The terms agreed in the WA reflect the position set out by the Brexit SIs; it is simply, as previously stated, that these would come into effect after a transition or implementation period if there were a WA on these terms. Additional provisions compensate for the key differences between the Brexit SIs and the WA. These include provisions for the protection of Geographical Indications (and similar rights), and the sharing of information for assessment of marketing authorisations between the MHRA and the EMA and vice versa, which would not be covered by the Brexit SIs but would apply additionally if the WA were in place.

The WA provides for an implementation/transition period from the date the UK leaves the EU (31 October 2019) to end of 31 December 2020, unless the transition period is re-negotiated or extended. If the WA is agreed, this transition period will mean that effectively the UK will continue to be treated as part of the EU from a legislative point of view. As the Commission's press release puts it, "During this period, the entire Union acquis will continue to apply to and in the UK as if it were a member state". IP registrations and enforcement will carry on as normal during this period. Until the end of the transition period you will still be able to acquire/register and maintain EU-wide IP rights that will have effect in the UK. See the detail in our summary section below. However, "as of the withdrawal date (ie including during the transition period), the UK, having left the EU, will no longer be part of EU decision-making. It will no longer be represented in the EU institutions, agencies and bodies, and persons appointed, nominated, or representing the UK, and persons elected in the UK, will no longer take part in the EU institutions, agencies, and bodies".

The accompanying political agreement document "Outline of the political declaration setting out the framework for the future relationship between the European Union and the United Kingdom" (currently a summary version, with a fuller version to follow) looks to the future relationship between the UK and the EU post-transition. There is mention of IP in the section on Economic Partnership, but all that is said is: "Protection and enforcement of intellectual property rights beyond multilateral treaties to stimulate innovation, creativity and economic activity". Under 'Basis for cooperation', the political agreement states that "Terms for the United Kingdom's participation in Union programmes, subject to the conditions set out in the corresponding Union instruments, such as in science and innovation, culture and education, development, defence capabilities, civil protection and space". There is also mention of "Cooperation in matters of health security". For more on the impact of no deal on the pharma industry see below and articles in our Patent & Pharma Updates on the UK Government's "no deal technical notices".

Summary of the WA's provision for IP and marketing authorisations

IP is dealt with under Title IV in Articles 54 to 61 – pages 89-103 of the 585 page WA. Most of this draft is the same as was previously agreed in the draft in March/June 2018 and as set out in the UK Government's no deal technical notices released in September 2018 (see our IP blog post on these here). Replacement of EU trade marks, Community registered and unregistered design rights and Community plant variety rights in the UK are covered, along with database protection and provision for geographical indication recognition. There is no mention of the UPC or unitary patents nor any specific provisions on pharmaceutical regulatory arrangements other than on marketing authorisations (see below). Pending applications for SPCs are covered (as in previous drafts).

1. The holder of any of the following intellectual property rights which have been registered or granted before the end of the transition period shall, without any re-examination, become the holder of a comparable registered and enforceable intellectual property right in the United Kingdom under the law of the United Kingdom (Art 54.1):
    - An **EU trade mark** (EUTM) holder shall become the holder of a UKTM for same sign for the same goods or services
    - A **Community registered design** (CRD) holder shall become the holder of a registered design right in the United Kingdom for the same design
    - A **Community plant variety right** (CPVR) holder shall become the holder of a plant variety right in the United Kingdom for the same plant variety
2. **Invalidity proceedings:** If one of these rights above is declared invalid or revoked, or, in the case of a CPVR, is declared null and void or is cancelled, in the EU as the result of an administrative or judicial procedure which was ongoing on the last day of the transition period, the corresponding right in the UK shall also be declared invalid or revoked, or declared null and void, or be cancelled (as of the same date). The UK will not be obliged to declare invalid or to revoke the corresponding right in the UK where the grounds for the invalidity or revocation of the EUTM or CRD do not apply in the UK. (Art 54.3)
3. **Renewal:** The first renewal date will be the renewal date of the corresponding intellectual property right registered in accordance with Union law. (Art 54.4)
4. **Filing dates, priority, seniority, revocation for non-use and reputation (TMs):** The replacement UKTM will have the date of filing or the date of priority of the EUTM and where appropriate seniority. The new UKTM will not be liable for revocation on the ground that the corresponding EUTM had not been put into genuine use in the territory of the United Kingdom before the end of the transition period. It will be possible to use reputation in the EU acquired by the end of the transition period as reputation as required under s.10(3) TMA; thereafter reputation will be based on use of the mark in the UK. (Art 54.5)
5. **Term, date of filing/priority (CRDs and CVPRs):** For replacements for CRDs and CPVRs, the term of protection under UK law will be at least equal to the remaining period of protection under EU law of the corresponding EU right, and the date of filing or date of priority will be that of the corresponding EU right. (Art 54.6)
6. **Fees, administration, surrender:** There will be no fees charged for the replacement rights. It will all be carried out free of charge by the relevant entities in the United Kingdom, using the data available in the registries of the European Union Intellectual Property Office, the Community Plant Variety Office and the European Commission. Holders will not be required to introduce an application or to undertake any particular administrative procedure and no correspondence

