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Expert Opinion

Brexit – The Consequences for Pharmaceutical Patents and Supplementary Protection Certificates

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ABSTRACT

Now that the UK has left the EU, and the transition period following this departure is over, we have a clearer view on the implications of Brexit on intellectual property rights and the consequences for UK based pharmaceutical companies. Although little has changed for UK applicants wishing to obtain a European patent via the European Patent Office, the UK's withdrawal from the Unified Patent Court and Unitary Patent is a huge blow to the realisation of the long-awaited Unitary Patent system. Meanwhile, breaking away from the EU has also had effects on how UK pharmaceutical companies can apply for supplementary protection certificates (SPCs), with further intricacies due to the Northern Ireland Protocol. The introduction of a new manufacturing waiver for medicinal products protected by SPCs in the UK and EU will allow pharmaceutical companies more leeway with regards to stockpiling and export provisions. Perhaps most interesting of all is how UK and EU laws will diverge over the following years, now that the UK is no longer under the jurisdiction of the Court of Justice of the European Union.

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INTRODUCTION

On 31 December 2020, the transition period that followed the United Kingdom's exit from the European Union ended and the UK officially became, in the eyes of the EU at least, a "third country". With the UK still bound by EU law during the transition period, and with trade negotiations being decided at the eleventh hour, it has been difficult to ascertain fully the changes and effects of Brexit on intellectual property (IP) rights. Indeed, there have been some quite substantial political developments since our 2017 article on this subject (Fraser and Stones, 2017).

Having now trudged through the political wrangling required to "get Brexit done", we now at least have some clarification on the effects on IP of the UK's withdrawal from the EU. One of the biggest implications for IP overall of course is that the UK no longer falls under the jurisdiction of the Court of Justice of the European Union (CJEU). We can therefore expect to see a slow divergence from EU law

over the coming years as UK case law develops independently of the CJEU.

In this article, we again focus on the changes to patents and supplementary protection certificates (SPCs), but also new EU manufacturing regulations for pharmaceutical compounds. To keep this article brief, the effect of Brexit on designs, copyright and trademarks, as well as issues associated with the use of IP rights (such as competition law, exhaustion of rights, etc.) will not be discussed.

PATENTS

There are no significant changes to the current system of obtaining European or UK patents post-Brexit. This is because the European Patent Office (EPO), which examines and grants European patents, is not an EU institution and thus does not fall within the jurisdiction of the CJEU. There are many countries which enjoy membership of the European Patent Convention (EPC) and yet are not part of the EU; the

same is now true for the UK, whose attorneys still have rights of audience before the EPO.

Crucially, the UK government has also expressed that there is no interest in changing the status of the UK's membership to the EPC. The effects of the UK leaving the EPC were laid bare in a joint report by the Chartered Institute of Patent Attorneys (CIPA) and the IP Federation on the EPC and its importance to the UK economy. It was pointed out that the biggest users of the EPC are US inventors working with UK patent attorneys, and that the impact on UK GDP from leaving the EPC would be a loss of around £837 million a year (Clayton 2020).

The European patent system allows for a central European patent application which upon grant is validated in as many of the Contracting States, Extension States and Validation States as desired (EPO 2021), currently a total of 44 countries. At this point, the European patent becomes a bundle of individual national patents (one granted national patent for each state).

Although this is undoubtedly a useful and convenient system, there has now been for some time a project called the Unitary Patent (UP) and Unified Patent Court (UPC) which strives to put in place a single pan-European patent (rather than a plurality of national patents) which will provide uniform protection across all participating Member States. Other aspects of the system include the possibility of litigating patents centrally, rather than having to litigate each national patent in each separate jurisdiction, and also having to only pay renewal fees equivalent to the combined cost of renewals for the four Member States who validate the most European patents, rather than separate renewal fees in all Member States. Despite drawbacks in the uncertainty of using a new patent system, pharmaceutical companies making use of the UP and UPC would be able to gain patent protection across Europe in a more cost-effective and simpler way.

Governed by EU law (EU 2012), the Agreement on a Unified Patent Court (UPCA) must be signed and ratified by 13 EU Member States, including the three Member States who are the biggest users of the EPC system (France, Germany and the UK). Despite the jurisdiction of the CJEU, the UK government was initially still intent on ratifying the UPCA post-

referendum. However, as a "hard Brexit" was pursued, the likelihood of the UK's continued participation slowly started to erode and in February 2020, the UK government made clear that the UK would no longer take part in the UPC system due to the jurisdiction of the CJEU (UK 2021). This was a blow to both the UP/UPC and also the UK pharmaceutical industry, especially as part of the central division of the UPC (hearing cases relating to chemistry, including pharmaceuticals and the life sciences) had been proposed to be based in London.

