CIPA
The Chartered Institute of Patent Attorneys

The impact of Brexit on intellectual property

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The UK is still a member of the European Union and will continue to be so until Article 50 of the Lisbon Treaty[1] is triggered, at which point, it will have two years to negotiate its exit from the EU. This period may only be extended with the unanimous consent of all EU Member States.[2]

It is anticipated that Article 50 will be triggered in early 2017. At the moment, a number of legal challenges are being brought to Court, seeking clarification on the Brexit process and its legality. Amongst other points, it is argued that the Prime Minister cannot take the decision to trigger Article 50 alone and that to do so, Parliament would have to pass an Act of Parliament which MPs would have to vote for by a majority. Once the UK leaves, part of the IP landscape in the UK will change, but much will not.

EU Regulations, EU Directives and the CJEU

European law will continue to affect the UK. It is important to distinguish between Regulations and Directives. EU Regulations are directly applicable to all EU Member States without the need for national legislation. In contrast, Directives must be implemented into national law before they take effect. Member States are given a time frame by which to achieve these objectives. In the UK, Directives are implemented by Statutory Instruments or Acts of Parliament.

After Brexit, Regulations will cease to be applicable, but as Directives have already been implemented into UK law, they will remain in effect unless the UK Parliament decides to repeal or amend the national laws that transposed them. The Biotech Directive[3] is of particular interest to the patent world. At the time of implementation in the UK, it did not have a major impact on UK law since national courts and the UKIPO had already been recognizing the validity of patents for biotech inventions, provided they met the necessary criteria.

Leaving the EU would mean that the Court of Justice of the European Union (CJEU) would cease to have jurisdiction over UK matters, although in practice, their decisions may still influence us. This is because the Boards of Appeal (BoA) of the EPO will continue to follow the CJEU rulings on the Biotech Directive and the UK Courts will continue to pay attention to the BoA decisions. In the past, the CJEU's interpretation of the Biotech Directive has caused some concern, in particular with regards to the patentability of stem cells. The UK courts may wish to diverge from CJEU precedent but are unlikely to do so as it would move away from the position of other EPO contracting states. Further, if the UPC goes ahead with the UK's participation, the UPC will be bound by the CJEU's decisions on the Biotech Directive.

[1] Article 50 Lisbon Treaty http://www.lisbon-treaty.org/wcm/the-lisbon-treaty/treaty-on-European-union-and-comments/title-6-final-provisions/137-article-50.html
[2] Art 50(3) Lisbon Treaty
[3] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions

EPC, PCT and UK patents

The European Patent Convention (EPC)[4] is not a piece of EU legislation and will therefore be unaffected when the UK leaves the EU, as will representation rights of UK-based European Patent Attorneys, who will still be able to represent clients in all work before the EPO. European patent holders will not lose any rights and patents already obtained via the European Patent Office will remain unaffected.

The President of the European Patent Office (EPO), Benoît Battistelli, issued a statement on the day of the EU referendum results to say that the UK's participation in the EPO remained unaffected and that the EPO expected the UK and the participating Member States to find a solution as soon as possible which would allow a full implementation of the UPC.[5]

The EPC system works well and there is no reason, nor plans, for the UK to leave it. The EPO will grant Unitary Patent (UP) patents when these become available.

Patent Co-operation Treaty (PCT)[6] applications will remain unchanged as this is not an EU treaty. There will also be no effect on UK patents granted by the UK Intellectual Property Office (UKIPO).

Community Trade Marks, Registered Community Designs and Community Plant Variety Rights

A number of intellectual property rights deriving from EU Regulations will no longer apply to the UK if we leave the EU. These include the Community Trade Mark (Regulation (EC) No 207/2009), Registered Community Designs (Regulation (EC) No 6/2002) and Community Plant Variety Rights (Regulation (EC) No 2100/94). The continued validity of these rights in the UK is uncertain. Transitional agreements may be negotiated to allow time for right holders to convert these into national rights or to file separate national rights. New applications can be filed as either EU (not acquiring UK rights) or UK national and priority can then be claimed in UK or EU as needed.