address in the UK will be required for 3 years after the end of the transition period. Renewal fees will be charged, however. Holders wishing to surrender their rights will be able to do so "in accordance with the relevant procedure" under UK law.

7. **International registrations (TMs and Designs):** The WA says that the UK will take measures to ensure that protection obtained before the end of the transition period for internationally registered trade marks or designs designating the EU under the Madrid system for the international registration of marks, or the Hague system for the international deposit of industrial designs, will have protection in the UK for their trade marks or industrial designs in respect of those international registrations. (Art 56)
8. **Applications and rights of priority (TMs and plant variety rights (PVR)):** For applications that are pending at the end of the transition period, there will be a 9 month period within which an application (for the same mark and goods/services, or same PVR) can be filed in the UK and will be given the same filing and priority date as the EU or Community right (and where appropriate seniority) which they replace in the UK. (Art 59)
9. **Geographical Indications, designation of origin, traditional speciality guaranteed, traditional terms for wine:** Where these are protected in the EU on the last day of the transition period, those persons who are entitled to use the geographical indication, the designation of origin, the traditional speciality guaranteed or the traditional term for wine concerned shall be entitled, as from the end of the transition period, without any re-examination, to use them in the UK, and will be granted at least the same level of protection under UK law as under the specific provisions of EU law. Where any of these cease to have protection in the EU after the transition period their protection in the UK shall cease also. Protection will not be given in the UK to such protections which are derived from international agreement to which the Union is party. (Art 54.2)
10. **Unregistered Community designs (UCDs):** The holder of a right in relation to a UCD which arose before the end of the transition period shall in relation to that UCD ipso iure become the holder of an enforceable intellectual property right in the UK, under the law of the UK, with the same level of protection as the UCD and term of protection at least equal to the remaining period of protection of the corresponding UCD. (Art 57)
11. **Databases:** Holders of sui generis database rights in respect of the UK, which arose before the end of the transition period, will maintain an enforceable right in the UK under UK law which affords the same level of protection as that provided under the Database Directive, provided that the right holder continues to comply with the requirements of Art 11 of that Directive. The term of protection shall be at least equal to the remaining period of protection for the sui generis database right.

    UK nationals and those with habitual UK residence and undertakings established in the UK (provided that where such an undertaking has only its registered office in the United Kingdom, its operations are genuinely linked on an ongoing basis with the economy of the United Kingdom or of a member state) will be deemed to fulfil the requirements of Art 11. (Art 58)
12. **Pending applications for SPCs in the UK:** Applications for SPCs for plant protection products and for medicinal products, and applications for the extension of the duration of such certificates, where such applications were submitted to an authority in the UK before the end of the transition period, in cases where the administrative procedure for the grant of the certificate concerned or of the extension of its duration was ongoing at the end of the transition period, will all be considered using the same process and criteria as set out in the current applicable EU Regulations (Regulations (EC) No 1610/961 and No 469/20092). Any SPC granted shall provide for the same level of protection. (Art 60)
13. **Exhaustion of rights:** Intellectual property rights which were exhausted both in the EU and in the UK before the end of the transition period under the conditions provided for by EU law shall remain exhausted both in the EU and in the UK post-transition. (Art 61)

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