Further issues for the UP/UPC have been ongoing in Germany, where in 2017 the German Constitutional Court asked the German legislator not to implement the corresponding legislation putting the UP/UPC into force. This was due to a complaint from a German attorney who alleged that the UP/UPC violated the German constitution because the required majority vote needed in the Bundestag had not initially been met. In March 2020, the German constitutional court upheld the complaint, which was said by Willem Hoyng, a member of the Drafting Committee of the UPC's Rules of Procedure, to "set back the UPC project at least five years" (Dijkman 2020). However, the Bundestag have since voted on and approved the UPCA with the required votes (UPC 2020), although as more challenges have since been filed at the German courts, it is still too early to say when (or indeed whether) the UPC will get off the ground.

SUPPLEMENTARY PROTECTION CERTIFICATES (SPCs)

While there are no significant changes to UK and European patents post-Brexit, there are notable developments with SPCs. SPCs are not patents, but instead an additional form of protection for patented plant or medicinal products which have also been granted a Marketing Authorisation (MA). The "basic patent" on which an SPC is based on may cover an active ingredient, a process to obtain the active ingredient or an application of the active ingredient. The additional protection of up to five years compensates for the time taken to obtain authorisation to place the relevant product on the market, and so the use of such extension of protection is invaluable to the pharmaceutical industry.

SPCs are national rights (each national SPC must be applied for and registered in each individual EU Member State), but the legal basis for SPCs is derived from EU regulations (EU 2009). UK SPCs were governed by EU regulations until the end of the transition period, with applications made before the end of this period still being examined and treated in the same way. From 1 January 2021, the provisions for UK SPCs are largely the same as the current EU system (UK 2019a). This is because, in preparation for Brexit, the statutory requirements for SPCs have largely been retained in domestic law as part of the Patents (Amendment) (EU Exit) Regulations 2019 (UK 2019b).

While the status of UK SPCs may seem the same, the uncoupling from EU regulations and CJEU departure has nevertheless had some effects. According to the 2019 Regulation, while it is still a requirement to have a UK patent (derived from either a GB application or a EP application) to be granted a UK SPC, the decentralised European Medicine Agency (EMA) is no longer able to provide a relevant MA for a UK SPC. Instead, an MA would have to be obtained only from the UK's Medicines and Healthcare products Regulatory Agency (MHRA). Pharmaceutical products which already have MAs authorised by the EMA before 2021 will still be accepted in an application for a UK SPC.

However, it became apparent following subsequent trade negotiations that this would have to be revised due to the complexities of the new relationship with Northern Ireland.

Due to the Northern Ireland/Ireland Protocol, EU pharmaceutical law continues to apply in NI. Therefore, a valid MA for that territory has to be granted by the EMA. As the 2019 Regulation required a "UK authorisation" (from the MHRA) to obtain a UK SPC, there was an incompatibility in the law for MAs. New legislation has now come into force, attempting to rectify this situation (UK 2020a). Accordingly, with the Supplementary Protection Certificates (Amendment) (EU Exit) Regulations 2020, an MA for a UK SPC can be granted for NI only, by the EMA, or for Great Britain only, by the MRHA. An unfortunate consequence for pharmaceutical companies is that whilst a UK-wide SPC can now be granted based on an NI or Great British MA, the SPC

will only have effect in the territory for which the MA applies. Pharmaceutical companies wishing to have SPC protection in the whole of the UK now need to have the relevant MAs granted in both territories before the SPC takes effect.

PAEDIATRIC EXTENSIONS OF SPCs

It is still possible to obtain a six-month 'paediatric extension' to the duration of an SPC following the completion of an agreed Paediatric Investigation Plan (PIP). Paediatric extensions are popular amongst pharmaceutical companies, with a recent study on the economic impact of SPC and pharmaceutical incentives in the EU noting their increase between 2007 and 2016 (CE 2018).