The decision to leave the EU will not affect holders of UK trade marks or design rights. CIPA and the Institute of Trade Mark Attorneys (ITMA) are working together to ensure that holders of EU trade marks and design rights will not lose protection in the UK upon Brexit. CIPA will work with ITMA and the UK Government towards the goal of ensuring that the terms of any settlement with the EU will include the ability for UK trade mark attorneys to continue to act before the EUIPO.

It would be prudent to review all licences/settlements/delimitation/co-existence agreements relating to portfolios of existing EU trade mark and design registrations now. CIPA expects that a transitional "non-use" period will be negotiated as part of the process for EU marks that were only used in the UK (that remain EU trade marks) and for new UK marks that were

[4] European Patent Convention 1973 http://www.epo.org/law-practice/legal-texts/html/epc/2016/e/index.html
[5] https://www.epo.org/news-issues/news/2016/20160624.html
[6] http://www.wipo.int/pct/en/

never used in the UK, prior to the effective date of Brexit. The mechanism for achieving this remains unclear but we will work with the UKIPO and other stakeholders to achieve the optimum outcome.

The UK will remain a member of the Paris Convention and the Madrid System after Brexit. CIPA expects that the UK will continue to recognize the priority filing dates of Madrid and/or EU trade marks that are currently in effect. All existing EU unregistered design rights and Hague registrations will continue, unaffected, until Brexit.

Trade secrets and data safety

There will be no change for the holders of trade secrets as the UK is already exceeding the minimum standards as specified by the EU Trade Secrets Directive (ref 2013/0402(COD)). There is no need for the UK to implement the new Directive and it might be best not to in order to avoid legal uncertainty.

The UK has had a cyber security strategy in place since 2011, which is regularly reviewed and updated. It has also had formal data protection measures in place since 1988, which will continue.

IP rights covered by EU Regulation

We expect the UK Government to re-enact the necessary EU Regulations and existing Statutory Instruments, at least in the short to medium term, to avoid any negative impact on IP protection.

The following rights (apart from copyright) are intimately connected with the EU regulatory framework for medicinal products. In particular, the duration of these right is triggered by the date of the first marketing approval in the EU. How closely these rights will continue in their present form in the UK is likely to depend on whether and to what extent the UK regulatory framework remains connected to or aligned with the EU system.

A great deal of work needs to be done to ensure that laws enacted during the UK's membership of the EU are fully reflected in UK law after Brexit. Constitutional experts believe that the sheer volume of parliamentary time required to re-enact more than 50 years of EU law by individual Act of Parliament means that most will be re-enacted en masse by UK Regulation. CIPA will press the Government for such action in relation to IP rights, including:

i. **SPCs**

SPCs were introduced in the UK through EU Regulation (EC) No 469/2009 (of 6 May 2009).[7] The rationale behind the introduction of the SPC Regulation is set out in the Commission's Explanatory Memorandum (COM (90) 101 final). SPCs are a form of patent term restoration to compensate for regulatory delays in the approval of medicinal products. They have a maximum term of five years and the holder of the

[7] http://ec.europa.eu/health/files/eudralex/vol-1/reg_469_2009/reg_469_2009_en.pdf

patent and related SPC on a pharmaceutical product can enjoy an overall maximum of 15 years patent plus SPC protection from the date when the product first obtained marketing authorisation in the EEA (now extended to 5.5 years and 15.5 years if the product is awarded a paediatric extension under Regulation EC No 1901/ 2006.[8])

SPCs are a national UK right and CIPA therefore anticipates that pending and existing SPCs will be unaffected (see above). However, some modifications may be necessary, for example, the Marketing Authorisation (MA) on which the time period of the SPC is based is currently the first MA in the EEA but it could be argued that this should become the first UK MA. In the longer term, it is possible that the UK may enact SPC rights after the UK's exit that are more favourable to innovator companies that carry out research and develop new products. For example, it has been suggested for some time that medical devices should be the subject of SPCs and other products that are effected by regulatory delays could also be considered. The effective term of pharmaceutical SPCs has also reduced over the years and this could also be the subject of review. The European Commission has announced its intention of carrying out a study on the effects of an SPC based on a Unitary Patent. The results of this study could influence UK policy as the UK is likely to still be a member of the EU when the study results are published. The effect of the UK leaving the EU on the UP is discussed later.

ii. Regulatory data protection (RDP)

RDP for pharmaceuticals in the EU is provided for by Regulation (EC) No. 726/2004[9] and Directive 2001/83/EC, as amended by Directive 2004/27/EC (implemented in the UK *inter alia* via the UK Medicines Act).