Any paediatric extensions to UK SPCs which were applied for before the end of the transition period will still be dealt with under EU law. After the transition period, many of the requirements for obtaining a paediatric extension remain the same, requiring completion of a PIP and an update to the MA and Summary of Product Characteristics. Requests for a paediatric extension must be made no later than two years before the SPC is due to expire, which is the same deadline as under the EU regulations.

A change that may benefit pharmaceutical companies in the UK, however, is that for extension applications made after the transition period, the agreed PIP no longer needs to be approved in all Member States of the EU (UK 2020b).

UNITARY SPCs

Finally for SPCs, it appears that there has been little progress on the concept of a "unitary SPC" i.e., a system of obtaining an SPC valid in participating Member States based on a UP. A summary of replies to a public consultation on such a system was published by the European Commission in 2018, with a majority of respondents said to be in favour of creation of a unitary SPC (EU 2018). Alas, with the current delay to the UP and UPC, it seems that such a system is, for now, only a distant possibility.

MANUFACTURING AND STOCKPILING WAIVER

On 1 July 2019, a new manufacturing and stockpiling exemption came into force across the EU (EU 2019).

The purpose of the waiver is to allow the manufacture and storage of products which would otherwise infringe an SPC, so that export can occur to a country that is not an EU Member State and/or that in the final six months of an SPC term, a company would be allowed to prepare for “day-one” market entry in EU Member States upon expiry of the relevant SPC. The manufacturing exemption applies to all certificates applied for after 1 July 2019 and also to those applied for before but taking effect after 1 July 2019, but in the latter case only from 2 July 2022.

According to the EU, the aim of the waiver is to encourage competitiveness of EU producers of generic medicines and biosimilars, while also removing the disadvantages faced by EU-based manufacturers compared with manufacturers not based in the EU.

Although the legislation was comfortably voted in, some Member States were not in favour, with the UK notably voting against it. Nevertheless, provisions from the manufacturing and stockpiling waiver were drafted into UK law in preparation for Brexit. However, there were some considerable issues to fix regarding the legislation and the effect of withdrawal from the EU, so the UK government ran a call for views shortly after the waiver came into force (UK 2020c).

Initially, the UK government intended to allow third parties to manufacture pharmaceuticals for export outside of the UK only, or for stockpiling for sale in the UK within the last six months of the SPC term. However, there was concern from respondents to the call for views, where it was noted that the draft legislation opened up export to the EU, which could be disruptive to the balance of protection the SPC system provides. The UK legislation was subsequently amended to state that third parties may manufacture in the UK for export outside both the UK and EU, and stockpiling is allowed in the UK in the final six months of the SPC term for sale in both UK and EU markets, effectively mirroring the EU regulation.

Third parties wishing to use the waiver in the UK can do so by notifying UK Intellectual Property Office (UK IPO) no less than three months before starting such activities.

CONCLUSIONS

There have undoubtedly been significant changes to the political landscape since the UK voted to leave the EU on 23 June 2016. The UK and European patent systems however remain largely unchanged, and the way patents will continue to be applied for, examined and granted will continue as usual. With the UK still a member of the EPC, UK attorneys will still be in demand from pharmaceutical companies to best position their patent rights.

With the UK no longer under the jurisdiction of the CJEU, it was perhaps only inevitable that the UK government would withdraw from the UP/UPC. The system itself still has not yet been implemented, and although there have been significant bumps in the road, there is still a chance it could be made a reality.

Although SPCs in the UK have been a right under European law, the UK has effectively mirrored the EU system and much of the SPC system has remained the same. The issues with Northern Ireland mean that UK SPCs are now effectively territorial, depending on where the MA is obtained. Changes to paediatric extensions of SPCs in the UK now have less stringent requirements with a PIP only required for the UK, which could be of benefit to smaller pharmaceutical companies.

The new manufacturing and stockpiling exemptions allowing third parties to make or store products protected by SPCs has in effect also been mirrored in UK law. The EU is to evaluate the effect of this new legislation every five years, with a particular focus on the stockpiling provision. The UK of course would not be obliged to follow the same route the EU takes on the matter.

Perhaps what will be most interesting over the next few years will be the slow divergence of UK case law from the rest of the EU. British judges have stated that they feel not only more than capable in dealing with issues related to SPCs, but have also indicated that they would like to rectify certain SPC judgements by the CJEU which are thought generally to have led to a lack of clarity. How this will affect IP rights down the road and whether pharmaceutical companies will benefit remains to be seen.

CONFLICT OF INTEREST

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