The regulatory data protection period in Europe is commonly referred to as '"8+2+1". This comprises:

- a period of 8 years true data exclusivity, running from first marketing approval in the EU, during which period the EMA may not progress an abridged marketing application which references an originator's regulatory data (pre-clinical and clinical trial data)
- a further period of 2 years market exclusivity during which a generic product cannot be placed on the market,
- A further 1 year marketing exclusivity may be obtained where the originator is granted a further MA for a significant new indication, within the original 10 year exclusivity period.

This regime applies to EU marketing authorizations applied for from November 2005 (and national applications from October 2005). Prior to this the duration of RDP was not harmonized within the EU, with a 10 year RDP period for MA's filed via the

[8] http://ec.europa.eu/health/files/eudralex/vol-1/reg_2006_1901/reg_2006_1901_en.pdf
[9] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:136:0001:0033:en:PDF

centralised procedure, and either 6 or 10 years, depending on the Member State, for MA's filed via the national or mutual recognition procedures.

Following the UK's exit from the EU, we expect that, at a minimum, the UK will continue to provide RDP at the existing level. As noted above, a major consideration will be whether RDP commences from the date of the first MA in the EEA or the first MA in the UK.

There may be the potential to enhance RDP protection in a separate UK system, for example in relation to the criteria for obtaining additional RDP for a new indication, or the duration of the protection.

iii. Orphan drug exclusivity

EU Regulation (EC) No 141/200010 provides incentives and rewards for developing medicines to treat rare diseases, and is currently in effect in the UK. It permits 10 years market exclusivity with respect to similar medicines for similar indications, and therefore has a broader scope than RDP. The Commission is currently undertaking a review of the concept of 'similarity' and while still a member of the EU the UK is able to input into this review. The duration of ODE is determined by the date of first marketing approval for the orphan indication in the EU. It is expected that at least in the short-medium term any separate UK legislation would be based on the current EU regulation, unless and until the UK ultimately introduces a national system for approving orphan drugs .

As for RDP, if the UK ultimately implements a separate national framework for approval of orphan drugs, there may be the potential to provide enhanced incentives and rewards, such as a longer period of protection, or different criteria for designating Orphan products.

RDP for pharmaceuticals is provided for by the UK Medicines Act which is based on various EU Directives and Regulations. We expect that, at a minimum, the UK will continue to provide RDP at the existing level. A major consideration will be whether RDP commences from the date of the first MA in the EU or the first MA in the UK.

iv. Copyright

We anticipate that, at a minimum, the UK will protect copyright (including existing copyrights) in accordance with the Berne Convention[11]. There may be an opportunity to review copyright protection.

[10] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2000:018:0001:0005:en:PDF
[11] http://www.wipo.int/treaties/en/text.jsp?file_id=283698

v. The Nagoya Protocol

CIPA has previously expressed its concerns about the damaging effect that EU implementation of the Nagoya Protocol to the Convention on Biological Diversity[12] may have on UK science in general and particularly on important biological research that may be conducted in the public interest in the UK.

The Nagoya Protocol, which came into effect in October 2014, codifies the right of all countries to control research on non-human genetic resources found within their borders and expanded on the principles found in the Convention on Biodiversity (CBD). This is to the effect that all research on genetic resources (including DNA and chemicals naturally produced within organisms) requires 'prior informed consent' and 'mutually agreed terms' from the 'country of origin'.

Nagoya also obliges countries housing users of genetic resources ('user countries') to respect laws of the 'country of origin'. Future research on genetic resources will therefore be regulated by the laws (if any) of 'countries of origin'; as well as the laws of 'user countries'.

The EU has implemented these requirements through Regulation 511/14. The intention of this Regulation is to ensure lawful use of genetic resources in accordance with the Protocol. However, CIPA believes that the obligations it imposes are unclear and onerous.

In particular CIPA believes that criminal sanctions for breach of the Regulation in the UK are disproportionate and unnecessary. If imposed at all, they should only be for flagrant and deliberate violations of the Regulation.

CIPA believes that leaving the EU offers the UK the opportunity to alter the implementation of the Protocol in the UK. CIPA therefore proposes that the UK Government should consult with the user community in the UK before introducing an amended implementation of the Protocol but specifically:

a) There should be no criminal penalty for inadvertent or unintentional breaches.
b) The three month time-limit on unsanctioned research vital for public health should be extended and, in the longer term, the UK Government should negotiate to adjust the Protocol so that provider countries lose their power of veto over such necessary research.

CIPA also urges the UK Government after it has re-implemented the Protocol to produce clear official guidance, with examples, as to what companies and researchers should do to comply with the Protocol, especially regarding due diligence. Detailed consultation should take place with the user community, whose concerns must be adequately addressed, so that all involved may prepare fully to meet their new obligations under the Regulation.

[12] https://www.cbd.int/abs/text/default.shtml

IP disputes

The UK has a sophisticated and highly successful litigation system, including the innovative and affordable Intellectual Property Enterprise Court (IPEC) which has many features in common with the UPC. The court started life as the Patents County Court (PCC) but in 2009 the Patents Courts Users Committee suggested proposals for new rules. These rules were enacted in October 2010 and were strongly influenced by the final draft of the EPLA (European Patent Law Agreement). The EPLA was, of course, relied on heavily in drafting the UPC. In 2012, a small claims track was added and in 2013 the PCC moved into the High Court, and changed its name to IPEC.

IPEC's procedure is governed by a set of rules which apply only in the IPEC and which, taken as a whole, set it apart from the procedure elsewhere in the High Court. The main differences are:

1. a cap on the costs which the losing party must pay the successful party (£50,00);
2. a cap on the damages which may be recovered (£500,000);
3. more detailed pleadings – these must be concise but must identify all arguments to be relied upon as well as the nature of the parties' cases;
4. limits on disclosure available - specific disclosure can be sought but must be justified and will be limited by reference to one or more issues; no disclosure reports are needed;
5. limits on evidence which can be adduced - expert evidence will only be permitted if the court is satisfied that it is needed; the scope of expert evidence will be also be limited by reference to issues and also sometimes by length, i.e. to a maximum number of pages; and
6. more active case management than is usual in the English High Court – the Case Management Conference is held before the presiding IPEC Judge; the trial will normally be less than two days.

The idea behind this type of court was born of a concern that parties who wanted to protect their IP rights were deterred from doing so by the cost of IP litigation. Not least, they were worried by the potential liability in costs payable to the opposing party if the litigation did not go as planned. These were for the most part small and medium enterprises, 'SMEs', and to some extent litigants in person. The consequence was that such parties' IP rights were frequently left unenforced and were comfortably ignored by infringers.

The new rules have led to a substantial increase in the use of the PCC/IPEC. In 2001, there were almost no cases and in 2010, 89 cases. This number increased to 157 cases in 2011 and 202 cases in 2012. It is still rising. In the same period since 2010, the number of IP cases filed in the Patents Court and general Chancery Division has not declined – the opposite, if anything.

Approximately 70% of the litigants before the IPEC are SMEs, the rest are larger companies and individuals. Cases can be transferred between High Court and IPEC and vice versa if the complexity or value of the case makes this desirable. Furthermore, partly in response to the success of IPEC, the High Court has since October 2015 also been piloting two schemes, the

Shorter Trials Scheme and the Flexible Trials Scheme, which translate some of the benefits of IPEC style procedure to cases in the High Court. Thus, the UK court system will continue to provide a fair and balanced system for litigation between parties post-Brexit.

Alternative dispute resolution methods are well respected and recognised in the UK, particularly by the courts. The UK has a well-developed arbitration system and London is often chosen as the seat of international arbitration. This will continue.

The UK is a signatory of a number of international conventions in relation to choice of forum (of the court, etc.), recognition of judgements and conflict of laws (for example the Hague Conventions). This will continue post Brexit and will continue to make the UK a good place to litigate IP disputes

All IP professionals in the UK enjoy a high level of legal professional privilege, which allows clients to be completely open with their legal advisors. There will be no change to these favourable privilege provisions.

The Unitary Patent and Unified Patent Court

The Unified Patent Court (UPC) Agreement13 is an EU project and the UK's continued participation after Brexit is uncertain. There has been a lot of support expressed for the UPC project to continue with the participation of the UK. At the 4th annual conference of the Unitary Patent and the Unified Patent Court held on 7 July at the EPO in Munich, a number of speakers including EPO President Benoît Battistelli, Chairman of the Select Committee, Jérôme Debrulle, and the Chairman of the UPC Preparatory Committee, Alexander Ramsay, all told the conference that they believed the UPC should go ahead with the UK's involvement. President Battistelli has also blogged about the topic on the EPO website. CIPA supports the UK's participation in the UPC project.

The UK is currently an EU Member State and can ratify the Agreement, if it so desires, as soon as it is ready to do so and would anticipate being able to negotiate arrangements for continued participation post-Brexit if it does ratify. Article 89 of the Agreement requires ratification by the "three Member States in which the highest number of European patents had effect in the year preceding the year in which the signature of the Agreement" took place. At the moment, these are the UK, Germany and France (the only one of the three to have ratified so far). If the UK does not ratify before Brexit, the onus of ratification will pass on to the next EU Member State- the Netherlands.

Article 7 of the UPC Agreement states that the Central Division of the UPC will have a seat in London, there will also be Central Division courts in Paris and Munich. If the UK left the EU after ratifying the Agreement, this requirement could only be changed by amendment of the Agreement. British European Patent Attorneys will be able to represent parties in the different branches of the UPC in Europe.

CIPA has a strong preference for the UK to participate in the UP and UPC system, if a solid legal basis for this can be agreed. The UK government, assisted by CIPA and other national stakeholders, has worked tirelessly over many years to create a system favourable to the UK

[13] https://www.unified-patent-court.org/sites/default/files/upc-agreement.pdf

and business which should simplify the patent system for businesses and reduce their costs. Plans were well advanced for part of the Court's central division to open in London, with Aldgate Tower in Whitechapel secured as the venue.

CIPA is working with other interested parties, including international colleagues, to optimise the chances of the UK's continued participation.

CIPA (along with others) has taken advice from a UK lawyer experienced in constitutional and EU law. His advice is that it is legally possible for the UK to participate in the UPC and the UP after Brexit. This would require a new international agreement with the participating member states and the EU to provide compatibility with EU law and a number of amendments would have to be made to the UPC Agreement. However, there are still significant political difficulties to overcome in both the UK and continental Europe in order to achieve this.

IP transactions

The UK continues to be a good venue for IP transactional work, with highly qualified, skilled and experienced legal professionals. The law of England and Wales will continue to be a favourable governing law for IP transactional agreements. Business continues as usual, and the English courts can still be specified with confidence as the forum for any disputes.

The UK has an enviable track record in technology transfer. The highly successful Lambert Toolkit of templates helps to facilitate agreements between UK universities and business. These templates are currently being updated.

Parallel imports and exhaustion of rights

The position may change following a Brexit depending on the precise arrangement reached. If the UK leaves the EU without joining any other Agreement (e.g EEA or EFTA), the existing rules on exhaustion of rights will cease to apply. This is a complex area and CIPA is working with stakeholders to achieve the optimum position. There is a possibility that a Brexit could enable a more advantageous regime for rights holders.

IP tax relief

There will be no change for companies claiming UK corporation tax relief via the Patent Box scheme on the profits they make from patented inventions. The opportunity should exist for discussions between the UK Government and stakeholders concerning make the system more attractive for those investing in the UK. There will also be no change to research and development tax credits.

Conclusion

In the short term (at least two years), UK patent and trade mark attorneys continue to have all the rights they have at the moment to work before the UK and European IP Offices. CIPA will work with the UK Government and other interested parties to ensure that as many of these rights as possible are retained after exit from the EU.

The UK is a great venue for business and for obtaining and enforcing IP rights in Europe. CIPA is committed to ensuring that this will continue.